S. HRG. 118–498

BRINGING TRANSPARENCY AND ACCOUNTABILITY TO PHARMACY BENEFIT MANAGERS

HEARING

BEFORE THE

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION UNITED STATES SENATE

ONE HUNDRED EIGHTEENTH CONGRESS

FIRST SESSION

FEBRUARY 16, 2023

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SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

ONE HUNDRED EIGHTEENTH CONGRESS

FIRST SESSION

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BRINGING TRANSPARENCY AND ACCOUNTABILITY TO PHARMACY BENEFIT MANAGERS

THURSDAY, FEBRUARY 16, 2023

U.S. SENATE,
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,
Washington, DC.

The Committee met, pursuant to notice, at 10:02 a.m., in room SR–253, Russell Senate Office Building, Hon. Maria Cantwell, Chair of the Committee, presiding.

Present: Senators Cantwell [presiding], Klobuchar, Tester, Rosen, Hickenlooper, Warnock, Welch, Cruz, Sullivan, Blackburn, Budd, and Capito

Also present: Senator Grassley.

OPENING STATEMENT OF HON. MARIA CANTWELL, U.S. SENATOR FROM WASHINGTON

The CHAIR. The Committee on Commerce, Science, and Transportation will come to order.

Today we are hearing about what is driving up the price of prescription drugs, a life or death matter for many Americans, and the skyrocketing prices that affect them. Six out of every 10 adults are currently taking at least one prescription drug, and about 1 in 4 of us take four or more prescriptions, so rising drug prices have really stretched Americans' budgets over the past decade. Since 2014, prescription drug prices have increased 35 percent, outpacing increases in wages, gas, Internet service, and food.

So what is causing this sharp increase? So today we are looking at the mysterious middlemen in this, the prescription drug benefit market, the pharmacy benefit managers. Most Americans, I am sure, have never heard of pharmacy benefit managers, but they dictate the price people pay at the pharmacy and how people get their prescription, and in some cases, what treatments they can even receive.

Diabetics have used insulin to treat their chronic conditions for the last 100 years, but in the past 10 years alone, the average price has doubled. Americans with diabetes cannot live without this drug, so when the prices go beyond what they can afford, they have to take drastic measures. For example, Molly Stenson, a Washington State resident, used to drive hundreds of miles to Canada to purchase insulin for $100 because of the price that shot up in the United States to $450 a month. Now that the state of Washington has temporarily capped the price of insulin at $100 a month,

she no longer has to make that lengthy trek. But millions of Americans face this dilemma. Nearly 3 in 10 Americans report when the cost of their medication goes up, they cut their pills in half doses or stop taking their medication. This is not the kind of healthcare choices we want people to make.

The evidence suggests that PBMs are part of the high drug cost increase. Just three PBMs control 80 percent of the PBM market. Pharmacy chains and health insurers now own the biggest PBMs, giving independent pharmacies, care providers, and patients nowhere else to turn when PBMs increase their price.

Today, we will hear our colleague, Senator Grassley, a staunch supporter for reining in PBMs and a co-sponsor of legislation that helps to do that. I am grateful for Senator Grassley and for his experience and passion involving this issue and has used the Judiciary Committee for oversight of this PBM market as well.

We will also hear from Ryan Oftebro of—CEO of Kelley-Ross Pharmacy Group, a Seattle-based independent pharmacy. Mr. Oftebro has had to stop serving long-time customers and close a location because of how PBMs dictate the amount his customers pay and what he can charge. In 2021, a PBM decision increased the copay on one drug from $15 to $141 for the same 90-day supply. That same PBM clawbacks cost one of his pharmacies over $538,000, up from just $81,000 in 2018. Mr. Oftebro will describe how the systematic interference by PBMs in the drug supply chain is picking the pockets of independent pharmacies and driving up consumer costs.

We will also hear from Dr. Debra Patt, a practicing oncologist in Austin, Texas. Her research clinical decisions in support predictive analytics, health economics, and outcomes research give her a unique insight into the relationship here.

Too often, the self-interested decisions of PBMS are overriding the skilled advice of M.D.s. Dr. Erin Trish is associate professor of pharmacy and health economics at USC School of Pharmacy and a—and a non-resident fellow in the economic studies of Brookings Institute. Her research focuses on the intersection of public policy in these health markets, and she will explain the structural reforms needed to address the complex role that benefit managers and other intermediaries play in pharmaceutical distribution. And finally, we will have Mr. Dr. Casey, a professor of economics at the University of Chicago, who I am sure will express his views about these issues as well. This gives us the importance to ask him questions about PBMs and their structure and their pricing.

This legislation passed out of the Committee, the Cantwell-Grassley legislation, in the last Congress by a vote of 19 to 9, and I hope that today we can have a similar Q&A of our members to ask any questions, and hope that we could not just move this bill out of Committee but out of the Senate and over to our House colleagues.

I'll now turn to the Ranking Member for his opening statement.

STATEMENT OF HON. TED CRUZ,
U.S. SENATOR FROM TEXAS

Senator CRUZ. Thank you, Madam Chair. Thank you to each of the witnesses. Welcome, Senator Grassley. I am used to joining you

in the Judiciary Committee, but it is good to see you over in Commerce as well.

Much like everything in healthcare, the cost of drugs historically has risen faster than overall inflation. Since 1980, per capita drug spending, as adjusted for inflation, has increased more than sevenfold. And while Americans spend more on healthcare than people in many other parts of the world, we also spend less out of pocket on prescription drugs than those in many developed countries, including Switzerland, Canada, and Ireland. Thus, much of the higher spending on pharmaceuticals is baked into insurance premiums.

Insurance companies know that Americans won't choose an unaffordable plan, so they hire a pharmacy benefit manager, PBM, to manage the drug portion of a policy. The PBM manages a formulary, or a list of covered drugs, which gives the PBM leverage to negotiate lower prices with big drug companies. Of course, the relationship between insurers, PBMs, drug companies, and others are complex, opaque, and confusing both to consumers and to providers. It is easy to see why PBMs might be singled out for more government regulation. They are the middlemen who are supposed to be negotiating lower drug costs from the big drug companies, wholesalers, and pharmacists. There is a lot of potential for PBMs to make a whole lot of enemies. Whether PBMs are deserving of this scrutiny is a question I hope we can get more answers on today.

The other question I hope we can answer is this: do PBMs harm or benefit consumers? The answer should be decided by looking at the economic data across the entire drug supply chain, not just related to PBMs. The bill before us from Senators Grassley and Cantwell, the Pharmacy Benefit Manager Transparency Act, would give the FTC substantial regulatory power over PBMs. It seems the FTC has now become a catchall agency that Congress and the White House look to to regulate complex markets, like prescription drugs or gas prices, even when those markets might be reflecting problems caused by other government policies.

I have long had concerns with the FTC's vague statutory authority, but at this moment, we cannot ignore the current state of affairs at the FTC. Under Chairwoman Lina Khan, the FTC has gone down an alarming path of regulatory activism and overreach. The extreme partisanship and concerning direction of Ms. Khan's FTC were exposed earlier this week with the announced resignation of the lone Republican FTC commissioner, Christine Wilson, a longtime friend and former colleague of mine when I worked at the FTC. Commissioner Wilson wrote in an op-ed, "I refuse to give Khan's endeavor any further hint of legitimacy by remaining." This op-ed is stunning, and I would encourage anyone interested in the FTC to read it carefully.

Ms. Wilson detailed how the agency has lost its way, citing Ms. Khan's willful disregard of Congress's limits on the FTC, including an attempt to regulate whole swaths of the U.S. economy with the Agency's first unfair method of competition: rulemaking. It is shocking that a commissioner would choose to resign rather than watch an agency's bipartisan tradition crumble in front of her eyes. Sadly, Commissioner Wilson's departure will now leave the FTC without a counterweight to Chairwoman Khan's activist agenda.

I worked at the FTC, and I can tell you that with the Agency's overreach and activism, which will no doubt be difficult to sustain in court, it is no surprise that FTC staff morale has dramatically dropped. And so I am going to approach any bill to expand FTC powers right now, including this one, with extreme caution, especially now that there will be zero Republican commissioners and three Democrats.

I'll flag one other concern for the bill. It would pre-judge the results of the FTC's current study on the economic effects of PBMs. Last summer, the FTC unanimously voted to initiate a study on PBMs considering the access and affordability of prescription drugs. Consistent with the current FTC dysfunction, this study has had its controversy. Chairwoman Khan reportedly attempted to skew the study by refusing to study PBM impact on consumers, which is probably the most important question. That departure from standard economic analysis caused major internal disagreement and the resignation of the FTC's chief economist. But thanks to the hard work of the FTC staff, Commissioner Wilson, former Commissioner Phillips, the study was greatly improved, and I'll be closely monitoring it to ensure, in light of the turbulence at the FTC, that it is conducted objectively. I think we should wait on that study before legislating, and I look forward to this hearing to shine further light on this complicated and important question.

The CHAIR. Thank you. We will now turn to Senator Grassley. Thank you so much for being here. Thank you for your leadership on this issue. I do not think this is something that you have been mildly involved in. I think this is something you have been actively involved in for a long time, so we welcome you to the Commerce Committee.

STATEMENT OF HON. CHUCK GRASSLEY,
U.S. SENATOR FROM IOWA

Senator GRASSLEY. Thank you for the invite to appear, and I hope this committee will have the same success that they had last session——

The CHAIR. Is his button on?

Senator GRASSLEY.—of voting this bill out of committee. My——

The CHAIR. Pull it a little closer. Yes, thank you.

Senator GRASSLEY. Sure, I can do that.

The CHAIR. Thank you.

Senator GRASSLEY. Is that OK?

The CHAIR. Yes.

Senator GRASSLEY. I hope this committee will have the same success voting this bill out. As you have said, I have been involved with Big Pharma for a long time. As Chairman of the Finance Committee, I hauled Big Pharma and PBM executives before that committee. I partnered with Senator Wyden on a two-year investigation into insulin price gouging. Our investigation found that PBMs' scheme encouraged drugmakers to spike the drug's list price in order to offer a greater rebate, and then, in turn, secure priority placement on covered meds at the expense of many patients because I believe, like Senator Cruz just said, that the consumer ought to be the point of everything that we are trying to accomplish. And of course, then last, I have worked with bipartisan re-

forms to lower prescription drug prices, like I am working with you, Senator Cantwell. But there is more that we can do.

Imagine a world where a cheaper product, yet equally effective, has a harder time selling. That is the prescription drug industry. One of the primary reasons for this is pharmacy benefit managers. Recently, as an example, a biosimilar competitor, through the high-cost Humira drugs, entered the market. While its competitor offered a 55 percent discount to its list price, the competitor cannot access patients. Why? According to the *Wall Street Journal,* "PBMs and health plans are expected to prefer the more expensive version to get higher rebates." So if you wonder whether you heard that correctly, PBMs are blocking a cheaper product. This mirrors what my insulin investigation found now playing out with other drugs.

PBMs will claim that they pass savings to consumers or through lowering premiums, but their spread pricing and their clawback tactics prove otherwise. Now, for your local pharmacist, and I will bet whether it is Texas or Washington, you hear about signing a contract at the beginning of the year, and then at the end of the year, getting a bill for thousands or maybe tens of thousands of dollars to pay back. That does not make sense to me. When PBMs go with a higher-priced product, consumers may pay more out of pocket before the deductibles kick in or through co-insurance. Today, three PBMs control 80 percent of the market. Now, that is why you hear me talking about the four big cattle slaughtering companies, controlling 40—80—85 percent of that slaughter, so the independent producers in my state cannot get a market because the big feedlots in Texas eat up 85 percent of the daily kill. So we must do something about the powerful middle people to lower drug costs for consumers.

In 2018, I asked the Federal Trade Commission to assess consolidation in the pharmaceutical supply chain and its impact on drug prices. It took until last year for the FTC to take action and even start studying PBMs. It is welcomed action, but it is not enough. To ensure a timely FTC report, last week the Judiciary Committee passed out on a voice vote, along with five other bills—or four other bills that we passed out affecting the pharmaceutical industry, that—and we did it by voice vote, called the Prescription Price for the People's Act, also something that I am partnering with you on, Senator Cantwell. It requires the FTC to study pharmaceutical intermediaries and issue a report and recommendations to Congress within 1 year.

A timely report on PBMs is critical, but we can stop some competitive action behavior right now. The Cantwell-Grassley PBM transparency bill directs the FTC to end well-known and documented PBM practices that drive up consumer price, namely, spread pricing and clawbacks. Both actions game the system and hurt consumers. Our bill has guardrails. It does not give FTC any new power or regulatory authority, and listening to what Senator Cruz says, I want to comment from this standpoint. If you would see where Senator Cantwell and I first started talking about this in July before the bill got out in September, you would see that this is a very, very narrow approach to this PBM problem through FTC, because I am like you. I do not want to give FTC more power, and if we give them more power, make it—circumscribe it, very much

so. So I just hope that you'll take that into consideration as you look at it.

So I want to repeat that little part I just read. Our bill has guardrails. It does not give FTC any new power or regulatory authority. The bill also puts sunshine on PBMs. Passing the PBM transparency bill is an important step to lowering drug costs. Thank you. And I am—I guess I thought I was going to get done in 3 minutes, and it took me 6 minutes. I am sorry. Thank you.

[The prepared statement of Senator Grassley follows:]

PREPARED STATEMENT OF HON. CHUCK GRASSLEY, U.S. SENATOR FROM IOWA

Thank you for inviting me here today. I'm committed to working with you to lower prescription drug costs

I've hauled *Big Pharma* and *PBM executives* before the Finance Committee.

I've also partnered with Senator Wyden on a 2-year *investigation* into insulin price gouging. Our investigation found that the PBM scheme encourages drug makers to spike the drug's list price in order to offer a greater rebate, and in turn, secure priority placement on covered meds, at the expense of many patients.

In addition, I've *worked* on bipartisan reforms to lower prescription drugs. But there's more we can do.

Imagine a world where a cheaper product—yet equally effective—has a harder time selling. That's the prescription drug industry.

One of the primary reasons for this problem is pharmacy benefit managers.

Recently, a biosimilar competitor to the high-cost Humira drug—entered the market. While its competitor offers a 55 percent discount to its list price, the competitor cannot access patients. Why? According to the *Wall Street Journal,* "PBMs and health plans are expected to prefer the more expensive version to get the higher rebates."

You heard it correctly: PBMs are blocking a cheaper product. This mirrors what my insulin investigation found—now playing out with other drugs.

PBMs will claim they pass on savings to consumers or through lowering premiums, but their spread pricing and clawback tactics prove otherwise. When a PBM goes with a higher price product, consumers may pay more out of pocket before their deductible kicks in or through co-insurance.

Today, three PBMs control *80 percent* of the market. We must do something about powerful middlemen to lower drug costs for consumers.

In 2018, I *asked* the Federal Trade Commission to assess consolidation in the pharmaceutical supply chain and its impact on drug prices. It took until last year for the FTC to take *action* and start studying PBMs. Its welcomed action, but it's not enough.

To ensure a timely FTC report, last week, the Judiciary Committee passed out on a voice vote the *Prescription Pricing for the People Act,* a Grassley-Cantwell bill. It requires the FTC to study pharmaceutical intermediaries and issue a report and recommendations to Congress within one year.

A *timely report* on PBMs is critical, but we can stop some anti-competitive behavior right now. The Cantwell-Grassley *PBM Transparency Act* directs the FTC to end well-known and documented PBM practices that drive up consumer costs, namely: spread pricing and clawbacks. Both actions game the system and hurt consumers.

Our bill has guardrails—it doesn't give the FTC any new power or regulatory authority. The bill also puts sunshine on PBMs.

Passing the *PBM Transparency Act* is an important step to lowering to drugs costs.

The CHAIR. Senator Grassley, we so appreciate your articulation of why the legislation is drafted the way it is. You are right, you and I had a conversation. I was looking at a broader anti-manipulation authority, which the FTC has used in other areas, and Senator Grassley said, no, let us get very specific about these activities. And so our staffs worked together over a long period of time to focus this so that the actions taken were very clear. So anyway, thank you for being here. I do not know if you have any questions

on that. If not, Senator Grassley, thank you very much for being here today.

Senator GRASSLEY. Thank you.

The CHAIR. We will now turn to our other witnesses. As I mentioned earlier, Dr. Ryan Oftebro, pharmacy—chief operating officer of Kelley-Ross Pharmacy in Seattle; Dr. Debra Patt, oncologist, Texas Oncology in Austin, Texas; Dr. Erin Trish, co-director and associate professor of pharmaceutical health economics at the Schaeffer Center, University of Southern California; and Dr. Casey B. Mulligan, Professor in Economics at the University of Chicago.

So welcome to all the witnesses. If you will join us at the witness table we would appreciate it. And we ask each of you to make a 5-minute opening statement about this particular issue, and we will then go to question and answers from our colleagues. So again, thank you all very much for being here today, and we will start with you, Dr. Oftebro. And you might have to push your button there to be——

STATEMENT OF RYAN OFTEBRO, PHARMD, FACA, CEO, KELLEY-ROSS PHARMACY GROUP

Dr. OFTEBRO. Good morning, Chair Cantwell, and Ranking Member Cruz, and members of the Committee. My name is Dr. Ryan Oftebro. I am a pharmacist of 20 years, and I am owner and—of Kelley-Ross Pharmacy Group in Seattle, Washington. I am a clinical associate professor at the University of Washington School of Pharmacy, and I am here today representing pharmacy as a member of the Washington State Pharmacy Association, the American Pharmacists Association, and the National Community Pharmacists Association.

Kelley-Ross Pharmacy is a better-known small business that has served the Seattle community since 1925. My father is a pharmacist and owned Kelley-Ross since 1973. I grew up in the pharmacy, and after serving in the Marine Corps, I attended pharmacy school at the University of Washington, and took over the practice in 2005. We currently have four locations providing high-quality care for our most vulnerable populations. Independent pharmacies like Kelley-Ross provide a crucial public safety role for our communities. Our ability to care for our patients is under a very real threat from harmful PBM practices that are costing our patients and limiting their access to pharmacy services. I appreciate the opportunity to speak in support of the PBM Transparency Act.

Since 1989, Kelley-Ross Pharmacy operated a location in a Seattle neighborhood that was the preferred pharmacy for a labor group made up of both active and retiree members. The retirees were enrolled into a single Medicare Part D plan. This was an uncommon situation for a community pharmacy. However, it has provided us with some unique insight into how a PBM can manipulate the system at the expense of our seniors. To illustrate how this happened, we can look at one drug, generic rosuvastatin. It is an inexpensive medication used to treat cholesterol. Historically, a 90-day supply of rosuvastatin cost the pharmacy approximately $10, and patient co-pays were set by the PBM at $15 for a 90-day supply.

Things changed in 2021, with patient costs increasing exponentially. The PBM moved rosuvastatin from their Tier 1 with a nominal co-pay to their Tier 3, which historically had been reserved for brand name medications only. This increased the patient co-pay, which was set by the PBM, from $15 to $141 for the same 90-day supply. There is no clinical rationale for this change, and there was no increase in drug costs. It simply created unnecessary out-of-pocket spend for the member, while creating a windfall for the PBM through the collection of retroactive generic effective rate, or GER, fees from the pharmacy.

GER fees are designed by the PBM to recoup overpayments from pharmacies. In this example, the PBM manipulated the patient co-pay to intentionally overpay the pharmacy, costing the patient an extra $500 a year in out-of-pocket expense without the PBM contributing a penny to the transaction. The overpayment was then retroactively clawed back to the PBM as a GER fee. This was not returned to the patient. We saw this happen over 150 times in 2021 with generic rosuvastatin, and it occurred with many other medications as well.

In 2018, our pharmacy had $81,000 clawed back from PBMs in the form of retroactive fees. This was a huge amount for us to incur, but we were able to remain sustainable. In 2021, this increased to over $538,000. It was largely driven by GER fees assessed by a single PBM for a single Part D plan, which resulted from artificial patient overpayments created by the PBM. This location was in the top 1 percent of all community pharmacies in the country in terms of our Medicare quality ratings for patient adherence, which means that presumably we were experiencing the lowest level of DIR fees. But because GER fees are assessed in aggregate across the network, there is no way of connecting a fee to a specific claim, but it is clear that the PBM was profiting at patient expense, essentially creating an invisible premium. These patients would have been better off without using their insurance, and that is not right.

There is obviously no way that a business could operate in these predatory and—with these predatory and unpredictable fees, so we made the difficult decision to close this location in 2022. Unfortunately, this is not the only type of PBM abuse that we have experienced. PBMs will argue that their business practices keep costs down. In reality, their vertical integration with payers and their own competing pharmacies create massive conflicts of interest and self-serving business practices that are harming patients, increasing costs to employers, and closing community pharmacies.

We need PBM reform, and this bill is a very good start toward providing transparency and protecting consumers and the pharmacies that care for them from these harmful PBM practices that add costs and unnecessary barriers to care. I would urge you to remove the exemption for PBMs that return rebates to the payer. My example demonstrated how a vertically integrated PBM could meet this exemption requirement and still cause economic harm to patients.

Thank you for the opportunity to share my story, and I look forward to any questions.

[The prepared statement of Dr. Oftebro follows:]

PREPARED STATEMENT OF RYAN OFTEBRO, PHARMD, FACA,
CEO, KELLEY-ROSS PHARMACY GROUP

Good morning, Chair Cantwell, Ranking Member Cruz, and members of the Committee.

My name is Dr. Ryan Oftebro. I am a pharmacist of 20 years and owner of Kelley-Ross Pharmacy Group in Seattle, WA. I am a clinical associate professor at the University of Washington School of Pharmacy, and I am here today representing pharmacy as a member of the Washington State Pharmacy Association, The American Pharmacists Association, and the National Community Pharmacists Association.

Kelley-Ross Pharmacy is a veteran-owned small business that has served the Seattle community since 1925. My father, John, is a pharmacist and owned Kelley-Ross since 1973. I grew up in the pharmacy, and after serving in the Marine Corps, I attended pharmacy school at the University of Washington and took over the practice in 2005. We currently have 4 locations providing high-quality care for our most vulnerable populations, including community pharmacy, Long Term Care, and community-based clinical services, and we have repeatedly been recognized for excellence and innovation by our profession.

Independent pharmacies like Kelley-Ross provide a crucial public safety role in our communities. In our rural and island communities, the pharmacist is not only the most accessible but often the ONLY healthcare provider available within miles. Our ability to care for our patients is under a very real threat from harmful PBM practices that are costing our patients and limiting their access to pharmacy services.

I appreciate the opportunity to speak in support of the PBM Transparency Act (S.127). This is a crucial piece of legislation to prevent PBM abuses, such as harmful "claw backs" after a prescription has been dispensed that are harming patients by overinflating their prescription drug costs and eliminating access to their preferred community pharmacies across the country.

I would like to share an example of these abuses, that resulted in a group of Medicare Part D beneficiaries being overcharged hundreds of thousands of dollars and the closure of the community pharmacy that had served them for decades, crushed by retroactive fees.

Since 1989, Kelley-Ross Pharmacy operated a location in a Seattle neighborhood that was the preferred pharmacy for a labor group, made up of both active and retiree members. The retirees were enrolled into a single Medicare Part D plan. This was an uncommon situation for a community pharmacy; however, it provided us with some unique insight into how a PBM can manipulate the system at the expense of our seniors.

To illustrate how this happened, we can look at one drug. Generic rosuvastatin is an inexpensive medication used to treat cholesterol.

A 90-day supply of rosuvastatin cost the pharmacy approximately $10.00 to acquire from our drug wholesaler.

The highly inflated and completely arbitrary Average Wholesale Price (AWP) for this drug was $805.40/90 tablets. This value is set by the manufacturer and used as a contracting benchmark by PBMs.

Historically, for a generic medication available from multiple manufacturers (multisource), we would submit the claim and the PBM would reimburse us at a level based on their proprietary software that determines the average actual acquisition cost of the drug. This is called the Maximum Allowable Cost (MAC) and is written into all PBM/pharmacy contracts. The pharmacy would be paid right around $15.00, and the patients' copay would be $15.00 or less. Because this medication is an inexpensive multisource generic, it was usually found in the lowest copay tier 1 of 4 so the patient copays were nominal.

Things changed in 2021, with patient costs increasing exponentially. The PBM moved rosuvastatin from Tier 1 with a nominal copay to Tier 3 which had historically been reserved for brand-name medications only. This increased the copay from $15.00 to $141.00 for the same 90-day supply. There is no clinical rationale for this change. It simply created unnecessary out-of-pocket spend for the member, while creating a windfall for the PBM through the collection of retroactive Generic Effective Rate, or GER fees, from the pharmacy.

GER fees are designed by the PBM to recoup "overpayments" from pharmacies.

In 2021, the PBM set a new Generic Effective Rate at AWP–90 percent. They then set the pharmacy's reimbursement to intentionally "overpay" at a rate of AWP–83 percent, which just happens to be $140.50/90-day supply. Because the copay for tier 3 medications was $141.00, the PBM covered none of the prescription cost and the copay for rosuvastatin was $140.50 instead of the $15.00 it was the previous year.

A difference of $125/90-day supply or over $500 more for the entire year out-of-pocket for the patient.

The PBM has now created a situation where the pharmacy was "overpaid" (in the form of patient copays) above the guaranteed GER of AWP–90 percent, at which point the PBM charges the pharmacy the difference (AWP–83 percent versus AWP–90 percent). This allowed the PBM to claw back over $80.00 that they never paid to the pharmacy. Extrapolate this over the Medicare population and the PBMs are profiting billions of dollars from patients' copays alone. This is just one of the ways that PBMs are profiting from obscure and completely nontransparent pricing. To make the process even more convoluted and untraceable the GER is not based on a per-prescription basis. It is based on an overall aggregate of all prescriptions across all pharmacies within a pharmacy services administrative organization or PSAO, which interacts with PBMs on behalf of independent pharmacies. That way there is no possible way to attribute the claw-back directly to an individual patient's copay.

This is just for one medication for one patient. We saw this happen over 150 times in 2021 with generic rosuvastatin, and it occurred with several other medications as well.

These patients would be better off without using their insurance and that is not right. In these situations, the pharmacy might be able to offer a much lower cash price, creating a better situation for both the patient and the pharmacy. However, the PBMs have created tools to disincentivize pharmacies from offering a competitive cash price to these Medicare patients. PBMs track patient adherence in the form of Medicare Star Ratings. If pharmacies fail to meet the PBMs expected adherence rate for cholesterol medications, which only happens when the patient's insurance is billed, the PBM penalizes the pharmacy in the form of increased direct and indirect remuneration (DIR) fees across ALL their claims. At the end of the day, the patient is faced with an unnecessarily high co-payment for a lifesaving medication, making it harder for them to take.

In 2018, this pharmacy had $81,000 clawed back from PBMs in the form of retroactive fees. In 2021 it increased to $538,810. This was largely driven by GER fees assessed by a single PBM for a single Part D plan, which resulted from artificial patient overpayments created by the PBM. This location was in the top 1 percent of all community pharmacies in the country in terms of our Medicare Star ratings for patient adherence, which means we experienced the lowest tier of DIR fees.

This contract move from MAC pricing to a GER also bypasses many pharmacies' ability to appeal a payment under laws enacted in most states typically referred to as MAC Appeals. This approach clearly attempts to circumvent legislative efforts to provide a level and fair playing field for all.

There is obviously no way that a business could operate with these predatory and unpredictable fees, so we made the difficult decision to close this location in 2022.

Unfortunately, this is not the only type of example of PBM abuses we have experienced.

Conclusion

PBMs will argue that their business practices keep costs down. In reality, their vertical integration with payer and their own competing pharmacies creates massive conflicts of interest and self-serving business practices that are harming patients, increasing costs to employers and closing community pharmacies. S. 127 is a great step towards providing the necessary transparency on how PBMs administer their pharmacy benefit and holding them accountable when they participate in unfair or deceptive business practices which ultimately harm the patient.

We need PBM reform, and S. 127 is a very good start. We need legislation that provides transparency and protects consumers and the pharmacies that care for them from the harmful PBM practices that add cost and unnecessary barriers to care.

I would urge you to remove the exemption for PBMs that return rebates to the payer. My example demonstrated how a vertically integrated PBM could meet this exemption requirement and still cause economic harm to patients.

Thank you for the opportunity to share my story, and I welcome any questions.

The CHAIR. Thank you, Dr. Oftebro, and thank you for your work at the University of Washington as well. Dr. Patt, welcome. Thank you for being here.

STATEMENT OF DEBRA PATT, M.D., PH.D., M.B.A., ONCOLOGIST, TEXAS ONCOLOGY

Dr. PATT. Thank you, Committee Chair Cantwell, Ranking Member Cruz, and members of the Committee. I appreciate the opportunity to testify on my experience with PBMs. My name is Dr. Debra Patt, and I serve as a breast cancer specialist in Austin, Texas. I serve in the leadership of Texas Oncology, a large independent community oncology practice, and I am the Vice President of the Community Oncology Alliance.

PBM transparency and accountability is critical because patients being able to get their oral cancer drugs in a timely, effective, and sustainable way allows them to realize the benefits of modern cancer therapy. PBMs steering the filling of these pills to their specialty and mail order, vertically integrated pharmacies all too often results in unnecessary delays, denials, and waste for cancer patients getting potentially lifesaving treatments.

This is a remarkable time when instead of cancer treatment disrupting how patients live and work or even being a death sentence, they can enjoy their life with their cancer and control it as a chronic disease, much like hypertension or diabetes. Many Americans with cancer can continue to live in their own lives, work at their jobs, teach at their schools, pick up their kids from soccer practice, and eat dinner at their dinner tables. Oral cancer therapy accounts for about 30 percent of these therapies today, and we anticipate this will grow to over 60 percent in the next few years, so this is a large issue and it is growing.

The increasing use of these effective, but expensive, specialty drugs and their profit potential has attracted the top PBMs, with the largest three controlling 80 percent of the prescription drug market, and adding the next three largest adds to 96 percent of control. This gives these PBMs, who are owned by or own the largest health insurers, substantial leverage in controlling what treatment patients get and how and when they get it. PBMs frequently delay and deter appropriate and timely therapy for my patients.

The delays and detours are difficult to anticipate and limit a doctor's ability to effectively control the cancer, and delays can lead to poorer disease control, morbidity, and mortality for the patients we serve. Doctors frequently modify treatment doses to optimize therapy and control toxicities, sometimes in as little as 1 to 2 weeks after starting a treatment. When a PBM mail order pharmacy is only willing to fill a 90-day script and supplies of cancer medications, then this can lead to extremely expensive waste as patients may get 1 to 2 additional months of drugs that they cannot ultimately use.

I urge you to read my testimony about my patient, Tonya, a 40-year-old woman with metastatic breast cancer that now is in her brain. Unfortunately, Tonya was blocked by PBMs and the insurer from getting the medication, abemaciclib, that I believe is one of the most effective therapies in treating her cancer and her brain metastases. As I saw her cancer metastasize and literally grow on the side of her trunk, I couldn't wait for the PBM and insurer to approve my appeal and had to resort to less effective and more toxic chemotherapy. Since December, Tonya has stopped working. When I saw her last week, we had to deal with two new brain me-

tastases we observed on her scans and initiate radiation therapy to address these.

I do not know for certain that Tonya would be better off if she had the pills I had prescribed. However, I do know that from the peer-reviewed literature, that she would have doubled her chances of living without cancer progression at this time in comparison to the chemotherapy that I had to give her, and that she would have had less toxicity, which would have allowed her to continue to work and live a more normal life, again, which is the dream of modern cancer therapy.

Due to the power of the top PBMs, the majority of oral cancer drugs are not filled at our medically integrated pharmacy, but are steered by the PBM to their corporate-affiliated specialty mail order pharmacy. PBMs will tell you that this is a cost-saving measure, but we do not see evidence that cost savings translates into patient or employer savings. In reality, PBMs control the practice of medicine. In addition, PBMs charge our—charge our medically integrated dispensing pharmacies steep DIR fees that are unanticipated expenses that are at a high percentage of total cost and increasing substantially. These are couched as quality measures, but DIR fees are not benchmarks on quality measures that are meaningful to my cancer patients. Things like the star rating is often benchmarked on hypertension and cholesterol medication filling. As a breast cancer specialist, you really do not want me controlling your hypertension or cholesterol, so this is problematic and not meaningful to cancer patients. We urgently need PBM transparency and accountability, and this legislation takes necessary steps to get us there.

Thank you for your leadership in shining a light of transparency on PBMs. While PBMs operate in the dark, Americans battling cancer and other serious diseases suffer. Thank you for this time, and I am happy to answer any questions.

[The prepared statement of Dr. Patt follows:]

PREPARED STATEMENT OF DEBRA PATT, MD PHD MBA, MEDICAL ONCOLOGIST, TEXAS ONCOLOGY

I thank Committee Chair Cantwell, Ranking Member Cruz, and members of the committee for the opportunity to share my views on PBMs.

What follows is my written testimony with links to relevant and important references included. I highly recommend that the committee read these materials, starting with the expose on PBM tactics/behaviors.

As background, I am Dr. Debra Patt, an oncologist specializing in breast cancer in Austin, Texas. I serve in the leadership of Texas Oncology, a large independent community oncology practice that is part of The U.S. Oncology Network, and I serve as Vice President of the Community Oncology Alliance.

PBM transparency and accountability is critical because patients being able to get their oral cancer drugs in a timely, effective, and sustainable way allows them to realize the benefits of modern cancer therapy. PBMs steering the filling of these pills to their specialty and mail order vertically integrated pharmacies all too often results in unnecessary delays, denials, and waste for cancer patients getting potentially life-saving drugs.

This is a remarkable time when instead of cancer treatment disrupting how patients live and work—or even being a death sentence—they can enjoy their life with their cancer and control it as a chronic disease, like hypertension or diabetes. Americans with cancer can work at their jobs, teach at their schools, pick up their kids from soccer practice, and eat dinner with their families.

Oral cancer drugs account for about 30 percent of cancer therapies and we anticipate this soon growing to 60 percent. The increasing use of these effective, but ex-

pensive specialty drugs, and their profit potential, has attracted the top PBMs, with the largest three controlling 80 percent of the prescription drug market and, adding the next three largest, the top six PBMs control 96 percent of the prescription drug market. This gives these PBMs, who are owned by or own the largest health insurers, substantial leverage in controlling what treatment patients get and how, when, and where they receive it.

PBMs frequently delay and detour appropriate and timely therapy for my patients. The delays and detours are difficult to anticipate and limit a doctors' ability to effectively control the cancer, and delays can lead to poorer disease control, morbidity, and mortality.

Doctors frequently modify treatment doses to optimize therapy and control toxicities, sometimes in as little as 1–2 weeks after starting treatment. When a PBM mail order pharmacy is only willing to fill 90-day supplies of cancer medications this can lead to extremely expensive waste or suboptimal dose modification.

As a breast cancer doctor, I will illustrate some PBM issues using the oral cancer drug abemaciclib (brand name Verzinio) as I write for this medication frequently for patients with ER+ breast cancer. This drug is incredibly beneficial and improves survival in patients with advanced breast cancer but has some substantial toxicity with diarrhea that requires management and dose modification. The medication is also unique because it is helpful in treating brain metastasis, which many cancer therapies do not treat.

Tania is a 40-year-old woman with metastatic breast cancer that has now metastasized to her brain. When her cancer grew in October 2022, I recommended we use abemaciclib in addition to other medications on November 1, 2022 and explained to Tania that because we would have to go through her insurance company and PBM I was uncertain how quickly she might get the medication. I told her that the therapy has been published in peer reviewed literature and I was optimistic it was her best shot at continuing her quality of life and slowing her disease progression—especially in her brain. After the pills were denied, and I appealed, I was informed it could take six weeks to even have a peer review and they couldn't tell me when in the next six weeks I would be called to appeal the decision. While this seemed unreasonable, because it would allow Tania to feel well enough to continue to work and allow her to keep her hair, I was inclined to continue to try to get the medication for her. In the coming weeks as Tania was off treatment her disease worsened and she developed metastasis in the skin on the side of her trunk. I could see it growing and I told her we really couldn't wait any longer to see if her insurance would cover the abemaciclib, and we would have to do something different. In December, when I still had not been able to talk to a doctor to have her treatment approved, I started her on traditional chemotherapy in addition to a targeted therapy. Since December, Tania has stopped working. When I saw her in follow up last week we spoke about her two new brain metastasis we observed on her brain scans and how we would try to address those with additional radiation treatments.

We very commonly see how vertically integrated PBMs and their corporately affiliated specialty pharmacies delay appropriate therapy, especially when they demand that patients use their mail order pharmacies to get their cancer drugs and other specialty therapies. The Community Oncology Alliance (COA) has done a good job of characterizing these challenges and relating real-life patient stories, which I have attached to this testimony. When you have an advanced cancer, delaying initiation of treatment can contribute to morbidity or mortality.

Most often, with the PBM involved, we don't know when the patient will receive the medication, and after it is initiated, the cadence of refills is also a challenge. What the PBMs do is effectively "rip" quality medical treatment out of providers' hands and the site of care. Rather than help in care coordination they disjoint care. This leads to delays, denials, waste, and poor patient outcomes.

For example, when I see patients with advanced breast cancer and I prescribe abemaciclib, I am seeing these patients every two weeks to make sure that their toxicity of diarrhea is well managed and so I can dose reduce as necessary. Dose reduction is common and important in cancer care as it can lead to improved tolerance of the medication and enhanced adherence. When patients receive oral cancer drugs at our office-based medically integrated pharmacy, we can see a patient, check labs, and made dose modifications prior to the refill. That does not happen when the drug is filled by a PBM vertically integrated specialty mail order pharmacy. Routine refilling usually happens from PBMs at the same dose, without real time dose modifications. This leads to wastage of a month's supply or the patient taking the incorrect dose that will make the therapy more toxic. For abemaciclib, that could result in well over $10,000 of waste per month.

I will note that when we are allowed to fill the prescription at the point-of-care in our clinic, our medically integrated pharmacy is subject to fees typically months

after the medication is filled. These fees are referred to as direct and indirect renumeration (DIR Fees). These are fees that are supposed to be anchored to quality but are based on factors that are not indicators of quality in the cancer patients we treat. These DIR Fees have grown considerably over time, with DIR Fees in our practice comprising less than four percent of total cost seven years ago to more than 11 percent of cost today. This is an unexpected expense that we cannot anticipate or influence. These DIR fees are based on quality metrics that are not reflective of quality treatment in the patients I serve. For example, filling drugs to treat blood pressure and high cholesterol is not something I usually do in a cancer practice. And I will additionally note that these onerous DIR Fees are also assessed on independent pharmacies across the country, causing many to close and creating pharmacy "deserts" for patients.

I want to underscore, that due to the power of the top PBMs, the majority of oral cancer drugs are not filled at our medically integrated pharmacy but are steered by the PBMs to their corporate-affiliated specialty mail order pharmacies. PBMs tell you that this is a cost saving measure, but in reality it allows them to effectively control the practice of medicine.

We urgently need PBM transparency and accountability.

I thank Senator Cantwell for her leadership in shining the light of transparency on PBM practices and for working with Senator Grassley, and his leadership, on an issue that knows no political divide. The lives of our patients, and your constituents across the country, are very at stake. ***Action to stop PBM destructive behavior is needed more than ever.***

Additional abuses of PBMs, including but not limited to the following:

- "Fail first" step therapy requiring cancer patients to first fail on inferior cancer treatment or supportive care therapy before getting the most effective medication.
- Using prior authorizations to unduly delay and even deny cancer treatment.
- "Trolling" patients to steer them to PBM-owned or affiliated mail order pharmacies causing patient confusion and worry.
- Using rebates literally to extort price concessions from pharmaceutical manufacturers that do not get passed on to patients and to block using the least expensive drug like a biosimilar.
- Using "co-pay accumulators" to pocket co-pay assistance funding that should be going to reduce patients' deductibles.

Rather than elaborate on all the PBM abuses I see on a daily basis, I am including with this testimony materials that will help the committee better understand the abuses of PBMs, and how they have infiltrated other areas of medicine. However, so as not to make this document unmanageable in e-mailing, I have included links (below) hyperlinked to the source material. This research was aggregated with the assistance of the Community Oncology Alliance.

Thank you for the opportunity of testifying and submitting this written testimony for the record.

PBM Studies:

- PBM Dirty Tricks Comprehensive Exposé Report: *https://communityoncology.org/featured/pbm-dirty-tricks-expose/*
- PBM DIR Fees Investigative White Paper on Background, Cost Impact, and Legal Issues: *https://communityoncology.org/wp-content/uploads/2017/01/COA_White_Paper_on_DIR-Final.pdf*
- Report on PBM "Performance" Based DIR Fees: *https://communityoncology.org/research-and-publications/studies-and-reports/performance-based-dir-fees-a-rigged-system-with-disparate-effect-on-specialty-pharmacies-medicare-part-d-beneficiaries-and-the-us-healthcare-system/*

COA Comment Letters and Filings:

- Formal Comments to FTC on Harm of Pharmacy Benefit Manager Integration: *https://communityoncology.org/research-and-publications/comment-letters/coa-formal-comments-to-ftc-on-harm-of-pharmacy-benefit-manager-integration/*
- Letter to DHA on Tricare PBM concerns: *https://communityoncology.org/research-and-publications/comment-letters/letter-to-defense-health-agency-on-tricare-pbm-concerns/*
- Amicus Brief on PBM Contract Pharmacy Takeover of 340B Program in AstraZeneca dispute: *https://communityoncology.org/research-and-publications*

/comment-letters/coa-amicus-brief-in-340b-contract-pharmacy-dispute-22-1676-az/

PBM Horror Stories Series: https://communityoncology.org/category/research-and-publications/pbm-horror-stories/

1. *https://communityoncology.org/research-and-publications/studies-and-reports/the-real-life-patient-impact-of-pbms-volume-i/*
2. *https://communityoncology.org/research-and-publications/studies-and-reports/the-real-life-patient-impact-of-pbms-volume-ii/*
3. *https://communityoncology.org/research-and-publications/studies-and-reports/the-real-life-patient-impact-of-pbms-volume-iii-2/*
4. *https://communityoncology.org/research-and-publications/studies-and-reports/pharmacy-benefit-manager-horror-stories-part-iv-2/*
5. *https://communityoncology.org/research-and-publications/pharmacy-benefit-manager-horror-stories-part-v/*

The CHAIR. Thank you, Dr. Patt, and best wishes to your patient you mentioned.

Dr. PATT. Thank you.

The CHAIR. Thank you for sharing her story. Dr. Trish, welcome.

STATEMENT OF ERIN TRISH, PH.D., CO-DIRECTOR, LEONARD D. SCHAEFFER CENTER FOR HEALTH POLICY AND ECONOMICS, ASSOCIATE PROFESSOR OF PHARMACEUTICAL AND HEALTH ECONOMICS, MANN SCHOOL OF PHARMACY AND PHARMACEUTICAL SCIENCES, UNIVERSITY OF SOUTHERN CALIFORNIA

Dr. TRISH. Great. Thank you. Chair Cantwell, Ranking Member Cruz, and other members of the Committee, thank you for the opportunity to testify here today. My name is Erin Trish, and I co-direct the Leonard D. Schaeffer Center for Health Policy and Economics at the University of Southern California.

The Schaeffer Center strives to measurably improve value in health through evidence-based policy solutions, research excellence, and public and private sector engagement. As part of this mission, my colleagues and I have been studying prescription drug markets for over a decade. Prescription drug markets are complicated, and it takes a lot of boxes and arrows to show you even a simplified version of how the dollars and goods flow. While that type of complexity keeps health economists like me in business, it still remains a mystery to most Americans, and we know that where there is mystery, there is margin.

Pharmacy benefit managers, or PBMs, which operate in the middle of the pharmaceutical supply chain, play an important role in drug pricing. Historically, PBMs were independent from health plans and added value by reducing prices, encouraging uptake of generics, and expanding the use of mail order services. However, a wave of consolidation and other activities in the last few years have distorted behavior. Unfortunately, evidence indicates that PBMs are now leveraging their position to extract profits in ways that are detrimental to patients, payers, and the drug innovation ecosystem more broadly.

Perhaps one of the most well-studied issues has been the use of rebates. Rebates drive a wedge between a drug's list price and its net price, or the amount the manufacturer actually receives. Schaeffer Center research has shown that for every $1 increase in estimated rebates, list prices increased $1.17 between 2015 and

2018. These rebates have grown considerably over the last decade, distorting the market and raising costs for many patients at the pharmacy counter.

The incentives are particularly perverse. Beneficiaries pay the most as a share of the net cost of the drug—for drugs that face the most competition where rebates tend to be largest. The ultimate result of these practices is to decrease the effective generosity of insurance by reducing premiums but increasing out-of-pocket costs. Put another way, the system transfers financial resources from sick patients to healthy premium-paying beneficiaries, the opposite of what insurance is supposed to do. Take insulin, for example. Insulin is a highly competitive drug class with rebates typically greater than 50 percent of the list price. Nonetheless, many patients face high out-of-pocket costs for insulin, precisely because list prices are inflated so PBMs can extract large rebates.

Schaeffer Center research also demonstrates the importance of following the money. My colleagues found that while total expenditures per unit of insulin remained relatively stable from 2014 to 2018, manufacturers are actually getting paid less year over year. Meanwhile, the share of spending captured by PBMs increased 155 percent over that 5-year period. At this point, less than half of each dollar spent on insulin goes to the manufacturers. Instead, the majority gets siphoned away by distribution system intermediaries, a parasitic loss, if you will.

Other examples abound. For one, a 2018 Schaeffer Center study found that 23 percent of prescriptions involved a patient co-payment that exceeded the cost of the prescription to the PBM, or a so-called co-pay clawback. That is, the patient paid too much and the PBM kept the difference. Another: investigations and lawsuits in recent years have illuminated the pervasive practice of spread pricing, where PBMs charge health plans and payers more for a given transaction than what they reimburse to the pharmacy, keeping the spread or difference. For example, a 2018 Ohio auditor report found that PBMs charged the state a spread of more than 31 percent for generic drugs for its Medicaid plans. And another: in 2020, PBMs extracted $9-and-a-half billion in price concessions, the type we have heard about from the previous two witnesses, from pharmacies on Part D—on Medicare Part D transactions alone, up over 1,000 percent from a decade prior.

These issues might be less concerning if we believed our current system of pharmaceutical distribution and reimbursement centered on and orchestrated by PBMs was working efficiently. Unfortunately, evidence suggests that it is not. When my colleagues and I compared cash prices for common generic drugs at Costco with their cost to the Medicare system, we found that Medicare overpaid on 43 percent of prescriptions in 2018, totaling $2.6 billion in overspending for the program in that year alone.

It is clear that reforms are needed to improve the functioning of the pharmaceutical distribution system and ensure that the system works to benefit patients and drive value. These could include things like increasing transparency, prohibiting tactics that feed off the current complexity, and further investigation to better understand the myriad ways the current system harms consumers and

reduces innovation. Thank you, and I look forward to your questions.

[The prepared statement of Dr. Trish follows:]

PREPARED STATEMENT OF ERIN TRISH, PH.D., CO-DIRECTOR, LEONARD D. SCHAEFFER CENTER FOR HEALTH POLICY & ECONOMICS, ASSOCIATE PROFESSOR OF PHARMACEUTICAL AND HEALTH ECONOMICS, MANN SCHOOL OF PHARMACY AND PHARMACEUTICAL SCIENCES, UNIVERSITY OF SOUTHERN CALIFORNIA

Key Points:

1) Structural reforms are needed to address the complex and influential role that intermediaries—especially pharmacy benefit managers (PBMs)—play in the pharmaceutical distribution system.
2) PBMs historically served a useful role to lower costs through price negotiation, greater use of generics, and expansion of mail-order services. But consumers have been left behind by recent trends in the PBM marketplace.
3) Rebates, spread pricing, clawbacks, vertical integration, and other practices allow PBMs to hide cost savings from patients and payers.
4) PBMs and other intermediaries capture an increasing share of drug expenditures—for example, more than half of spending on insulin—distorting drug pricing and reducing manufacturer incentives to innovate.
5) Greater transparency is needed in this marketplace, and PBMs should be required to share savings with consumers and plans.

Chairwoman Cantwell, Ranking Member Cruz, and other distinguished members of the Committee, thank you for the opportunity to testify before you today about the need for transparency and accountability in the pharmacy benefit manager market. The opinions I offer today are my own, and build on previous statements.

My name is Erin Trish and I co-direct the Leonard D. Schaeffer Center for Health Policy & Economics at the University of Southern California. The Schaeffer Center strives to measurably improve value in health through evidence-based policy solutions, research excellence, and public-and private-sector engagement. As part of this mission, my colleagues and I have been studying prescription drug markets for over a decade.

Prescription drug markets are complicated, and it takes a lot of boxes and arrows to show you even a simplified version of how the dollars and goods flow. While this complexity keeps health economists like me in business, it still remains a mystery to most Americans. And where there is mystery, there is margin.

Pharmacy Benefit Mangers ("PBMs")—which operate in the middle of the U.S. pharmaceutical supply chain—play an important role in drug pricing. PBMs manage drug benefits on behalf of health insurers (including Medicare Part D plans) and employers, creating formularies and leveraging their bargaining power to negotiate rebates from manufacturers.

Historically, PBMs were independent from health plans and added value by reducing prices, encouraging uptake of generics, and expanding mail-order services. However, a wave of consolidation in the last few years—including health insurers buying up PBMs and PBMs expanding their footprint in pharmacy markets—and other activities have distorted behavior. Unfortunately, evidence indicates that PBMs are now leveraging their position to extract profits in ways that are detrimental to patients, payers, and the drug innovation system more broadly.

Perhaps one of the most well-studied issues has been the use of rebates. Rebates drive a wedge between a drug's list price and its net price, or the amount the manufacturer actually receives. In fact, increasing rebates are one of the key drivers of increasing list prices over time; Schaeffer Center research has shown that for every $1 increase in estimated rebates, list prices increased $1.17 between 2015 and 2018.

Our research sheds light on how patients have been harmed by rebates in the Medicare Part D program. Rebates—as a share of total drug costs in Medicare Part D—have more than doubled over the last decade. We estimate that about half of Part D beneficiaries who do not receive low-income subsidies would pay less out-of-pocket if rebates were applied at the point of sale. The incentives are particularly perverse—beneficiaries pay the most (as a share of the net cost of the drug) for drugs that face the most competition, where rebates tend to be largest.

PBMs have deflected blame for these rebate practices by pointing out that they pass through most of the rebates they collect to health plans, who may then use them to keep premiums low for beneficiaries. But the ultimate result of such prac-

tices is to decrease the effective generosity of insurance by reducing premiums but increasing out-of-pocket costs. Put another way, this system transfers financial resources from sick patients to healthy premium-paying beneficiaries—the opposite of what insurance is supposed to do. Instead, with the current system, patients who do not respond to cheaper therapies are subject to "double jeopardy"—not only is their condition recalcitrant, but now they have to pay more out-of-pocket.

Beyond these distributional issues, rebates distort market incentives. There is indirect evidence to suggest that PBMs favor high list price, high rebate drugs over drugs with a lower net cost, although it is hard to prove definitively without access to actual rebate data. But, as an example, one analysis of Medicare Part D formularies demonstrated that 72 percent placed at least one branded drug in a lower cost-sharing tier than its generic product.

The recent FDA approval of the first interchangeable insulin biosimilar provides another instructive example. Viatris simultaneously launched two versions of the drug—a branded product (Semglee) with a relatively high list price and presumably large rebates, and an authorized but unbranded version (Insulin Glargine) with a list price 65 percent lower than Lantus (the reference drug). Despite that significant discount, Glargine has not gained traction on PBM formularies.

Insulin is a highly competitive drug class, with rebates typically greater than 50 percent of the list price. Nonetheless, many patients face high out-of-pocket costs for insulin—precisely because list prices are inflated so PBMs can extract large rebates. Efforts to cap patients' out-of-pocket spending on insulin help, but they are a Band-aid for a much more systemic disease.

Schaeffer Center research also demonstrates the importance of following the money. My colleagues found that, while total expenditures per unit of insulin remained relatively stable from 2014 to 2018, manufacturers are actually getting paid less year-over-year. You might ask who is making more. It turns out the share of spending captured by PBMs increased 155 percent over the five-year period. When we are spending roughly $400 billion per year on drugs, that increasing margin adds up.

At this point, less than half of each $1 spent on insulin goes to manufacturers. Instead, the majority gets siphoned away by distribution system intermediaries—a parasitic loss, if you will. This trend is true across other drugs too. This reduces incentives for innovation and redirects spending away from the companies developing new therapies to improve health and save lives.

PBM issues expand beyond rebates—take generic drugs, which typically do not provide rebates to PBMs. Nonetheless, there is evidence that PBMs often overcharge for generic drugs. My colleagues and I compared the prices that Medicare Part D plans pay for common generic drugs to the prices at Costco pharmacies. We found that—relative to Costco's member prices—Medicare Part D plans overspent on generics by $2.6 billion in 2018. While there is robust competition among these common generic drugs, the marketplace leaves room for PBMs and other intermediaries to capture the value rather than share it with beneficiaries and taxpayers.

Other examples abound. A 2018 Schaeffer Center study found that 23 percent of prescriptions involved a patient copayment that exceeded the cost of the prescription to the PBM—or a so-called copay "clawback." This finding stands in stark contrast to testimony offered a year prior by a PBM lobbyist to the Senate HELP Committee that PBMs did not support the practice of collecting patients' copay in excess of the cash price and that, if such practices happened, they were "outliers."[i]

It is not only patients who bear the cost of these market distortions, but increasingly pharmacies too. In 2020, PBMs extracted $9.5 billion in price concessions—categorized as direct and indirect remuneration ("DIR")—from pharmacies on Medicare Part D transactions alone, up over 1,000 percent from a decade prior. Moreover, investigations and lawsuits in recent years have illuminated the pervasive practice of "spread pricing," where PBMs charge health plans and payers more for a given transaction than what they reimburse to the pharmacy, keeping the "spread" or difference. A 2018 Ohio Auditor report—one of the earliest such investigations—found that PBMs charged the state a spread of more than 31 percent for generic drugs for its Medicaid plans, with taxpayers ultimately footing the bill.

It is clear that reforms are needed to improve the functioning of the pharmaceutical distribution system and ensure that the system works to benefit patients and drive value. In today's market, PBMs are exploiting its complexity and opacity to increase profits while avoiding scrutiny.

More transparency is sorely needed, and policy solutions that work toward that goal should be pursued. Existing PBM tactics that feed off market opacity—like

[i] Testimony of Mark Merritt, CEO of PCMA, to Senate HELP Committee, October 17, 2017. See exchange with Senator Susan Collins beginning at 1:15:55.

spread pricing and clawbacks—should be prohibited. More transparency is needed on the structure and magnitude of rebates and other fees, particularly as contracts and fee structures of PBMs and their affiliates evolve. Likewise, additional insight is needed into PBM-pharmacy reimbursement, particularly as PBMs play an increasing role in pharmacy and specialty pharmacy markets, with increasing vertical integration interjecting additional layers of complexity and scope for arbitrage.

While policy to provide such transparency is needed now, there is also more to learn. Further investigation is warranted to better understand the myriad ways the current system harms consumers and reduces innovation—especially innovation that will lower costs for everyone. In such a complex and opaque market, research using publicly-available data can only get us so far; more detail is needed to better follow the money. Regardless, more competition between PBMs would help, and increased transparency is an important first step toward achieving that goal.

I look forward to your questions.

The CHAIR. Thank you very much, Dr. Trish. Thank you in general for your work. Dr. Mulligan.

STATEMENT OF CASEY B. MULLIGAN, PROFESSOR OF ECONOMICS AND PROGRAM DIRECTOR OF THE INITIATIVE ON ENABLING CHOICE AND COMPETITION IN HEALTHCARE, UNIVERSITY OF CHICAGO

Dr. MULLIGAN. Good morning, Chairman Cantwell, and Ranking Member Cruz, and members of the Committee. Thank you for this opportunity to comment on the economics of pharmacy benefit management.

Prescription drugs greatly contribute to public health, but they are expensive to develop, which brings economics front and center. Drug insurance plans understand that it is wasteful, namely requiring premiums that are too high to attract members to have third-party payment and leave the benefit unmanaged. Benefit management is fundamentally an economic activity involving planned design, such as allocating drugs to different co-pay tiers, drug utilization reviews that help improve drug effectiveness, obtaining rebates and discounts from those providers whose sales are increased by the plan.

Group purchasing and negotiated discounts are even more valuable when manufacturers and pharmacy companies are monopolistic or oligopolistic. Buyers' clubs can and do take a small amount of competition among sellers and magnify it. Naturally, they benefit buyers, but it is not a zero sum game. Buyers' clubs benefit buyers more than they cost sellers, and sometimes benefit sellers too.

Group purchasing and negotiated discounts are tools familiar from buyers' clubs, such as Costco and Sam's Club. Costco members may not have a particularly price-sensitive demand for specific brands of, say, skateboards, but skateboard manufacturers, if they dealt with them individually, would hike their prices, but Costco limits who can sell to their members to those pricing the lowest. Sellers' best response in this situation is to steeply discount and partly make up on volume. Lower prices in higher quantities are the proof that buyers' clubs are pro-competitive.

PBMs are buyers' clubs for members of multiple drug plans. Much like Costco excludes skateboard manufacturers, PBMs can place a manufacturer's products to incentivize discounts for consumers. Any buyers' club requires resources. These costs limit the scope and degree of involvement of buyers' clubs in the economy.

Costco and PBMs have innovated to become more productive and thereby expand their contribution. Keenly aware of the common economics, Costco itself has gotten hugely into the business, purchasing, I believe, three PBMs of different types.

Regulation is likely to be the opposite of this process by raising management costs and reducing discounts received by members of health insurance plans. Indeed, drugs plans and their PBM agents have done a remarkable job at getting prescriptions to the patients who need them. Studies repeatedly show that drug utilization is essentially as high before patent expiration as it is after, even though the cheaper generics are available only after expiration. PBMs and plans also do the advanced financials for unique new drugs under development so that plan members can get access as soon as possible after FDA approval. Sadly, European patients do not have PBMs working for them, and they are treated with less effective, older generation oncology and other drugs.

With the Federal Government as a partner in paying premiums and medical procedures that can result from poor adherence, PBMs help taxpayers, too, and thereby the wider economy. I estimate that benefit management expands the economic pie more than $145 billion per year. The other side of the coin is that manufacturers and pharmacy companies may push for regulations to restrict the activities of buyers' clubs. I estimate that a variety of such regulations benefit manufacturers and pharmacy companies to some degree, but at greater cost to patients, plans, and taxpayers, because their regulations forego part of that $145 billion.

In the likely case that large, incumbent PBMs better adapt to regulation than smaller new ones do, another unintended consequence would be reduced competition, namely, growing up big PBMs at the expense of the little ones. Section 2 of today's bill gives PBMs two compliance options, one requiring them to publicly disclose their remuneration, and the other prohibiting pharmacy discounts that are obtained "arbitrarily, unfairly, or deceptively." How will Chairman Khan interpret those words, I do not know, so I have worked out a few different scenarios.

One scenario involves significant costs to protect pharmacy companies from competition, adding between $8 and $11 billion annually to the Federal deficit. Another scenario is dominated by the mandatory disclosures that, as DOJ, FTC, and others have warned, may undermine competition among manufacturers, and among pharmacies, and among PBMs. The annual net costs of producing just manufacturer competition could easily exceed $25 billion annually and add $20 billion annually to the Federal deficit. Also, reducing pharmacy and PBM competition could potentially bring the total addition to the deficit of $40 billion annually.

Thank you, and I welcome your questions.

[The prepared statement of Dr. Mulligan follows:]

PREPARED STATEMENT OF CASEY B. MULLIGAN, PROFESSOR OF ECONOMICS AND PROGRAM DIRECTOR OF THE INITIATIVE ON ENABLING CHOICE AND COMPETITION IN HEALTHCARE, UNIVERSITY OF CHICAGO

Good morning Chairman Cantwell, Ranking Member Cruz and Members of the Committee. Thank you for this opportunity to comment on the economics of pharmacy benefit management.

Benefit management is fundamentally an economic activity. Because it is about contracting, coordination and trade, market-level economic analysis is required to fully understand its effects.

Including a 2018–19 leave of absence to serve as the Chief Economist of the White House Council of Economic Advisers (CEA), I have been a Professor of Economics at the University of Chicago for 20 years, and Associate and Assistant Professors before that. I have published extensively on regulatory economics including healthcare regulation.[1] I cowrote the textbook *Chicago Price Theory,* which is novel in terms of its emphasis on the role of what we call "buyers' clubs" in the economy. My research into the details of PBM operations began in 2018 when President Trump directed the CEA to estimate the economic and fiscal effects of rebate regulation.[2] Hearing from various industry participants and government experts, I built an artificial intelligence (AI) model of the regulatory effects. Six months later, the AI platform I created for answering regulatory and many other economic and statistical questions won a 2019 Wolfram Innovator Award.[3] Returning to the University of Chicago, I prepared research papers specifically relating the economics of buyers' clubs to employer-sponsored health insurance (Mulligan 2021a) and pharmacy benefit management (Mulligan 2022). Most recently I completed the development of an open-source quantitative model of the economic and fiscal effects of regulating pharmacy benefit management.[4]

My conclusions and opinions are based on my own research, teaching, and experience with economic regulation. They do not necessarily represent the views of the University of Chicago or of the prior administration.

The Economics of Benefit Management in the Context of Prescription-Drug Markets

The path from medical innovation to health

Prescription drugs have reduced mortality and morbidity from heart disease, cancer, infectious disease, and many other health conditions.[5] The U.S. market size is approaching $500 billion annually, with about two-thirds of adults using them and almost 300 million people participating in prescription-drug insurance plans. With the market so profoundly affected by public policy, it is essential to understand its structure, conduct and performance.

A fundamental fact is that even cost-effective new drugs are expensive to develop (Lichtenberg 2019), which drives a demand for third-party financing, both of which can distort drug utilization. Drugs may be underutilized because of high marginal costs to the patient, lack of patient knowledge, inadequate supply chain infrastructure, or the moral hazard involved with preventing conditions whose medical expenses are themselves covered by insurance.[6] Moral hazard may also result in drug misuse and health harms, as it did with opioid prescriptions (Council of Economic Advisers April 2019), or in fraud and improper payments. With the stakes so high, identifying business models that would permit better utilization and lower cost could have tremendous value.

Why patients and plan sponsors seek a managed benefit

Drug insurance plan sponsors understand that it is wasteful—requiring premiums that are too high to attract members—to have third-party payment and leave the benefit unmanaged. Pharmacy benefit management services (PBM services) is the industry term for the management of patient utilization, processing of prescription

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[1] These include Mulligan and Shleifer (2005), Mulligan (2015), and Mulligan (2021b).

[2] Chapter 10 of *You're Hired! Untold Successes and Failures of a Populist President* describes the genesis of the "rebate rule" (84 FR 2360) and its regulatory impact analysis.

[3] My *TheoryGuru* platform, which is written in the Wolfram Language, has been the basis for cooperation with computer scientists who specialize in the type of artificial intelligence known as "automated reasoning" or "quantifier elimination" (QE). See Mulligan, Bradford, *et al.,* (2018a), Mulligan, Bradford, *et al.,* (2018b), or Mulligan, Davenport and England (2018). Although the domain of QE is narrower than the more famous chatbot systems (such as ChatGPT), QE rigorously adheres to arithmetic and logical deduction and never contradicts itself.

[4] Mulligan (2023). In conducting these last two studies, I received financial support from the Pharmaceutical Care Management Association, understanding that it had no control over the ultimate findings or their distribution.

[5] Lichtenberg (2003, 2007, 2019).

[6] Moral hazard refers to the distorted incentives that come with "spending other people's money" (Klick and Stratmann 2007). See also Burns' (2022, p. 603) description of the "implementation of outcome-based contracts requir[ing] significant investments in infrastructure (data collection and analytics capabilities)." The Food and Drug Administration (2020) cites the lack of financial incentives and quality management systems as two of the "root causes" of drug shortages.

drug claims, and negotiating plan savings from other actors in the healthcare supply chain. A PBM is a company that specializes in providing PBM services on behalf of plan sponsors. The services include plan design features such as allocating drugs to different copay tiers or requiring plan authorization prior to patient access, drug utilization reviews that help improve drug effectiveness and prevent adverse drug reactions, obtaining rebates and discounts from those providers whose sales are increased by the plan, and managing specialty drugs. PBM services thereby expand the economic pie in prescription markets.

PBM services also redistribute from manufacturers and pharmacies to consumers as negotiations and plan design fuel competition that lowers net retail and manufacturing prices. PBMs ultimately, if not intentionally, encourage drug innovation by increasing utilization early in a drug's patent life where sales are most important in terms of creating a financial return. By saving governments money and thereby limiting their need to increase distortionary taxes, PBM services also benefit the wider economy.

Perhaps public policy changes could increase competition among drug manufacturers and among retail pharmacies. But until that happens, competition can still be enhanced by group purchasing and negotiated discounts. PBMs do exactly that, in some of the same ways that Costco, Sam's Club, and other buyers' clubs obtain manufacturer discounts on behalf of their members.[7]

Buyers' clubs induce sellers to limit their exercise of market power by presenting them with a more price-elastic demand curve (Jaffe, *et al.,* 2019). The members of Costco may not have a particularly price-elastic demand for particular brands of, say, skateboards. Skateboard manufacturers know this and hike their prices when dealing with consumers individually. But Costco limits the number of manufacturers who can sell to their members to one or two manufacturers pricing the lowest. In effect, each manufacturer bidding to be in Costco faces a very price-elastic demand from the club because a small increase in price will cost them all sales through Costco. With a low price of skateboards in the store, Costco members buy more skateboards than they would if there were no buyers' clubs in that market. Quantity discounts obtained by buyers' clubs serve much the same purpose (Murphy, Snyder and Topel 2014). Either way, lower prices and higher quantities are the proof that buyers' clubs are procompetitive.

In much the same way that Costco excludes skateboard manufacturers and restaurants exclude soda vendors, PBMs can exclude manufacturers, or place a manufacturer's products less favorably in the plan, to incentivize the favored manufacturers to deliver drugs to plan members at a lower price. As Patricia M. Danzon put it, "[t]he basic principle is that PBMs can drive discounts on drug prices and pharmacy fees by restricting patients' choice of drugs or pharmacies, thereby increasing volume for preferred suppliers that accept the discounted prices. Thus, more restrictive drug formularies or pharmacy networks generally obtain larger discounts."[8]

Components of the value of management: utilization, drug innovation, and taxpayer savings

From the perspective of consumer demand, the first potential source of underutilization is the gap between list price and the marginal cost of producing, delivering, and administering the drug. This source is especially relevant for newer branded drugs that are still under patent and thereby available only from a single manufacturer, although other manufacturers may sell chemically different drugs that treat the same condition. It is also relevant for the purchase of retail pharmacy services. Economics has long noted that gaps between list price and marginal cost open opportunities for mutually advantageous trade between seller and buyers where the buyers receive a discount for purchasing more than they would at list price (Oi 1971, Telser 1994, Lakdawalla and Sood 2013). PBMs arrange such trades by (i) obtaining manufacturer rebates in exchange for placement in the plan's benefit structure that helps the manufacturer make additional sales to plan members and (ii) obtaining pharmacy discounts and higher-quality retailing in exchange for favorable pharmacy placement in drug plan pharmacy networks, which is valuable to the pharmacy due to the traffic it directs to the retail stores.

To put it another way, benefit management improves drug utilization both as a condition of receiving manufacturer and pharmacy discounts and because of the re-

[7] Costco is a buyers' club for a range of consumer products, including prescription drugs. Specifically, Costco owns the PBM Costco Health Solutions and is a partial owner of another PBM (Navitus).

[8] Danzon (2015, p. 246). See also FTC's (2014) conclusion that the "ability of health plans to construct networks that include some, but not all, providers (so-called 'selective contracting') has long been seen as an important to enhance competition and lower costs. . . ."

duced net prices.[9] Reduced net prices help plans reduce their premiums and enhance their benefits. Better utilization improves health, which itself reduces nondrug medical expenses (Lichtenberg 2007). Reduced premiums and medical expenses yield substantial government savings due to subsidies for health insurance premiums through Medicare and other government plans, the Affordable Care Act, and the exclusion of employer-plan premiums from income taxable by the personal income and payroll taxes.

Because drug sales revenue is an essential motivation for private-sector drug development and PBMs work to obtain reduced drug prices, drug development and PBM services would appear to be in conflict. However, additional utilization, and not just rebates, is also an outcome of plan-manufacturer negotiations. The relative importance of these two outcomes varies across drugs according to their age and characteristics. Manufacturers of unique new drugs—the drugs that add the most value—benefit from plan-manufacturer negotiations because of the additional utilization that occurs while paying a comparatively low rebate rate. In contrast, plans (or PBMs on their behalf) extract greater rebates from the manufacturers of older or "me too" drugs.

Unique new drugs are a small fraction of all drugs, as evidenced by the fact that 90 percent of drugs dispensed are generics. Even among spending on branded drugs, only a fraction is on single-source drugs, which means that the patent has not yet expired. Even among those, many faced significant competition from manufacturers of alternative drugs treating the same condition (Lakdawalla and Li 2021). In this way PBM services reduce aggregate manufacturer revenue while increasing the revenue for the small fraction of drugs that are unique and new.

The size of the utilization and net price effects of benefit management are interrelated quantitative questions. They can be assessed, as I have in two recent studies, from the empirical magnitude of rebates on branded drugs. Alternatively, the magnitude of branded rebates can be assessed from the fact that the generic substitution occurring after patent expiration results in no discernible increase in overall utilization (Lakdawalla and Philipson 2012). Both approaches similarly show that benefit management substantially increases drug utilization as it reduces net prices. On this basis, I conclude that pharmacy benefit management is worth at least $145 billion annually beyond its resource cost (Mulligan 2022).

Regulatory Impact Analysis

The risk-reward ratio: pharmacy DIR regulation

The PBM Transparency Act of 2023 and other PBM regulations put some of these economic gains at risk by constraining the use of benefit-management tools; discouraging investment in the capital assets that help manage utilization, claims, and other activities of drug plans; and creating barriers to further innovation and entry in the PBM business. In the likely case that large incumbent PBMs are better able to adapt to the regulations than smaller new PBMs are, the regulations would have the unintended consequence of reducing competition—growing large PBMs at the expense of smaller ones—while they increase the resource costs of managing pharmacy benefits. Even if a new regulation eliminated only 10 percent of the value of benefit management—something like $14 billion annually—it would not pass a cost-benefit test unless it also resulted in a commensurate regulatory benefit.

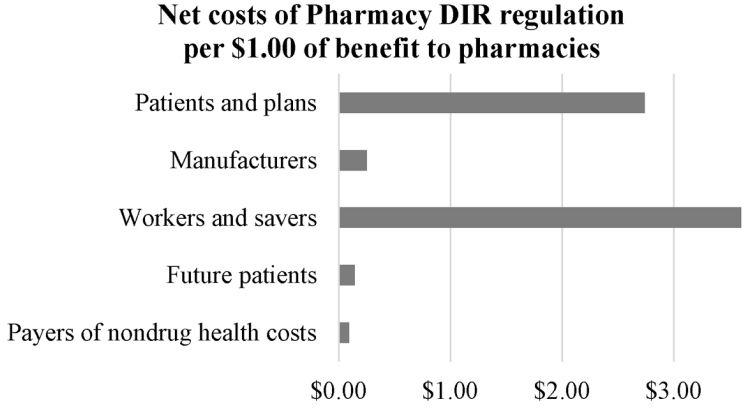
The PBM Transparency Act of 2023 includes provisions related to pharmacy direct and indirect remuneration (DIR), spread pricing (PBMs charge plans a different drug price than they pay to manufacturers), and mandatory disclosure of the terms of contracts that PBMs negotiate with manufacturers or pharmacies.[10] Section 2 of the Act specifically would give PBMs two compliance options: one option requiring PBMs to publicly disclose their remuneration and prohibiting them from retaining any of the discounts paid by manufacturers and pharmacies and another option pro-

[9] The net manufacturer price refers to the difference between the manufacturer's list price and the discount or "rebate" paid by the manufacturer to PBM or plan sponsor. The net pharmacy price refers to the difference between the pharmacy's list price for retail services and the discount received by the PBM or plan sponsor from the pharmacy. As part of their task of reducing costs while encouraging proper utilization, PBMs also keep plans informed as to the availability of generics and encourage generic substitutes to be dispensed when they are appropriate and available. This is one reason why generic utilization rates are significantly greater in the U.S. than in Europe (Wouters, Kanavos and McKee 2017), where PBMs are much less common.

[10] As negotiated by PBMs on behalf of their client plans, pharmacies receive funds from the plans up front—at the point of sale—for dispensing prescriptions and conducting drug-adherence programs. After the point of sale, payment adjustments are made and pharmacies return some of the funds to the extent that performance metrics were not met during the year. These various post-sale fees and settlement payments from pharmacies to plans and PBMs are known in the Medicare Part D program as pharmacy direct and indirect remuneration, or "pharmacy DIR."

hibiting (among other things) pharmacy DIR that is obtained "arbitrarily, unfairly, or deceptively." Because it remains to be seen how these terms would be interpreted and which of the two compliance options would be chosen by PBMs, I estimate the net (monetary and opportunity) cost of Section 2 for a couple of different scenarios.

One scenario is that a significant number of PBMs choose the pharmacy DIR restriction, which results in a reduction in the discounts provided by retail pharmacies. Pharmacies are potentially more profitable, but a far greater combined cost is imposed on patients, plans, manufacturers, and ultimately taxpayers. The chart below shows the net costs separately by type of market participant, expressed per dollar of pharmacy benefit.



While potentially benefitting pharmacies by providing a degree of protection against competition, pharmacy DIR regulation in the 2023 PBM Transparency Act would increase the costs of benefit management. The resulting increased pharmacy fees, increased plan premiums, and reduced utilization impose net monetary and opportunity costs on patients, plans, manufacturers, workers and savers, future patients, and payers of nondrug health expenses.

The net cost summed across the five categories is $6.82 for each dollar of pharmacy benefit.

Source: Table 3 of "Restrict the Middleman? Quantitative models of PBM regulations and their consequences." (Mulligan 2023)

Restrictions on pharmacy DIR reduce drug utilization directly because pharmacy DIR is an essential tool for incentivizing pharmacies, which are more proximate to patients than manufacturers or PBMs are, to help plans achieve adherence goals. The restrictions also reduce drug utilization indirectly by increasing the net price of retail pharmacy services, which are an essential part of the drug supply chain. Therefore, while DIR restrictions are expected to allow pharmacies to charge more for their retail services and spend less pursuing plans' management goals, these advantages accrue to fewer scripts due to the lower utilization. The redistribution from patient and plan to pharmacy has a side effect of lost opportunities from productive partnerships between pharmacy and plans.

As patients utilize less while net prices are higher (pharmacy charges apply to both brands and generics), pharmacy DIR regulation increases premiums for both drug plans and nondrug medical plans due to the additional medical costs that come with reduced drug adherence. Taxpayers—that is workers and savers who pay income and payroll taxes—are responsible for much of the added premium. They too miss valuable opportunities as they struggle to adapt to a greater tax burden, which is why the chart also shows a comparatively large burden on workers and savers.[11] Overall, pharmacy DIR proves to be a particularly oblique way of adding to pharmacy profits as patients, plans, and others ultimately pay more than $6 for each $1 of pharmacy benefit. If all PBMs adhered to this compliance option in the PBM Transparency Act of 2023 (rather than Section 2's detailed disclosure and other requirements), pharmacies would gain one or two billion dollars annually at an annual cost of nine or ten billion to the rest of the market and wider economy. In this

[11] Of course, the fiscal effect of any one regulation is small on the scale of overall Federal taxes collected. Nevertheless, because taxpayers are numerous, the value of the lost opportunities in labor and capital markets is not small on the scale of that one regulation's other costs and benefits. See also CEA (March 2019, Chapter 2).

scenario, the Act would add between $8 billion and $11 billion to the Federal deficit every year.

The risk-reward ratio: disclosure requirements

At last year's hearing, and elsewhere, it is alleged that (i) excess PBM profits increase drug costs and (ii) disclosure requirements would reduce drug costs by reducing excess PBM profits. Even if (i) were correct, (ii) does not necessarily follow because disclosure requirements could have unintended consequences that increase drug costs and perhaps even create excess PBM profits. A quantitative economic model such as that provided in Mulligan (2022, 2023) helps identify some of the unintended consequences and to assess their magnitude as compared to the intended benefits of the disclosures that would be mandated by the PBM Transparency Act of 2023.[12]

Mandatory disclosure may, among other things, hinder investment and innovation in benefit management.[13] One of the major intended (and procompetitive) results of a managed insurance benefit is to maintain different prices of products and services produced by monopolistic or oligopolistic manufacturers and pharmacies (Lakdawalla and Sood 2013). Because the systems for doing so are intellectual property that is rarely protected by patent or copyright, disclosure of proprietary information about those systems would remove much of the financial incentive to invest in advancing them because competitors could use the disclosed information to more rapidly imitate. Unlike other areas of healthcare where the product is a chemical, procedure, or device, much of the product of benefit management is the pricing and other contract provisions.

Unintended effects on investment and innovation may explain why, despite the presence of multiple PBMs as well as several other large companies in a position to enter the PBM business, voluntary full disclosure is, so far, hardly passing the market test.[14] If voluntary disclosure ultimately succeeds, then perhaps government mandates are not needed. Otherwise, plan-sponsor choices reveal that most of them assess the costs of publicly disclosed benefit management parameters to exceed the benefits.

The annual costs of PBMs are about $21 billion, of which about $7 billion is accounting profit (Sood, *et al.,* 2017). Because much of the accounting profit of PBMs is a competitive return on the capital essential for managing benefits, any public policy that succeeded in reducing PBM profits through enhanced competition would at best be reducing annual profits by $1 or $2 billion in a $350 billion prescription market.[15]

Disclosure requirements like this may stifle competition among manufacturers, among pharmacies, and among PBMs. On the first point, public disclosure of PBM contracts could facilitate collusion because the disclosure would allow competing manufacturers to know, in a more timely fashion, the amount of rebates that competing manufacturers were offering. In the context of disclosure of health care contract data, the Federal Trade Commission (2015) warned that "[w]hile [trans-

[12] Section 2 specifically requires, as a compliance alternative to the aforementioned pharmacy DIR requirements, that the "pharmacy benefit manager, affiliate, subsidiary, or agent provides full and complete disclosure of—(A) the cost, price, and reimbursement of the prescription drug to each health plan, payer, and pharmacy with which the pharmacy benefit manager, affiliate, subsidiary, or agent has a contract or agreement to provide pharmacy benefit management services; (B) each fee, markup, and discount charged or imposed by the pharmacy benefit manager, affiliate, subsidiary, or agent to each health plan, payer, and pharmacy with which the pharmacy benefit manager, affiliate, subsidiary, or agent has a contract or agreement for pharmacy benefit management services; or (C) the aggregate amount of all remuneration the pharmacy benefit manager receives from a prescription drug manufacturer for a prescription drug, including any rebate, discount, administration fee, and any other payment or credit obtained or retained by the pharmacy benefit manager, or affiliate, subsidiary, or agent of the pharmacy benefit manager, pursuant to a contract or agreement for pharmacy benefit management services to a health plan, payer, or any Federal agency (upon the request of the agency)."

[13] Burns (2022, Chapter 10) provides a history of PBM innovations. Burns points out (p. 603) that, among other investments, "implementation of outcome-based contracts requires significant investments in infrastructure (data collection and analytics capabilities)."

[14] Economics conceptually distinguishes disclosure from simple pricing, whereas some of the new PBM entrants have tied them together in practice. Lakadawalla and Sood (2013) and others find that complicated pricing provides substantial value in terms of high levels of utilization of unique drugs that are still under patent. Complicated pricing also helps to align incentives of various market participants (*e.g.,* financially aligning pharmacies with a plan sponsor's adherence goals). Whether the complicated pricing remains propriety information is a different question that is the topic of Sections 2 and 4 of the PBM Transparency Act.

[15] Some public policies that reduce profits also make consumers pay more because the policies create costs that are partly passed on to consumers. Making it more difficult for PBMs to do business may discourage companies from getting into the PBM business.

parency] laws can be procompetitive, [they] may require public health plans to publicly disclose competitively sensitive information, including *information related to price and cost.* Such disclosure may chill competition by facilitating or increasing the likelihood of unlawful collusion, and may also undermine the effectiveness of selective contracting by health plans. . . .”[16] The two anti-competitive concerns cited by the FTC are relevant to the PBM Transparency Act of 2023, because the Act specifically targets “cost, price and reimbursement” for disclosure and because selective contracting is an essential tool for pharmacy benefit management. Moreover, both the Department of Justice and the FTC (1996) note that the anti-competitive effects are especially likely when data is disclosed for individual sellers or that aggregate data is disclosed for which an individual seller contributes more than 25 percent to the aggregate. These are exactly the disclosure conditions set forth by Section 2 of the PBM Transparency Act.[17]

Consider, for example, three branded therapies competing. Absent disclosures, one pays a 20 percent rebate, a second pays 30 percent, and a third pays 40 percent. The second and third understand that they are rebating more than another competitor but are unaware that the gap from the more expensive competitor is a full 10 percentage points. As full disclosure reveals the gaps, the second reduces its rebate to 21 percent while the third reduces to 22 percent. In other words, full disclosure reduces the average rebate from 30 percent to 21 percent.

I estimate that the annual net costs of reducing brand competition in this way would be more than $25 billion, which already nets out the extra profits for brand manufacturers. About $40 billion would be added to the deficit annually as the Federal government spends more and sees its income tax base reduced as drug plan premiums increase.[18] A similar reduction in competition among pharmacies would have net costs of $8 billion per year. Reducing competition among PBMs, even if unintentional, could cost up to $48 billion per year. These are the risks of disclosure to be weighed against a potential reward of transferring one or two billion dollars annually from PBMs to other market participants.

Conclusions

Manufacturers and pharmacies sometimes refer to dedicated pharmacy benefit management companies (PBMs) as “middlemen” as if the PBMs were supply-chain toll collectors performing no legitimate economic function.[19] Insurance-plan sponsors—including state and Federal governments in their roles as plan sponsors—do not agree. In pursuit of better value for their members, plans consistently retain PBMs to help design their benefit, negotiate prices, and process claims. In several instances plans have launched their own PBMs to service plan members. Leaving the drug benefit unmanaged would be expensive and wasteful, even if it did partially relieve manufacturers and pharmacies of competitive pressures.

To be clear, neither PBMs nor their client plan sponsors invent or manufacture drugs or dispense them to patients. Their important effects on utilization and costs operate through the marketplace, especially as they help coordinate the various supply chain actors to discover and realize mutually beneficial gains from trade. Predicting effects of PBM regulations requires expertise on the operations of markets, from inventor and manufacturer through to the final consumer. Among the testimony you are hearing today, mine is unique in reflecting market level analysis, incorporating the various components of both supply and demand. None of the others is offering or relying upon an open-source quantitative market model of PBM regulation, which allows rigorous and transparent assessment of the tradeoffs and unintended consequences inherent in regulatory policy.

The PBM Transparency Act of 2023 is more of an economic regulation than a healthcare regulation. It would restrict pricing in business-to-business transactions and require disclosure of proprietary information. This by itself does not say whether the Act would have net benefits or net costs, but particularly the price controls

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[16] Emphasis added. The Minnesota Department of Human Services (2015) also concluded that “classifying plan-provider contracts as public data would offer little benefit but could pose substantial risk of reducing competition in health care markets. Such disclosure may reduce the incentive for all providers to offer low prices and may facilitate collusion among providers. High levels of market concentration . . . would facilitate these outcomes.”

[17] These conditions may also be set forth by Section 4 of the PBM Transparency Act, depending on if and how the disclosed data is presented to the public or to competitors.

[18] An analogy is the 2020 rebate rule (84 FR 2340), which the Congressional Budget Office (2019) and the Office of the Actuary of the Centers for Medicare and Medicaid Services (84 FR 2360) separately projected to add about $20 billion to the annual deficit, even though that rule would not apply to the commercial segment, whereas the Transparency Act would apply to all segments.

[19] Wilson (2021).

are a warning that the unintended consequences may be numerous and profound.[20] I estimate that the pharmacy DIR restrictions in Section 2 would cost patients, plans, and others more than $6 for every $1 of benefit provided to pharmacies. I estimate that disclosure requirements could impose tens of billions of dollars in annual net costs by discouraging competition among manufacturers, among pharmacies, and among PBMs. Ten billion dollars, and perhaps much more, would be added to the annual Federal deficit by the PBM Transparency Act of 2023.

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[20] The Federal government's Executive Branch acknowledges the high regulatory risk-reward ratio for price regulations in the Office of Management and Budget's (2003) Circular A–4. A–4 notes that imposing price regulations would, "in light of both economic theory and actual experience," require a "particularly demanding burden of proof."

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The CHAIR. Thank you very much. I am—I am reminded this morning of a time when we had a similar issue, derivatives, and one of our colleagues on the Senate floor said we cannot regulate derivatives, we do not understand them, and then shortly thereafter, our whole U.S. economy blew up. So I guarantee you we can look at this market, and we can understand what is going on, and we certainly can benefit from more transparency.

Since I served on the Judiciary Committee for a short period of time and then started this work on Senator Grassley, we were able, in the Affordable Care Act, to give CMS and the Department of Justice the ability to look at these numbers without disclosing them. And it is that kind of policing in the market that we expect people to do so that consumers, from the vertical integration that has happened, do not suffer from the concentration.

So I love the Costco model. In fact, I am trying to drive it into some other healthcare decisionmaking because if you buy in bulk, yes, you should get a discount. The question here is, who is getting the discount? Is the consumer getting the discount, or are the very manufacturers who own the PBMs getting the discount and pocketing it? And when we looked at this issue when it was Merck Medco, that is exactly what was happening. People were negotiating with King County and a union just like you discussed, and saying, OK, we negotiated a 35-percent discount. They gave the union 5 percent of the discount, and the company and the drug manufacturer pocketed the 35 percent, the very people who owned the drug. So these are the practices that are driving Americans crazy, and they want some transparency.

So I want to go back to you, Dr. Trish, since you are the resident expert here on the long study of this. What has changed? All the witnesses mentioned the vertical integration, so what has happened here is fewer people own the ability to create competition and buy the price. So I want you to explain what has changed over the last decade about that that has allowed this concentration of power. And then, if you could, also explain why this discount is not being passed on, and why now it is squeezing Dr. Oftebro because he has no recourse. He's a buyer. He's buying the drugs, but then he's not getting reimbursed for the price of the drug. So that is what is going on here. So why has this market power and concentration been accelerated over the last whatever period of time it is? I am saying it is 10 years, but maybe it is shorter or longer. I do not know.

Dr. TRISH. Absolutely. So if you look at the history, what we have seen is a considerable degree of integration in this industry where PBMs are no longer freestanding entities, but instead they—all of the three biggest PBMs are integrated, are owned by a health plan, a health insurer. Many of them also own or have a footprint in the pharmacy market, or at least in the specialty pharmacy market, and some in the healthcare provider market as well. And so that is now an entrenched set of incentives where they can, you know, have an incentive to essentially steer funds to themselves preferentially over to other independent pharmacies or other examples like that.

So if you look at the world where—you know, there are certainly examples where vertical integration can improve the way that markets function, but it also raises questions about incentives, right? And so if you are a PBM that is integrated, or affiliated, or owned by a health insurer, and you are thinking about do I want to preferentially have my contract benefit my health insurer relative to the other health insurers in the market, you know, that is the type of question that we need to better study. Likewise, if you own the pharmacy or a set of pharmacies, and you want to have more favorable reimbursement terms to the pharmacies that you own or that are affiliated with, or steer the business there, that can harm the independent pharmacies that are not affiliated. And that is exactly the type of contract structure that we need more insight into to understand how this is playing out in the market.

The CHAIR. Well, I definitely do not want a concentration of power, and then there are some—and there are some, who are even

these companies, who do not even want—they just want all mail order. That is what they want, and I could tell you, I believe in the pharmacists. I believe in the interaction that they have with the patient. I believe that it is a consult that is valuable to keep in our community.

So with that aside, it is the consumer who is not getting the discount. If you are buying on my behalf, whether it is a plan for, you know, the U.S. Government, a county or a business, I am hearing complaints now from big businesses in my state who are saying I—these people are cornering the market. It is affecting big employer plans, because they are doing the same thing. They have that much concentration of power. So we have no transparency onto what discount. Do you have any idea what kind of discounts are being driven? Do you have an idea about what percentages?

Dr. TRISH. So what we do know, I can tell from the work that—especially in the insulin space where there is a bit more transparency of things to some of the State efforts and other things that have happened. What we have seen is that over time, PBMs have, in fact, been effective at lowering the net—the net prices that those insulin manufacturers are receiving, but that, as you just described, is not the price that we as people or patients actually care about. What we care about is how much we are spending on these products. And the research that we showed—that we have done has shown that that has roughly been flat over time, but the—what is happening is the share of those dollars that are going to the supply chain have increased rather than the dollars that are going to manufacturers, but you are right, that the consumers themselves are not benefiting.

The CHAIR. Thank you. Senator Cruz.

Senator CRUZ. Thank you, Madam Chair. Welcome to each of the witnesses. Thank you for being here, Dr. Patt. Always good to see a fellow Texan. Welcome to D.C. I'll note, Chairwoman Cantwell observed that all four of our witnesses are doctors. It reminds me of the scene from the classic comedy "Spies Like Us," doctor, doctor, doctor, doctor, so welcome, doctors.

Dr. Mulligan, no one wants higher drug prices, and I think we need to look for creative solutions to lower them, but with every legislative solution, we got to consider the tradeoffs, especially when our solution is to grant additional authority to a government agency to regulate a particular market. Government regulation can create substantial compliance costs. It can also create barriers to entry for competitors in their market. This bill imposes both contractual disclosure requirements, meaning it tells PBMs they must share data on how much they pay providers and manufacturers for each drug, and it also prohibits things like clawbacks and spread pricing.

Dr. Mulligan, one argument for the bill is that there is too much consolidation among PBMs right now. We have heard that argument made this morning. In your analysis of the bill, could the bill's requirement lead to more or less market consolidation of PBMs?

Dr. MULLIGAN. It could lead to more——

Senator CRUZ. Please turn your microphone on.

Dr. MULLIGAN. It could lead to more. We doctors maybe should try not to do no harm. Regulations generally, they disproportionately burden the small businesses, and this bill does not have any exemption for smaller businesses. And the vertical integration that has been described is especially problematic with respect to this bill because the requirements are going to be telling the bigger PBMs how much does your left hand pay to your right hand? Well, they can just answer that any way that pleases the FTC. It does not really matter. What is going to matter is for the smaller companies.

Senator CRUZ. So I want to follow up on the question. So you are saying it would be beneficial, if you want to avoid market consolidation, for the bill to have some sort of exemption for smaller PBMs. Is that——

Dr. MULLIGAN. It would be better not to have the bill, but the bill with an exemption for smaller businesses, like we do with so many other regulations, would be an improvement.

Senator CRUZ. OK. That is—that is—that is helpful. If this bill was enacted into law, based on your economic analysis, how would it impact drug prices for the average American?

Dr. MULLIGAN. How would—300-million-plus Americans are on insurance, and insurance companies, they are the benefit managers or they hire people to do the benefit management for them. That is what they want. They want lower prices and better utilization, and you are undermining that activity, and so drug prices will go up. I estimate just the pharmacy part alone could add to premiums about $10 billion a year in aggregate.

Senator CRUZ. So explain how that is for someone at home who is watching this. Look, we have all been in a situation where you are paying too much, you are frustrated, you are dealing with the bureaucracy, and it pisses you off. Explain what you believe would be the negative consequences of this bill for a consumer at home that wants high-quality healthcare, high-quality pharmaceuticals at an affordable price. If I understand you correctly, you are concerned this bill would be counterproductive for that.

Dr. MULLIGAN. That is right, and we have pharmacy companies and manufacturers who have market power, and the best way consumers will be able to deal with that is to join these buyers' clubs, like they do with Costco. And now you are going to undermine the one tool they have had to try to create some competition in that space by burdening the very companies that—whose job it is and who have successfully gotten lower prices for the consumers.

Senator CRUZ. So if you are correct that this bill would hurt patients by driving up costs, typically when one group is being hurt in the economy, somebody else is doing better. So if consumers would lose money, who would get the money? Who makes out well under this bill?

Dr. MULLIGAN. Well, it is not a zero sum game, so the winners actually gain less than the losers from this bill, but the winners are the manufacturers. There would be lots of competition among manufacturers. They would——

Senator CRUZ. So like Big Pharma.

Dr. MULLIGAN. Big Pharma and the pharmacy companies.

Senator CRUZ. So your testimony is this bill benefits Big Pharma and allows them to make more money. Is that right?

Dr. MULLIGAN. Yes, and the report I put in the record has a numerical estimate of—to that effect, yes.

Senator CRUZ. And based on your analysis of the legislation, what do you calculate would be the additional costs to the Federal Government if this bill passed?

Dr. MULLIGAN. I still have to see how Chairwoman Khan interprets some of these words in the bill, but easily $10 billion a year to the Federal deficit, maybe $40 billion a year, maybe more.

Senator CRUZ. So over 10 years, you are talking somewhere between $100 billion to $400 billion in costs to the taxpayers?

Dr. MULLIGAN. Yes, it is in the ballpark of that rebate rule that was scored by OACT and CBO.

Senator CRUZ. Wow. OK. Thank you, sir.

The CHAIR. Senator Welch. Oh, OK.

STATEMENT OF HON. PETER WELCH, U.S. SENATOR FROM VERMONT

Senator WELCH. Thank you very much. Where is it? Right here. Thank you. I want to talk about the impact of PBMs. We have a real crisis in Vermont with the pressure on local pharmacies. In my view, local pharmacies are absolutely essential to the delivery of quality healthcare. In my experience, and it includes personal experience, a physician will give you a prescription, and everybody's prescription is not necessarily how it ultimately has to be. And the capacity of a patient to go into a local pharmacy where there is some trust and knowledge and have that physician be—or, pardon me, that local pharmacist be able to essentially talk through what some of the reactions are and help that person get the medication utilization that is actually the maximum benefit, is really essential to the well-being of the patient.

And we have got a healthcare system that is just crushing primary delivery people in it, and they are the most essential in it. And the local pharmacies with the PBMs are having inflicted on them something that is truly astonishing in a capitalist economy, and that is, they are allowed to sell it at price X, and 3 months later they get a clawback saying you owe us money. How in the—how in the world is that fair? Seriously. How in the world is that fair? And it is not just that it is a rip-off for the local pharmacist. It is crushing the capacity of those folks who care about the people in their community to be able to help the fellow citizens in their community. And it is just flat-out wrong.

So Senator Tester and I are working on something to try to protect our local pharmacies, and that is because we think those people are doing work that our—the folks we represent really, really need. So I'll ask each of you, how do we end this clawback? It is totally, completely unjustified and unfair, and we will just go down the line and people can tell me, are you for it or you against it?

Dr. OFTEBRO. Thank you, Senator Welch. As an independent pharmacist, I am against it because it is causing real harm. These fees are totally unpredictable and make it completely impossible to run a sustainable business.

Senator WELCH. Right. Let other people do it, but thank you for your good work.

Dr. PATT. So I concur. I think that DIR fees are not meaningful measures of quality. They have grown, from around 7 years ago, 4 percent of total costs to over 11 percent of total costs in our pharmacy today, and they are not anchored on any measure of quality. So if they were truly quality clawbacks, then I think that it would make sense, but, again, in my practice, it would measure things like have you had your hypertensive medications filled by our pharmacy. Have you had our cholesterol medications filled, and have you filled your oral oncolytics every 30 days?

Senator WELCH. You are giving me a headache. You have to deal with that?

Dr. PATT. Well, and so as a cancer specialist, frequently I hold medication because of toxicity to make sure patients can——

Senator WELCH. Right.

Dr. PATT.—remain adherent and benefit from therapy. So I would say actually they facilitate poorer quality——

Senator WELCH. Right.

Dr. PATT.—in the patients we serve, and they are anchored on unmeaningful measures. The other thing is, I think that you cannot just say DIR fees go away and it has one effect on the economics of the healthcare ecosystem because what happens is wholesale acquisition cost changes as DIR fees change, and so we would anticipate that the market reacts. But DIR fees clearly are not a measure of quality, and they diminish the ability for a pharmacist——

Senator WELCH. Thank you.

Dr. PATT.—to do meaningful work.

Senator WELCH. Thank you very much.

Dr. TRISH. Thank you. I am a health economist but sit in the School of Pharmacy at USC, so very much appreciate and have that firsthand experience of the important role that pharmacists play in our healthcare system.

I think, you know, I actually agree with Professor Mulligan that PBMs do need tools to effectively negotiate, right, that we do want the—our healthcare system to reflect the value of those negotiations. But when that happens in a highly opaque and complex market where PBMs are the one holding the information and initiating many of these fees after the fact in somewhat arbitrary or confusing or—in ways that, you know, as we have just heard, do not necessarily even reflect value, that is a concern, and that is a problem.

Senator WELCH. Thank you. Thank you very much.

Dr. MULLIGAN. I am a technocrat.

Senator WELCH. My time is up.

Dr. MULLIGAN. And technocrats are the last ones that should be asked to—asked to—what policies should be. We can tell you about the tradeoffs in elected officials. Now I will remind you of some of the tradeoffs, and it is—we practice this in the executive branch, that you are talking about regulating contracts, price controls. These can have side effects, unintended consequences that are—that are pretty bad, and so at least we need to do the due diligence around what the tradeoffs are.

And one of the tradeoffs are, if you are going to regulate contracts between pharmacies and other businesses, then that means that those businesses are going to tend to merge, and you are going to have, as Senator Cruz and I were discussing, you'll tend to favor the big guys.

The CHAIR. Dr. Mulligan, we have to—we have to move on, but I will——

Senator WELCH. Thank you, Madam Chair.

The CHAIR.—I will—I will send Senator Grassley to talk to you about that because I am pretty sure he does not agree with your interpretation. Neither do I, but I think, more importantly, let us—let us have him talk to you why he wanted the legislation designed this way. We do not think it is setting a price. It is taking activities that we think are unlawful in how they are acting. No one thinks spread pricing or clawbacks are the way to make the market function.

OK, we are to Senator—let us see. Senator Budd is here. Senator Budd.

STATEMENT OF HON. TED BUDD,
U.S. SENATOR FROM NORTH CAROLINA

Senator BUDD. Thank you, Chair. So I have had two—I have heard directly from patients in North Carolina. They cannot afford the medications that they need. The cost of drugs covered by Medicare grew at a rate faster than inflation. You know, it is serious for families that are struggling to keep up with the rising cost of grocery, utilities, seniors living on fixed incomes. So pharmacy benefit managers were created to negotiate drug prices and address these costs. There are concerns that patients are not seeing the savings that get negotiated.

Now, the healthcare industry is complex. We need to examine what is causing this cost increase and consider ways to bring more transparency to the drug supply chain. So, Dr. Oftebro, you discussed how PBMs retroactively claw back fees and reimbursement dollars from the pharmacy after a patient picks up a prescription and the pharmacy has paid for its service. Now, can you explain how this impacts your ability to provide care to patients?

Dr. OFTEBRO. Well, we have to close our pharmacies.

Senator BUDD. Can you—can you talk a little bit about the basic economics that would—that would lead to that?

Dr. OFTEBRO. Well, so we have no say in whether or not we incur these fees. We have no negotiation ability in these contracts. And so, when we are presented with these fees, they are clawed back, and it impacts our operating budget. We are not able to hire staff. We cannot afford to have pharmacists to provide these additional services, and we ultimately need to close our doors.

Senator BUDD. You shared that the vertical integration in the drug supply chain creates conflicts of interest. I think massive conflicts of interest is what you said. Can you expand on how that creates that conflict of interest?

Dr. OFTEBRO. Yes. One of our other pharmacy practices in downtown Seattle serves a large population of patients living with HIV. We dispense a lot of HIV medications. One of the large PBMs sent us a letter and said that they were going to move all of our—all

of the HIV medications into a specialty category, and that if we wanted to continue to be able to dispense these medications, we would need to seek third-party accreditation, pay the PBM thousands of dollars in fees. We would have to leave our PSAO, which is the entity that helps negotiate contracts on behalf of independent pharmacies, and sign a direct contract with the PBM. We had to do all of those things before they would show us a contract.

Because this was such a crucial service to a vulnerable patient population, we had no choice, and when we received that contract, it was a significantly lower reimbursing contract. We lose hundreds of dollars on every fill of these HIV medications that they would prefer to steer into their own specialty pharmacy. There is a study out of the state of Florida by three access advisors that demonstrates that in those situations, those PBM-owned specialty pharmacies are actually charging more for those medications than when they are paid for in the independent pharmacies.

Senator BUDD. Thank you. Dr. Trish, you mentioned in your written testimony that there is evidence to suggest that PBMs favor high list price drugs, but you also noted that this is hard to prove definitively without access to rebate data. Could you share more about what it is from data that is needed to complete the picture and whether that data is proprietary?

Dr. TRISH. Yes, absolutely. So it just—these are considered confidential. You know, trade secrets are a part of the industry. So unlike, for example, in the world of physicians and hospitals where it is the case that insurers negotiate networks of providers, and we have the same dynamic where you are trying to, you know, essentially extract a lower price in exchange for an expectation of higher volume, in that world, we know what those prices are, right?

When I pay my cost sharing, it is based off that negotiated price, not what the hospital is charging, but the actual negotiated price. And the—we know that the amount that the health insurer is paying to the physician is the—is the same as what they are turn—turning around and charging to the employer, right, that there is no spread or difference there. In the PBM world, it is the opposite. All of that is kept in secrecy and is very complex and very hard to understand, the way that this is actually playing out.

Senator BUDD. Thank you, and my time is short, but, Dr. Mulligan, "yes" or "no," do you think that adding rebate data to the analysis of rising drug costs would be tapping into proprietary information?

Dr. MULLIGAN. Yes.

Senator BUDD. Thank you. So I appreciate you all taking time to share your insights, and I look forward to continuing to examine the cause of rising drug prices and take the appropriate steps to solve this problem. Thank you. I yield back.

The CHAIR. Thank you, Senator Budd. Senator Tester.

STATEMENT OF HON. JON TESTER, U.S. SENATOR FROM MONTANA

Senator TESTER. Thank you, Madam Chair, and I want to thank you and the Ranking Member for having this hearing. I think it is a really important hearing.

I got to be honest with you. The way I see the situation on PBMs is I do not know why the hell they even exist. Now, they were set up for all the right reasons: going to negotiate drug prices, going to pass along benefits to the consumer. But what I see them doing in my state, I do not think the consumer gets much benefit, and they are shutting down small businesses on Main Street right and left, and those are called our local neighborhood pharmacies. So as far as holding the big pharmaceutical companies accountable, I do not see it, and the reason I do not see it is because there is no transparency in PBMs. None. Zero. Nada. Kaput. Nothing. And quite frankly, when you combine that with anticompetitive tactics, this is a recipe where the only people that win in healthcare costs are the PBMs.

So, Mr. Oftebro, tell me about some of the anticompetitive tactics that PBMs are using to squeeze small pharmacies like yours, like the one we have in my hometown, population 600, and how they are pushing you out of their network and limiting your abilities as a rural community provider?

Dr. OFTEBRO. Thank you, Senator Tester. Yes, as I stated earlier, you know, we see every day patient steering, whether it is the use of the specialty category of medications that will steer patients into PBM-owned mail order pharmacies, mandatory mail order practices, just the way that we are forced to contract with PBMs where we have absolutely zero negotiating power. These are take-it-or-leave-it contracts, and the terms and conditions are totally unbearable. The fees that I described, both the DIR and the GER, and the ones that they haven't even invented yet, they are—they are impossible to predict, and it—and it makes it impossible to provide the level of care that our communities deserve.

Senator TESTER. So do you have—do you have any sort of numbers or metrics on how much of the drugs that go out your shop's doors are drugs that are impacted by PBMs?

Dr. OFTEBRO. Virtually all of them.

Senator TESTER. OK. So you get these practices and know fully well any small business or any business, no matter what it is, if you do not turn a profit, you do not stay open. And are they—would it be fair to say they are squeezing you to the point where your profitability is to a point where you are going to have to close your doors if we do not do something in Congress about this?

Dr. OFTEBRO. In 2022, we closed our pharmacy in a—in the Eastlake neighborhood of Seattle. It is the only pharmacy in the neighborhood, and we closed it precisely because of these retroactive fees.

Senator TESTER. I am going to stay with you: spread pricing. I am interested, when charging for a common generic drug, antibiotics, you know, the list is long. Let us say we have a little pharmacy in Big Sandy, Montana, and the PBM reimburses a diabetes medication for $10. How much does the PBM then charge the insurer? Could you say? So they are paying you 10 bucks.

Dr. OFTEBRO. They are paying us 10——

Senator TESTER. What are they charging on the other side?

Dr. OFTEBRO. I have no idea.

Senator TESTER. On generics.

Dr. OFTEBRO. I have no idea.

Senator TESTER. OK. Would new transparency requirements, if they were implemented the way this bill intends, do you think that would put unduly burdens on you as an independent pharmacy?

Dr. OFTEBRO. Would PBM transparency put a burden on small pharmacies?

Senator TESTER. The new—yes, correct.

Dr. OFTEBRO. I do not believe it would put any burden on us, unless of course, the PBM uses it as a reason to extract more from pharmacies.

Senator TESTER. Which is my next question. Do you think more transparency would make medications more profitable for the patient or less?

Dr. OFTEBRO. It should make it less——

Senator TESTER. OK.

Dr. OFTEBRO [continuing]. Less cost to the patient.

Senator TESTER. OK. I have got to tell you, I—as these were first set up, I am sure they were set up for the best of reasons. But anytime you have a situation where these guys can go do what they want, and a lot of the big PBMs are owned by insurance companies, I do not see where the patient is getting the benefit. In fact, I see where this has it—these PBMs have a tremendous potential for further drying up rural America, and we need to be focused on a lot of these rural areas when it comes to healthcare because it is not like driving 2 blocks down the street to see your doctor. It is more like driving 65 or 100 miles one way to see that doc. And it is the same thing with small pharmacies. If you do not have one in your town, and we didn't have one in our town for a while, it makes healthcare much more complicated. Thank you, Madam Chair.

The CHAIR. Thank you, Senator Tester. Senator Capito.

STATEMENT OF HON. SHELLEY MOORE CAPITO, U.S. SENATOR FROM WEST VIRGINIA

Senator CAPITO. Thank you, Madam Chair, and thank you all for being here today at this very important hearing. So as I sit here and listen to this, and I voted for the bill when it came through committee last year, I believe, a couple things come to mind. So this is what would have been really helpful, I think, for everybody to bring: a flowchart that starts from the research of the drug to the person who actually gets it and what they pay for.

So I made a little list myself. You have got the research, the manufacturing, the distributor, the PBM, the insurer, the doctor or hospital, the pharmacy, and then it gets to the patient. And I guarantee you, looking at a flowchart, if we looked—if we actually had that in front of us, it would be more difficult to read than a flowchart from the Corps of Engineers because it would be "if this, that, "if this, that," and before you know it, total confusion, which is what I think we have in terms of the lack of transparency with PBMs. You know, the old saying—I cannot remember what the movie was, and Senator Cruz will know, because I think he is a movie afficionado: "follow the money." This is what the flowchart would also show us. Follow the money. What movie is that?

Senator CRUZ. That would be "All the President's Men."

[Laughter.]

Senator CAPITO. I thought it was the one with Tom Cruise. Anyway, so much for that. So my question is to Dr. Oftebro, and you have answered several of the questions that I already have. I know that—have you ever had success in amending or negotiating a contract to alleviate some of these issues? I think you answered that, but if you could repeat your answer there, please.

Dr. OFTEBRO. We have made multiple attempts to try and negotiate better terms on contracts, and we have yet to be successful.

Senator CAPITO. Did I accurately portray, in your mind, what a flowchart might look like? How would you respond to that if you had to bring a flowchart here?

Dr. OFTEBRO. No, I think what you described was not complicated enough.

Senator CAPITO. OK. OK. I know a few states, my state of West Virginia being one, you mentioned in your—in your hearing, the—I hope I say this right—rosuvastatin.

Dr. OFTEBRO. Mm-hmm.

Senator CAPITO.[—and that you had talked about the impacts of that and PBMs on that. Is this something that is unique to you, or is this occurring all across the country?

Dr. OFTEBRO. Well, this was a large national Medicare Part D plan.

Senator CAPITO. Mm-hmm.

Dr. OFTEBRO. It is happening in every pharmacy in the country.

Senator CAPITO. Mm-hmm.

Dr. OFTEBRO. And it was not just this one drug. It happens with many, many drugs——

Senator CAPITO. Mm-hmm.

Dr. OFTEBRO.—every day for all kinds of plans.

Senator CAPITO. OK. Also, I note that Washington's—West Virginia has passed a number of bills trying to get at some of these issues. I mean, the last thing is probably a patchwork issue that we need because of a lot of complications with mail ordering other things. Has Washington State attempted to pass similar laws to help you out here?

Dr. OFTEBRO. We have passed some legislation, and we are working on additional legislation right now.

Senator CAPITO. Has it been helpful?

Dr. OFTEBRO. The biggest challenge that we have had in Washington State is that our existing legislation has exempted ERISA plans, so self-insured plans. And so our existing rule—our existing laws only cover about 10 to 20 percent of the prescriptions that we dispense, so.

Senator CAPITO. Yes. On my flowchart on insurance—insurers, I would have to have a couple of little buckets over there because of all the different things. Dr. Trish, last question. You talk about the historic role that PBMs have played in lowering costs. Obviously, Senator Tester said that was the immediate, the first goal. But you say over the last decade that this situation has deteriorated. What do you believe has caused this shift? Is it the consolidations?

Dr. TRISH. I do think, you know, part of it has been the consolidation and integration. I think what we see now is that CVS Health and United Health Group are actually the 4th and 5th biggest companies by revenue on top of the Fortune 100 in the U.S.,

and Cigna, or Express Scripts, or Evernorth I think is number 12 now. I mean, these are—these are pretty significant companies here in the U.S. I think we have also continued to see that the market has gotten increasingly complex, and that makes it harder and harder to understand, and enables more opportunities for this type of arbitrage and kind of deceptive practices.

Senator CAPITO. OK. So then, you know, last thought. Put yourself in the shoes of the person going to the counter to try to purchase a much-needed drug. And I think we should not lose sight in any hearing such as this as to the magnificent of our pharmaceutical industry in terms of curing and also managing diseases. That it something that is—that is phenomenal for all of us. And how is anybody supposed to know? I mean, if they went from Dr.—I want to not pronounce it—Oftebro's pharmacy, and then went to another pharmacy in West Virginia, they could pay totally—they could pay different prices. You know, it is just confuse—I think it is—the confusion masks where the money is going, and I think in the end, the intent is to get it to that person at the counter. Thank you all very much.

The CHAIR. Thank you. Senator Sullivan.

STATEMENT OF HON. DAN SULLIVAN,
U.S. SENATOR FROM ALASKA

Senator SULLIVAN. Thank you, Madam Chair, and I want to thank the witnesses here. I think the themes are starting to emerge from this hearing, which are not terribly surprising. From Alaska's perspective, we have had several Alaskan-owned independent pharmacies that have gone out of business over the last several years. Obviously, it is happening all over the country, and the issue of the lack of transparency seems to be front and center. Anchorage right now, our largest city, my hometown, only has one independent pharmacy left. That is Bernie's Pharmacy run by a great Alaskan named Teresa Hall, who is doing a great job trying to serve local Alaskans in Sitka. We do not have a Walgreens or a CVS. We do have an Alaska family owned independent pharmacy. The White family runs that. They do a great job, but I hear about their struggles.

The numbers are pretty dramatic here. According to a 2022 report from the National Association of Insurance Commissioners, there are 66 PBM companies, with the three largest—Express Scripts, CVS Care, and Optum Rx—controlling more than 80 percent of the market and serving 270 million Americans. That is some serious market power. This is the opposite of small business.

So what I wanted to ask each of the panelists, two questions, and you can take them in order. I will just let all of you respond. One is transparency. The bill that we are talking about today, is it the right amount of transparency? Are there other things we can do with regard to transparency for PBMs? I think that is a really obvious starting point, but how deep do we need to go on that, and what are we missing on that idea of transparency that may or may not be in this bill? And then second, this is a little bit more current but it is—I want you to kind of look at the current situation. I have concerns about the current situation. But structurally, is the FTC

the correct avenue to address this transparency issue? Are there other agencies we should be looking at?

I am starting to have increasing concerns about the leadership at the FTC. I did not vote for the Chair, Lina Khan. There was a *Wall Street Journal* article just recently, the last Republican Commissioner on the FTC is resigning, and she is doing so in part because she said, "Khan's willful disregard of congressionally imposed limits on agency jurisdiction, defiance of legal precedent, abuse of power." So I am getting a little nervous about the FTC, both currently with the leadership, but also, is it structurally the right Federal agency to be taking a look at the transparency issues? And I think that is what the current—what the law that we are looking at proposes. So both those questions, I would open up to all the witnesses.

Dr. OFTEBRO. Thank you, Senator, and I would like to say that Bernie Klouda was a dear friend and mentor of mine.

Senator SULLIVAN. Oh good. Well, he did great work, but there, you know, it is tough. And that is——

Dr. OFTEBRO. Yes.

Senator SULLIVAN. You know, that is our big city, Anchorage, right?

Dr. OFTEBRO. Yes.

Senator SULLIVAN. And they are it in Anchorage.

Dr. OFTEBRO. They are it. To answer your first question about is this the right amount of transparency, I do not know yet the answer to that question, but what I do know is that what we have now is not working.

Senator SULLIVAN. Yes.

Dr. OFTEBRO. And we just—we want to see PBMs regulated the same way that everybody else in healthcare is regulated.

Senator SULLIVAN. Do you have a view on the FTC?

Dr. OFTEBRO. I think my answer is the same, but what I—what I can tell you is that, you know, from our perspective, we are seeing unfair and anticompetitive business practices in terms of our interactions with PBMs.

Senator SULLIVAN. OK.

Dr. OFTEBRO. And I think that is how I—you know, I do not know who else would——

Senator SULLIVAN. Yes.

Dr. OFTEBRO.—help us deal with that.

Senator SULLIVAN. Any other witnesses on both the transparency question or the FTC question?

Dr. PATT. So to the first question about transparency, I do think that this is really important, probably the most important piece of legislation to deal with the issue, to bring light to many of the other problems. There are other issues: co-pay accumulators——

Senator SULLIVAN. Yes.

Dr. PATT.—H.R. 830, gag clauses, fail first-step therapy, and other things. So there are other problems, but as you deal with PBMs, I frequently feel like it is a game of whack-a-mole. And transparency, I think, sheds light on many of the other challenges that is the best way and most comprehensive way to move forward to make meaningful change. The second issue of jurisdiction I do not know.

Dr. TRISH. I think also on the transparency and the scope, I think another sort of perhaps less appreciated actor in this market has been the role of the benefits consultants or the people who are trying to help employers navigate this and pick what PBM contract they should be signing. In many cases, those benefit consultants are not fiduciary—are not playing a fiduciary role for the employer but are actually being compensated by the PBMs as well. And so to look at even if the, you know, supposed brokers of information here are being incentivized in ways that are detrimental to the system as well.

I'll just say on the second, you know, there is also the GAO. There are also other agencies that can be involved in this, too. I think, you know, to the extent that there are issues at the FTC, that needs to be addressed more broadly, right, obviously, for many reasons.

Senator SULLIVAN. Any views on that?

Dr. MULLIGAN. I would point you to the references in my testimony of FTC, DOJ, and others are very concerned about the effects of the transparency, particularly the way it is laid on in Section 2. Way too granular. With any regulation, as an economist, I like to be able to see the law have clearly defined terms, and there are a lot of terms that the administrative state is going to be able to interpret. And I share the concerns that the FTC we have now would reinvent the lexicon, to be frank.

Senator SULLIVAN. Thank you. Thank you, Madam Chair.

The CHAIR. Thank you. Senator Blackburn.

STATEMENT OF HON. MARSHA BLACKBURN, U.S. SENATOR FROM TENNESSEE

Senator BLACKBURN. Thank you, Madam Chairman, and thank you, each of you, for being here today. It is wonderful to hear from you on your perspective about what is going on, the FTC, with the work that they are doing, also looking at the vertical integration, and the access to different patient pharmaceuticals.

And, let us see, Dr. Patt and Dr. Oftebro, I wanted to ask you about access to specific pharmaceuticals for patients, and how the PBMs affect that, and the choices that they are making. And how often are you—how often do you see this as a problem for patients getting precisely what they need for the period of time that they need it?

Dr. PATT. Thank you, Senator, and I'll say I work closely with Dr. Patton and Dr. Schleicher in—from Tennessee Oncology and the Community Oncology Alliance.

Senator BLACKBURN. Right.

Dr. PATT. So they are well familiar with these issues.

Senator BLACKBURN. Yes.

Dr. PATT. We frequently see that PBMs in their insurance, vertically integrated partnerships, determine which therapies can be given first. I think a great example of that is in breast cancer. When I want to treat a patient with a class of drugs called a CDK46 inhibitor, there are three drugs that are approved on the market, and I might choose one because of very specific patient issues. One has better evidence for brain metastases. One is not as good if the patient has diarrhea. And I am frequently not able to

make those choices based on what is best for the patient because of direction and formulary restriction on the part of the PBM.

In addition to that, frequently, the PBM makes preferential choices that might be more expensive for the patient. So my colleague, Miriam Atkins, who practices out of Augusta, Georgia, prescribed imatinib for her patient with GI stromal tumor, the patient out-of-pocket cost was going to be $1,500 if run through insurance because of the way that they contracted with the—with the brand name drug. But whenever they did not apply it to—and the patient was not going to take their medication. They were just not going to treat their metastatic cancer. Instead, they just sold it and ran it out of their office, and they were able to get it for about $150, and they were able to take the medication. So it should not be the case that patients have more options by not using the insurance that they pay for, and these are some of the pivots that we are directed to because of PBM management.

Senator BLACKBURN. Well, thank you for that, and thank you for mentioning Tennessee Oncology and the great work that they do there. We appreciate what they do in our community. Dr. Oftebro?

Dr. OFTEBRO. Thank you, Senator. I would echo we see the exact same issues in community pharmacy when patients and providers are restricted in their formulary choices, and one medication might be more appropriate, but it is not available to the patient. The other thing that we see quite a bit of is mandatory mail order, and it may be mandatory mail order in general or for specific medications that pharmacy benefits managers have deemed as specialty, and there may not be any clinical rationale for a medication being designated as specialty. It is just in the PBM's economic benefit to categorize it as a specialty medication. And when those medications are not available to patients to access through the community pharmacy, that can—that can lead to gaps in therapy.

We have had this happen with patients in—in our prep clinic. We run a pharmacist-run clinic for patients who are—to prevent HIV, and this requires labs, and then daily medication.

Senator BLACKBURN. OK.

Dr. OFTEBRO. And when they go without that medication because it does not show up on time in the mail, they have to restart all of that lab work.

Senator BLACKBURN. Wow.

Dr. OFTEBRO. It is additional costs to the Medicaid program and the—and the health insurers.

Senator BLACKBURN. So listening to the two of you, PBMs actually get in the way and prohibit proper care. Let me ask each of you, if given the choice, would you completely eliminate PBMs?

Dr. OFTEBRO. I think all that we are looking for is to see that PBMs are regulated in the same way that the rest of us are as healthcare providers.

Senator BLACKBURN. OK.

Dr. OFTEBRO. They are—they are a part of the healthcare system. They need to be regulated, and we need a fair landscape.

Senator BLACKBURN. OK. Dr. Patt?

Dr. PATT. It is so tempting to say that I would completely eliminate PBMs, but the truth is, I do not know that that is the right answer. I think it would improve upon things currently. I will say

that I take issue with the analogy of PBMs being like group purchasing like you would see with a Costco because I think that analogy only holds if Costco is the only place that you can shop, because the challenge is that discounts that PBMs negotiate may not be translated to employers and patients. In fact, we do not see evidence that it is.

Senator BLACKBURN. Right.

Dr. PATT. In contrast to the Costco analogy where shoppers have the ability of choice, we do not act like that in healthcare, and so it is a limited analogy. And while PBMs might purchase at discounts, we need to see evidence of where those discounts are going, and I suspect that they are not going to patients and employers. At least when I talk to patients and employers, we do not see any evidence of that.

Senator BLACKBURN. I am yet to find a patient who says a PBM has saved them money. I have found many patients who tell me the PBM would not allow them to have what the doctor prescribed. Thank you so much for being here for our hearing today. Thank you, Madam Chairman.

Senator WELCH [presiding]. Senator from Colorado.

STATEMENT OF HON. JOHN HICKENLOOPER, U.S. SENATOR FROM COLORADO

Senator HICKENLOOPER. Thank you, Mr. Chair. I want to start—well, first, I want to thank you all for being here, and appreciate how busy you are and taking the time out to come and answer our questions. You add real value and perspective.

Dr. Trish, the Schaeffer Center found that for every dollar Americans spend on insulin, less than half ultimately goes to the manufacturer. Instead, that money gets rerouted and taken by middlemen along the way, like PBMs. All the while, the list continues to grow. The list continues to go up, even on drugs like insulin that have been around for more than 100 years. I think that is really at the heart of why we need transparency. Where is the money going? Why are we paying so much? So Dr. Trish, you mentioned that transparency is a key, but further investigation is needed to truly understand how to reform the system and protect patients. What areas—what other areas do you believe need to be investigated?

Dr. TRISH. So thank you for the question. I think, you know, one of the key other issues here is the extent to which this is integrated has changed the incentives. And I was—I had the good fortune the other day of giving a talk at a health system where I had both the chief pharmacy offer—chief pharmacy officer and the H.R. person for the health system in the room. They were talking about this issue that we heard about, this report in Florida, but essentially, they—because they are a health system, they own a specialty pharmacy, right? They dispense drugs to their patients. They were saying that their PBM for their beneficiaries is in—is basically requiring them to use the in-house specialty pharmacy that is owned by the PBM, even though they can see that that specialty pharmacy that is owned by the PBM is charging them more than 3 times more for the drugs than what they dispense in their specialty pharmacy themselves.

And those are the types of things where, you know, that is—that is harmful. That is not generating value. The extent to which that is also further affecting the types of rebate negotiations across drugs more broadly, that is what we need better insight into as well.

Senator HICKENLOOPER. Right. Well, certainly, a lot of what you are describing we see throughout healthcare, which is the lack of mission, that it—when I was a kid, and that is pretty long ago, doctors, nurses, pretty much everyone you met in a hospital or a medical center was there because they wanted to help bring reliable healthcare at the lowest possible cost to the—to the people of their community, and somehow we have lost that.

Dr. Patt, more often than not, consumers do not have the necessary information available to them about how much their drugs cost, much less information about the role of PBMs, drug manufacturers, insurance companies, you know, ad infinitum, that help each other raise prices. I think additional transparency clearly is important, but we must make sure that the information actually reaches the patients. So, Dr. Patt, do you often find that your patients struggle to navigate the system? Does that come back to you? How can we make sure that PBMs provide the information in an accessible and easy-to-understand format without layering it under, you know, portals, and portals, and portals?

Dr. PATT. It is a great question, and I'll say I work closely with the Rocky Mountain Cancer Center doctors, so I am grateful for your question. I think that we need to give more information to patients because frequently the cost of drugs prohibits patients from being compliant with care. I gave the example of the patient with imatinib, that if they had run it through their insurance, their co-pay would have been $1,500 per month. And whenever they did not go through insurance, it was going to be just $150 a month at the practice. Well, if the doctor and the pharmacist did not have an ability to have that discourse with the patient, the patient would have just not taken the medication and not benefited from the medication.

We know from a study published in the *Journal of Clinical Oncology* in 2017 that patient adherence to their medication is directly related to their co-pay that they—that they have to—that they have to pay every month. And if it is cost prohibitive for patients, they are not going to be compliant. They ration their medications. I have seen that time and time again, so that leads to ineffective care.

So when you have pharmacists and medically integrated pharmacies where doctors talk to their patients, they are able to help navigate these complex systems, especially with expensive medications. So I think that interaction is really invaluable. And had that patient just simply been referred to a mail order pharmacy where they did not get their—where they would have to pay to get their drug, they just would have not gotten their drug. So this interaction with the healthcare team becomes really critical so we can help patients navigate this complex environment.

Senator HICKENLOOPER. Exactly, and I could not agree more. I mean, that is—the additional hidden cost is all those patients that end up not taking a prescription that would, you know, alleviate

their suffering or their discomfort, and, in many cases, prevent them from getting well. So anyway, transparency has got to be at the root of all this stuff. Thank you. I yield back.

Senator WELCH. Thank you. Senator Warnock.

STATEMENT OF HON. RAPHAEL WARNOCK,
U.S. SENATOR FROM GEORGIA

Senator WARNOCK. Thank you so very much, Senator Welch. Last week, I invited Lacy Mason from the state of Georgia as my special guest at the State of the Union speech. She is a type 1 diabetic. She needs insulin to survive. Even with insurance, insulin was too expensive for her to afford, and she had to resort to black market insulin in the United States and borrowing expired insulin from friends. She told the story about meeting people she did not know she met on Facebook in parking lots to get insulin. And while I am glad that my proposal to cap insulin at $35 per month for Medicare beneficiaries is now law, the fight is not over. There are still too many Georgians who are not able to afford the insulin they need to live. Dr. Trish, do you agree that prescription drug prices like insulin are too high?

Dr. TRISH. So that is a—there is a lot to unpack in that question. I think that insulin is an example where—it is a prime example really where the list prices are particularly high, and they have really increased over time in ways that harm patients at the pharmacy counter. The research we have done at the Schaeffer Center shows that the net prices that manufacturers receive has actually declined, although the total amount that we are spending when you take in—when you account for what the PBMs and other intermediaries are taking home has not declined, right? So this is an example where it depends what price you are asking about, but it is absolutely problematic for patients, yes.

Senator WARNOCK. So in a sense, while it was important for us to have this cap, you are pointing to the larger root cause and the issues around PBMs. So related to that—and you point out the drug pricing is complex. That said, it is no secret that pharmacy benefit managers, or PBMs, have played a role in high drug prices, and that is what we are examining in this hearing today. How are PBMs contributing to high list prices for drugs, especially for insulin?

Dr. TRISH. Absolutely. So they are—essentially, PBMs are in a position where they make more money as the list price goes up, as they get a percentage of the rebate or some other type of fee that is based on that increasing list price. And so you have seen, even though this is—insulin is a very highly competitive drug class, there is multiple products that exist there, and the rebates are enormous, typically more than half of the list price. But nonetheless, the pressures and the incentives have made it so that if—when manufacturers have opted to offer lower price drugs, PBMs will not put them on their formularies.

Senator WARNOCK. So they are incentivized to be bad actors in this space, costing people like Lacy, literally.

Dr. TRISH. Particularly when those patients face cost sharing that is based on the list price of the drug, then that is absolutely problematic for them, yes.

Senator WARNOCK. I agree. I think Congress needs to address the role that PBM rebates play in high drug prices, and that is why I was proud to vote the Pharmacy Benefits Manager Transparency Act out of committee last year and look forward to supporting it again this year. Dr. Oftebro, I do not want to butcher your name. My last name is Warnock. I get called "Warlock" and all kinds of things.

[Laughter.]

Dr. OFTEBRO. That was perfect.

Senator WARNOCK. Is it uncommon for pharmacists to see folks come in unable to afford their medicine?

Dr. OFTEBRO. Senator Warnock——

Senator WARNOCK. Speaking of insulin.

Dr. OFTEBRO. Senator Warnock, we see that every day. The out-of-pocket costs for patients, there is no way that it is not a barrier, and it is forcing—it is forcing patients to make very difficult decisions whether they take their medicine, whether they ration their medicine, whether they do not take it at all. But it is clearly an unbearable outcome.

Senator WARNOCK. Yes. In fact, a recent article on NPR says that manufacturers have increased the price of insulin by more than 600 percent over the last 2 decades. Six hundred percent, a drug that was created 100 years ago, patent was sold for $1. Do you believe this leads to rationing—you pointed that out—or finding other ways for patients to drag out how long the medicine will last or refill? What kinds of effects does this have on patients' health because I think as we work on the policy, we have to center real people. What is the impact on the patient?

Dr. OFTEBRO. Well, when a patient is not taking their medication as prescribed, there are all kinds of negative impacts, but they are ultimately deteriorating health. They are using the healthcare system inappropriately, more ER visits, and, you know, these have cost all of us at that point.

Senator WARNOCK. So it costs them more, and it costs us more.

Dr. OFTEBRO. Correct.

Senator WARNOCK. So thank you so much. Look, hearings like this are incredibly important so we can come together and work to get something done for our constituents. And everything we do on drug pricing, it seems to me we have to center the patients because they are the ones who are really caught in the middle, and I hope we can get some progress. Thank you for everything you do on this front.

Senator WELCH. Thank you. Senator Klobuchar.

STATEMENT OF HON. AMY KLOBUCHAR, U.S. SENATOR FROM MINNESOTA

Senator KLOBUCHAR. Thank you. Dr. Trish, my bill with Senator Grassley, the Preserve Access to Affordable Generics and Biosimilars Act, passed out of the Judiciary Committee for a second time last week, and it would limit anticompetitive deals where brand name drug companies pay generic competitors to stay off the market. It is known as "pay for delay," costing consumers millions of dollars, stifling competition. Do you think measures like this

would help lower drug prices, and why is it important that we include biosimilars?

Dr. TRISH. Absolutely. So I think it is—it is very important to recognize, right, if you go back to the Hatch-Waxman Act, right, the idea here was to kind of preserve the incentives to produce innovative products, but with the expectation or return being that once those products went generic, they would be widely available at low cost and providing value to many Americans. And I think it is important that we ensure that we are delivering on the promise of that bipartisan legislation that, you know, worked so well for so long.

I think some of the things that we have concerns about are whether PBMs are actually getting in the way of that kind of grand bargain working out for society by inflating the cost of generic drugs and other things like that when they do get to market, and, ultimately, not delivering on the value when they become generic that we expect.

Senator KLOBUCHAR. Another question. The House Oversight Committee recently found—as you know, I chair the Competition Policy, Antitrust, Consumer Rights Subcommittee over in Judiciary. And House Oversight found in an investigation of high drug prices that drug companies use strategies to suppress competition and maintain monopoly pricing by pursuing contracts with PBMs and insurers that condition drug manufacturer rebates and price discounts on excluding competitor products from PBM and health plan formularies. Do branded drug manufacturers offer larger rebates to or force bundled contracts on PBMs in order to keep potential competitors off the market, and what effects do those contract terms have?

Dr. TRISH. So it is certainly the case that as part of the negotiation between PBMs and manufacturers, you know, the kind of goal of what PBMs are trying to pursue or extract value is to basically say, offer us a bigger discount or a lower price in exchange for us driving more volume toward your product rather than a competitor's product. I think the—when that works and when those savings are passed to consumers, that can be beneficial in driving value. But the issue is that when those savings or the benefits of that transaction or negotiation do not reach consumers, then we are not really getting the value that we are supposed to be out of these types of negotiations.

Senator KLOBUCHAR. OK. Very good. Thank you, and next up, price transparency. Do you think we need more price transparency in the medication supply chain? I guess I'll ask you, Mr. Oftebro, and thank you so much for your work. Could you answer that?

Dr. OFTEBRO. We absolutely need more transparency in the prescription drug price chain. We have—we have no idea. I am not only a pharmacist, I am an employer——

Senator KLOBUCHAR. Mm-hmm.

Dr. OFTEBRO.—so I deal with these issues as an employer as well. And even as a pharmacist and understanding how the drug chain—supply chain is supposed to work, it is so difficult for me as an employer to get the visibility into our own drug spend that we clearly have a problem.

Senator KLOBUCHAR. OK. Thank you. Back to you, Dr. Trish. One issue that I have been working on for years—Senator Collins and I passed a major bill on this—is drug shortages and going to drug manufacturers in other countries when we have a shortage. Some of these shortages, as you know, have returned. What are PBMs and drug manufacturings doing to better anticipate and forecast demand for medicines and avoid shortages, and what do you think we should do?

Dr. TRISH. So I think this is absolutely an important issue. You are starting to see, for example, new entrants into the market, like the Mark Cuban Cost Plus Drug Company. We have heard a lot about what they are doing on the PBM side, but they are actually also stepping in as a manufacturing plant to manufacture some of these drugs that are in short supply. I believe they are—last I heard, they were starting with sterile water, which is actually a very important part of the healthcare system that receives probably less attention than it should. So these are some of the ways that the market is stepping in to help, but I think that the issues that are created by the dynamics and pressures that they are having throughout the supply chain are exactly the type of thing into which we need more insight.

Senator KLOBUCHAR. All right. Thank you very much.

Senator WELCH. Senator Rosen.

STATEMENT OF HON. JACKY ROSEN,
U.S. SENATOR FROM NEVADA

Senator ROSEN. Well, thank you, Senator Welch. Appreciate that. We are really pleased that you are holding this important hearing today because bringing down the high cost of prescription drugs, it is one of my top priorities for Nevadans from Ely to Pahrump, all across our state. And as we continue to build on the successes of the Inflation Reduction Act—excuse me—including allowing Medicare to negotiate for the lowest price of prescription drugs and capping insulin costs for seniors at just $35 a month, I am really glad to see that there is a commitment in this committee to work toward lowering prescription drug prices for everyone.

And I want to continue along the lines of Senator Tester and Senator Sullivan on the impact of PBMs on rural and independent pharmacies because they are just a critical lifeline for our rural Nevadans. And in my state, like so many others, independent pharmacies, they serve not only as accent—access points for rural Nevadans to receive their prescription medication, but they often provide clinical services, like blood pressure, glucose monitoring for those with high blood pressure and diabetes. Unfortunately, between 2003 and 2018, more than 1,200—1,200—independently owned rural pharmacies across this country have closed, including in Nevada. In fact, there are many communities in my state that have just one or no rural pharmacies remaining. And so one challenge is that prices for what should be cheap generic drugs end up being higher for these pharmacists—pharmacies in the larger chains.

I have heard from independent pharmacies across my state and in Reno who are going to work every day to provide patients with lifesaving medication. But as a result of the current prescription

drug reimbursement ecosystem, they are struggling just to keep the lights on and serve the people that they care about in their communities. And so, Dr. Oftebro, you are based in Seattle, but like in my state of Nevada, Washington State, you have numerous rural communities that have lost their independent pharmacies, due in part to the practices of PBMs. So what are you hearing from your fellow pharmacists in rural areas across your state about that pressure they feel from current dispensing reimbursement policies?

Dr. OFTEBRO. Thank you, Senator, for the question. You are absolutely right. Our independent community pharmacies in our rural communities are vital lifelines, and Washington State is no exception. We have—we have pharmacies in rural areas. We have pharmacies on islands. A good colleague, Rick McCoy, is on Lopez Island in the San Juans, and he is the only pharmacy on the island, and he was able to provide thousands of COVID vaccines during the pandemic, and he is—he is struggling. And, you know, if he is not able there—to be there to provide for his community, people on the island are going to have to travel hours via ferry to get to the next closest pharmacy.

So it is—it is an absolutely crucial issue, and we need to ensure that these rural pharmacies, who are the only access point of healthcare for many communities, remain viable.

Senator ROSEN. Thank you. And I want to build on that, thinking about rebates because they are intended to lower costs for consumers, but the reality on the ground looks very different for far too many families, and especially Nevada families. And there is limited Federal transparency in the rebate process, so it is hard to know how we can best ensure savings from rebates, that they are actually passed on to the consumer. So, Dr. Trish, how can we ensure that rebate savings are actually passed on to the consumer in order to lower costs at the pharmacy counter? These are lifesaving drugs. People need them, and we want to give them the best price.

Dr. TRISH. Yes, you are absolutely right. So I think all too often, these rebates are not being shared at the pharmacy counter. We have done research showing the impact this has had, estimating that about half of Medicare Part D beneficiaries pay more out of pocket then they would have had rebates been shared with them at the pharmacy counter, some of them, about 20 percent on the order of more than $100 extra per year. Interestingly, it also lead—or has led to accelerated Federal spending on the Reinsurance Program in Medicare Part D as well, so it has many, many different effects.

I think, you know, there are policies that could encourage or promote sharing at the pharmacy counter with patients, but I think the other thing is, as we heard, there is a bit of a game of whack-a-mole here. And so, as we have shined more of a light on rebates, there are now contracts that at least require more rebate sharing with the plans themselves, but that has led to other types of fees, and offshore rebate aggregators, and all these other things where it is hard to keep up and make sure that once we focus on something, it is not just going somewhere else. And that is where we need kind of true transparency and a true understanding of all of the—where the dollars are flowing across the board.

Senator ROSEN. Well, I am glad you brought that up. I do not have time for any more questions, but I do want to have some explanations on this rebate administration fee, and so we will put that for the record because, again, these can be the way that people are shuffling these charges around, ultimately hurting the consumer. Thank you, Mr. Chair. I yield back.

Senator WELCH. Thank you, Senator Rosen. The hearing record will remain open for 3 weeks, until March 9, 2023. Any senators who would like to submit questions for the record should do so in the next 2 weeks. That is by March 2, 2023. Witnesses, by the way, thank you so much for your testimony. We ask your responses be returned to the Committee as quickly as possible, but no later than March 9.

And that concludes today's hearing. Thank you very, very much.

[Whereupon, at 11:51 p.m., the hearing was adjourned.]

A P P E N D I X

PREPARED TESTIMONY BY REPRESENTATIVE MARK TAKANO (CA–39)

Thank you for allowing me to submit my testimony.

As the panelists today have outlined, Pharmacy Benefit Managers hold a tremendous amount of power in determining the cost of prescription drugs. This impact is felt by Americans everywhere, including myself.

As a Member of Congress, I have an insurance plan that I get through the DC Marketplace. Like most Americans, I rely on prescription medication, and—like many Americans—I have walked up to the pharmacy counter with no idea of how much my next refill was going to cost. The fluctuating prices are subject only to the oversight of the PBM.

As an example, I recently went to pick up a prescription I needed and found that the copayment had ballooned to triple its price. If I paid out-of-pocket, that cost wouldn't count against my deductible. Ultimately, I chose to use a drug coupon to cover a portion of the cost of the drug, but this isn't a solution. Drug coupons are a band-aid fix that does not address the deeper systemic issues with the industry's cost-setting mechanisms.

This is an all-too familiar experience for so many, and the bottom line is this: the majority of Americans rely on prescription medication, and the monopolistic practices of these PBMs are forcing them to make extreme and excruciating choices between paying their rent, buying their groceries, and keeping the lights on—or getting the medication they need to survive. I hear from constituents on a daily basis that have far more complex conditions that require access to prescription medication in order to manage them.

There is no other option for them. Because of the vertical integration, the consolidation, and the self-dealing that occurs in PBMs, American consumers are left without other safe options. Senator Cantwell cited examples of patients crossing the border to seek their medications, rationing drugs, and foregoing necessary doses because they can't pay the prices set, and the sad reality is that every Member of this representative body has constituents that are forced to make those choices.

Monopolistic business practices driven by profit are bad enough in any industry, but when that industry controls Americans' access to basic healthcare needs—that is despicable. I thank the Chairwoman and Ranking Member for their attention to this issue and the panelists for their participation.

PREPARED STATEMENT OF FMI—THE FOOD INDUSTRY ASSOCIATION

On behalf of the food industry, including many thousands of supermarket pharmacies and those of our member companies that provide health care coverage to their employees, we at FMI—the Food Industry Association thank Chairwoman Cantwell, Ranking Member Cruz and the Senate Committee on Commerce, Science, and Transportation for holding this hearing to shine a spotlight on the conflicts of interest embedded in the structure of the pharmacy benefit manager (PBM) industry while considering how the *Pharmacy Benefit Manager Transparency Act* (*S. 127*) would bring increased transparency into PBM business practices and prohibit several anticompetitive PBM tactics. The legislation would also give the Federal Trade Commission (and state attorneys general) greater enforcement authorities to prevent PBM abuses, which is particularly important given the Commission's ongoing *inquiry* into the impact of vertically integrated PBMs on the access and affordability of prescription drugs and following its *decision* to increase enforcement against those PBMs participating in rebate schemes that block access to lower cost drugs.

FMI strongly agrees with the Committee that the largest PBMs—both in terms of how they are allowed to operate and due to the lack of transparency surrounding their operations—contribute to significantly higher costs for patients, pharmacies, other health care providers, and employers. We are particularly concerned about the

way PBMs threaten the country's most accessible and trusted health care professionals—pharmacists and their pharmacies.

Supermarket pharmacies are especially important access points for consumers in underserved, low-income, rural, and urban communities, but PBM practices and the lack of meaningful Federal oversight are preventing FMI member companies from opening new pharmacies and causing some to leave the pharmacy business altogether. FMI thanks Chairwoman Cantwell and Sen.

Grassley for championing the *PBM Transparency Act* and the Senate Commerce Committee for advancing the bill previously, and we urge swift passage of this bipartisan legislation in the 118th Congress.

As the food industry association, FMI works with and on behalf of the entire industry—from retailers who sell to consumers, including supermarket pharmacies, to producers who supply the food and other products sold in grocery venues—to advance safer and more efficient consumer supply chains for both food and pharmaceuticals. In total, FMI member companies, which range from independent operators to the largest national and international players, operate roughly 33,000 grocery stores and 12,000 pharmacies, ultimately touching the lives of more than 100 million U.S. households on a weekly basis and representing an $800 billion industry with nearly 6 million employees. Throughout the ongoing COVID–19 health emergency, our members have been and continue to be a critical component of ensuring the availability of food, pharmacy and health care services in communities across this Nation. Moreover, supermarket pharmacies have played an outsized role in the COVID–19 vaccination effort while also serving as a bridge between our communities and other providers, offering patients immediate care that is close and convenient to home. *www.fmi.org*

Background

Although unknown to much of the American public, PBMs are powerful middlemen at the center of the U.S. prescription drug system. Historically, PBMs played an important role in the administration of prescription drug programs—designed to take the paperwork burden away from pharmacists. However, in recent years, the PBM marketplace has transformed considerably, and they are doing just the opposite. As a result of consolidation among PBMs, health insurance companies and acquired pharmacies, a small number of large corporations now wield nearly limitless power and influence over the prescription drug market for 260+ million Americans. Among other things, PBMs negotiate drug costs, dictate which drugs will be included on plan formularies, and control how those drugs are dispensed. In other words, they control which medicines are prescribed to patients, which pharmacies patients can access, how much patients will pay at the pharmacy counter, and the amount pharmacies are ultimately reimbursed. Yet, PBMs are one of the least regulated sectors of the healthcare system and drug supply chain; there has been almost no Federal antitrust enforcement, oversight, or regulation.

Supermarket Pharmacy

PBMs' market concentration empowers them to offer supermarket pharmacies of all sizes take-it-or-leave-it contracts: The pharmacy must either accept a PBM's mandated contract terms (including, among other things, allowing the PBM to unilaterally set prices for certain drugs and then later impose retroactive fees based on an opaque methodology), or give up the ability to serve the many customers whose health plans contract with the PBM, which would include existing customers who have longstanding relationships with their pharmacists. Therefore, these nonnegotiable, take-it-or-leave-it contracts allow PBMs to create endless schemes to reduce reimbursement, claw back funds, restrict networks, require extensive audits and effectively force pharmacies to provide drugs below cost.

PBMs frequently assert that below-cost reimbursement is a problem only for poorly run pharmacies and that low PBM reimbursement rates create an incentive for such poorly run pharmacies to improve their purchasing practices. However, the PBM industry has resisted attempts to force price transparency that would reveal the basis for these claims. Furthermore, pharmacies of all sizes—not just "poorly run" ones—are suffering as a result of PBMs' below-cost pricing. Even FMI's largest members—Fortune 500 companies with efficiencies, expertise in supply chain logistics, and economies of scale—struggle to operate financially viable pharmacies.

Unlike independent pharmacies, FMI supermarket pharmacy members are not dependent solely on their pharmacy operations for survival, and therefore, PBM abuses may not threaten to force them to close their doors to grocery operations. However, PBM practices make it likely that grocers will be forced to continue leaving the pharmacy business—either by outsourcing their pharmacy operations to the biggest, PBM-affiliated players in the market, or worse, by abandoning pharmacy

operations altogether. Supermarket pharmacy closures, and abandoned expansions, thus contribute to the overall trend of decreased access to pharmacies and "pharmacy deserts." The effect of such closures is particularly acute in certain rural and urban communities, where closures are more prevalent and detrimental to a community's access to health care. The closure of pharmacies in recent years has created "pharmacy deserts" in some underserved communities.

Employer Health Care

As employers that sponsor plans to provide health care coverage to their employees, FMI member companies see how PBM practices exploit inherent conflicts of interest to the detriment of health care plans and beneficiaries. Case in point, PBMs are responsible for developing health care plan formularies, or lists of drugs that a plan will cover, and drug companies compete to have their drugs listed on those formularies by offering compensation to PBMs in the form of rebates. PBMs base formulary access decisions on the amount of the rebates, which incentivizes drug manufacturers to offer higher rebates to secure preferred status and the PBMs, in turn, to put higher-cost drugs on their formularies, because the rebates are based on a percentage of a drug's list price. Put simply, PBMs may be making decisions on inclusion of a drug based not on clinical research or evidence-based efficacy and safety, but on which manufacturer offers a higher rebate payment.

Therefore, in pursuit of higher rebates, PBMs routinely deny access to formularies, change drug formularies, or require prior authorization for drugs that may be best for a patient's condition, even in cases where a more affordable medication is available. For example, a PBM often excludes a lower priced generic or biosimilar because the higher priced branded drug offers higher rebates. Meanwhile, our members' health plans have little visibility into these rebates, making it difficult for them to monitor whether their contracted PBMs are choosing drugs to reduce plan costs or to increase the PBMs' own financial models. In short, the current system incentivizes PBMs to give higher–priced drugs more favorable health-plan coverage, directing patients toward more expensive drugs.

Conclusion

PBMs have been allowed to operate without oversight, shrouded in secrecy, to the detriment of consumers, pharmacies, providers and employers. Now, Congress has an opportunity to advance legislation that would help control consumers' drug costs, stabilize the operating environment for pharmacies, and incentivize transparent PBM practices that enhance employer-sponsored health coverage for beneficiaries and get PBMs back to their original mission—reducing paperwork so pharmacists can spend more time with patients. We look forward to working with the Senate Commerce Committee, Senate leadership and the many pharmacy champions throughout Congress to get this legislation across the finish line.

FMI thanks the Committee for the opportunity to provide input on this critically important topic. If you have questions about these comments or would like additional information, please feel free to contact Peter Matz at *pmatz@fmi.org* or (202) 452–8444.

Sincerely,

PETER MATZ,
Director, Food and Health Policy.

PREPARED STATEMENT OF NATIONAL COMMUNITY PHARMACISTS ASSOCIATION (NCPA)

Chair Cantwell, Ranking Member Cruz, and Members of the Committee:

Thank you for conducting this hearing on pharmacy benefit managers and the need for transparency on their anticompetitive practices that harm patients and small business pharmacies. In this statement, NCPA offers support for S.127, the Pharmacy Benefit Manager Transparency Act of 2023, which would provide plan sponsors/employers much needed transparency on how PBMs administer their pharmacy benefit and clarify the Federal Trade Commission's enforcement authority to prohibit unfair or deceptive business practices in which PBM-insurers engage in the commercial health insurance market.

NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care (LTC) services and play a critical role in ensuring patients have immediate access to medications in both community and LTC settings. Together, our members represent a $78.5 billion health care marketplace, employ 240,000 individuals, and provide an expanding set of health care services to millions of patients

every day. Our members are small business owners who are among America's most accessible health care providers.

Our pharmacies and the patients they serve have long had concerns about PBM-insurers, their anticompetitive practices, and the role they play in ever-increasing drug costs. PBM-insurer practices continue to cause these small businesses to struggle to remain viable and open to provide continued access and care. We appreciate the longstanding efforts of Chair Cantwell and Senator Grassley to address these practices and the negative impact they have on patients and small business independent pharmacies with the introduction of this legislation last Congress and its advancement through the Commerce Committee on a bipartisan basis.

NCPA has been proud to work with the sponsors of this legislation since its introduction last Congress as it would bring much needed transparency to and ultimately stop PBM-insurers' unjust and deceptive practices. For years, NCPA has highlighted the problems posed by increasing consolidation in the health care industry, specifically that three PBM-insurers now control approximately 80 percent of the market. Advancing this legislation will clarify the FTC's enforcement authority when addressing the deceptive and anti-competitive business practices perpetrated by the consolidated PBM-insurer industry, including spread pricing and clawbacks.

NCPA applauds the committee for holding this important legislative hearing, and we support passage of S.127, the Pharmacy Benefit Manager Transparency Act of 2023. As the bill advances through the Senate Commerce Committee, NCPA hopes that the bill language will be tightened to ensure provisions align with many state laws. NCPA thanks Chair Cantwell and Senator Grassley for your leadership in addressing this issue, and we look forward to working with you to get this bipartisan legislation across the finish line this Congress.

PREPARED STATEMENT OF PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

Introduction

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to provide this statement sharing the PBM industry's concerns with how the PBM Transparency Act would impact the market for prescription drugs. PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans and operate home delivery and specialty pharmacies for more than 275 million Americans with health coverage through public and private employers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits (FEHB) program, and the exchanges established by the Affordable Care Act (ACA). Our members work closely with health plans and health insurance issuers to secure lower costs for prescription drugs and achieve better health outcomes.

As pharmacy benefit experts, PBMs generate tremendous value, estimated at $145 billion annually for society,[i] and save payers and patients an average of $1,040 per person per year.[ii] For many years, evidence has also shown a return of 10:1 on investments in PBM services for clients.[iii] Even with the substantial savings generated by pharmacy benefit companies, over a quarter of adults say it is difficult to afford their prescription drugs[iv]—demonstrating the need for policymaker action focused on areas of dysfunction in the private market.

Competition is the Best Way to Lower Prescription Drug Costs

PBMs work to improve prescription drug affordability by providing prescribers with information about less expensive generic alternatives, setting performance standards for pharmacies to encourage generic fills, and ensuring patients are aware of lower cost alternatives. Due in large part to these efforts by PBMs, 90 percent of prescription drug fills are generics.[v] Pharmacy benefit companies also support increased uptake of biosimilars through business decisions, such as preferring both the brand and a biosimilar to ensure patients and providers have the proper incentives to choose lower cost options and the choice to continue with a drug they may be reluctant to move away from, and policy proposals, including eliminating the

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[i] National Bureau of Economic Research. 2022. *https://www.nber.org/papers/w30231.*

[ii] Visante. 2023. *https://www.pcmanet.org/wp-content/uploads/2023/01/Pharmacy-Benefit-Managers-PBMs-Generating-Savings-for-Plan-Sponsors-and-Consumers-January-2023.pdf.*

[iii] Visante. 2023. *https://www.pcmanet.org/wp-content/uploads/2023/01/The-Return-on-Investment-ROI-on-PBM-Services-January-2023.pdf.*

[iv] Kaiser Family Foundation. 2022. *https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/.*

[v] AAM. 2021. *https://accessiblemeds.org/sites/default/files/2021-10/AAM-2021-US-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.*

interchangeability designation to reduce costs and confusion, stopping patent abuses, and making it easier for Medicare Part D plans to update formularies as new biosimilars come to market.

Toward that end, PCMA recently proposed the following three keys in a policy platform supportive of a more sustainable health care future:

> *Key #1: Ensure System Sustainability by Promoting Competition.* Enabling a robust private prescription drug marketplace that promotes competition is the best way to drive down prescription drug costs and make more affordable alternatives available for patients.
>
> *Key #2: Support and Equip Clinicians with Tools and Data to Serve Patients Optimally.* Pharmacy benefit experts support efforts to help clinicians, including pharmacists and other health care practitioners, "practice at the top of their license" to optimize use of their clinical expertise and counseling abilities. Pharmacy benefit companies also work to increase clinicians' administrative efficiency by offering information and tools to help serve patients.
>
> *Key #3: Enhance Patient Outcomes and Improve the Patient Experience.* Pharmacy benefit companies use their prescription drug expertise to support better health outcomes and provide recommendations to meet each patient's needs.

Our *Affordable Future* policy platform proposes numerous solutions to build on the private market system and facilitate collaboration among patients, regulators, PBMs, clinicians, health plans, and pharmacies to work toward a more functional, equitable, and affordable market for prescription drugs.

PCMA supports numerous pieces of legislation introduced by Members of the Senate Commerce Committee and others, including the package of bills approved by the Senate Judiciary Committee just last week and in the previous Congress. These measures align with the solutions proposed by our organization, and we continue to support the Interagency Patent Coordination and Improvement Act of 2023, the Prescription Pricing for the People Act of 2023, the Stop STALLING Act, the Preserve Access to Affordable Generics and Biosimilars Act, and the Affordable Prescriptions for Patients Act. PCMA also supported Senator Rosen's *Expanding Access to Affordable Prescription Drugs and Medical Devices Act* to improve the competitive landscape for prescription drugs.

The PBM Transparency Act of 2023 Includes an Unprecedented Expansion of FTC Powers

This bill would egregiously expand the power, authority, and jurisdiction of the Federal Trade Commission (FTC), placing the agency in the middle of private business dealings normally handled by contracts, and allowing the agency to pick industry winners and losers. Further, the bill would do nothing to lower drug costs and would instead have the opposite effect by reducing competition among prescription drug manufacturers and pharmacies and increasing costs throughout the system.

The FTC is currently conducting a 6(b) study on PBMs, which significantly overlaps the data requested in the FTC reports proposed in this bill. Our industry is confident the ongoing study will find, as other FTC reports have, that the PBM market is competitive and diverse, with more than 70 individual companies of varying size operating across the Nation in a variety of markets. Before taking any legislative action, Congress should wait and see what the FTC finds and recommends.

Regardless of the outcome of the study, it is important to note that the Pharmacy Benefit Manager Transparency Act of 2023 is not aligned with the historical focus of the FTC, which has in the past focused its transparency efforts primarily on consumer protection and education. This expansion of the FTC's authority would set a precedent for allowing the FTC to micromanage business practices and regulate prices, which could be applied to any industry.

Beyond the dramatic expansion of the FTC's authority, providing state attorneys general with enforcement discretion over private contracts would create an opportunity for them to wield that power to insert themselves into the private dealings of PBMs and mail-order pharmacies. If a state attorney general had an interest in a particular drug or class of drugs and wanted information about who is buying, selling, shipping, or otherwise distributing that drug, they could use the authority granted to them under this Act as a pretext for accessing personal health information that would otherwise be private. Further, this expansion would create the need for coordination between the FTC and 50 or more state, district, or territory attor-

neys general[vi] and would require significant additional taxpayer-funded resources for the Commission to manage this complicated patchwork of enforcement and standards.

It is difficult to estimate the total requirement for resources, as the language under section two prohibiting arbitrary, unfair, or deceptive business practices is unclear. Two of the three prohibited practices terms are clearly defined in established law, but one is not—"deceptive" and "unfair" are clearly defined, "arbitrary" is not. The lack of clarity around this term could cause attorneys general to make inconsistent attempts at enforcement, creating costs for the Commission as it tries to reconcile these disparate approaches, and businesses as they attempt to defend themselves. The FTC has a long history of enforcing Section 5 of the FTC Act, which prohibits "unfair or deceptive acts or practices in or affecting commerce."[vii] Delegating this authority to states therefore seems unnecessary.

There is no similar history of prohibiting practices simply because they are arbitrary. In fact, the FTC may not have the authority to prohibit acts or practices that are neither unfair nor deceptive, but are simply arbitrary. Congress has also never enacted a law against arbitrary business practices. When used in a legal context, the term "arbitrary" generally protects the public from arbitrary government overreach (*e.g.,* "arbitrary and capricious" is a judicial standard of review). The use of this term as it relates to private business is out of place, and its inclusion could lead to actual, prohibited arbitrary enforcement by the FTC or the states.

At present, no other industry is regulated in the intrusive and anticompetitive manner proposed in the legislation, which would force businesses to provide potential customers, suppliers, and the public with proprietary information. The bill also would give the FTC review and enforcement authority of any private contract related to pharmacy benefit managers and set a precedent for allowing the FTC to manipulate prices, which Congress could apply to any industry.

This Bill Would Increase Consumer Costs

This bill would do nothing to lower prescription drug costs for consumers, and actually threatens to increase them. Requiring the exposure of proprietary contracting information would allow competitors to learn of others' price concessions, which would facilitate tacit collusion and increase costs. The FTC has historically spoken out against over-exposing information about private business dealings because such an approach is deeply damaging to a competitive marketplace, stating, "If pharmaceutical manufacturers learn the exact amount of the rebates offered by their competitors (either because the safeguards on subsequent disclosure by purchasers and prospective purchasers are insufficient or because the mandated disclosure to prescribers provides sufficient information for pharmaceutical manufacturers to calculate these amounts) then tacit collusion among manufacturers is more feasible. Consequently, the required disclosures may lead to higher prices for PBM services and Pharmaceuticals."[viii]

The FTC is not alone in this assertion. Recently, in speaking about concerns related to anticompetitive information exchanges, Principal Deputy Assistant Attorney General Doha Mekki noted on behalf of the Department of Justice (DOJ) that, "Courts have long recognized that the exchange of competitively sensitive information can subvert the competitive process and harm competition." Attorney General Mekki also spoke of the United States Supreme Court's concern that sharing current pricing information risks greater harm than sharing old, stale information, and specifically stated that, "transparency in the health care arena may lead to tacit collusion and higher prices."[ix] She went on to say:

[vi] The legislative text does not clearly state whether it is only *states* or also the Federal District of Columbia and territorites' attorneys that would gain these powers.

[vii] FTC Policy Statement on Unfairness. 1980. *https://www.ftc.gov/legal-library/browse/ftc-policy-statement-unfairness);* see also: FTC Policy Statement on Deception. 1983. *https://www.ftc.gov/legal-library/browse/ftc-policy-statement-deception);* see also: Enforcement Policy Statement on Deceptively Formatted Advertisements. 2015. *https://www.ftc.gov/system/files/documents/public_statements/896923/151222deceptiveenforcement.pdf;* see also: Statement of Enforcement Principles Regarding "Unfair Methods of Competition" Under Section 5 of the FTC Act. 2015. *https://www.ftc.gov/system/files/documents/public_statements/735201/150813section5enforcement.pdf.*

[viii] FTC. 2004. *https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-comment-hon.greg-aghazarian-concerning-ca.b.1960-requiring-pharmacy-benefit-managers-make-disclosures-purchasers-and-prospective-purchasers/v040027.pdf.*

[ix] DOJ. *Principal Deputy Assistant Attorney General Doha Mekki of the Antitrust Division Delivers Remarks at GCR Live: Law Leaders Global 2023.* 2022. *https://www.justice.gov/opa/speech/principal-deputy-assistant-attorney-general-doha-mekki-antitrust-division-delivers-0.*

> Courts also have looked at the degree to which the exchanged data has been aggregated. These decisions considered how, in light of the facts and market realities at the time, the information could facilitate and result in the type of behavior that the antitrust laws condemn. The Second Circuit explained in Todd that "[p]rice exchanges that identify particular parties, transactions, and prices are seen as potentially anticompetitive because they may be used to police a secret or tacit conspiracy to stabilize prices Courts prefer that information be aggregated in the form of industry averages, thus avoiding transactional specificity." But facial aggregation of data alone has been held to be insufficient to save otherwise problematic information exchanges. In Todd, the Second Circuit looked beyond data that appeared to be somewhat aggregated to conclude that the defendants had the ability to effectively disaggregate it, raising serious antitrust concerns.[x]

The language under "exceptions" is not clear and can be interpreted as requiring full disclosure from and to every business entity in the prescription drug payment chain including pharmaceutical manufacturers, pharmacies, employers, wholesalers, physician groups, and hospital systems, which could lead to tacit collusion among pharmaceutical manufacturers and pharmacies. The language states that the PBM must provide full and complete disclosure of the cost, price, and reimbursement of the prescription drug as well as fees, markups, and discounts, to each health plan, payer, and pharmacy with which it does business. Since pharmaceutical manufacturers have health plans, the language makes it sound like manufacturers themselves would have full access to this data, including information about all of their competitors' pricing. This information sharing would likely damage the private market as Mekki warns, "A softening of competition through tacit coordination, facilitated by information sharing, distorts free market competition in the process."

This Bill Puts Patients' Privacy at Risk

By expanding state authority to review patient- and drug-specific information, this bill threatens patient privacy and exposes individuals and employers to state enforcement, posing a significant risk that state agencies could use patient- or plan-specific information to enforce laws outside of the scope of this legislation.

PBMs Presently Comply with Numerous Disclosure Requirements

Pharmacy benefit companies already operate under Federal transparency requirements and adhere to myriad contractually required transparency previsions imposed by their own clients.

PBMs are subject to regulations promulgated by the Department of Health and Human Services (HHS), the Department of Labor, the Department of Treasury, the Food and Drug Administration, and states. PBM practices are overseen by state Medicaid agencies, state-based consumer protection agencies, private accreditation organizations, and their own clients—health plan sponsors and PBMs are directly regulated by state departments of insurance or other state agencies.

Several Federal departments and agencies require extensive reporting from various health care entities on drug pricing, which require input from PBMs. The Centers for Medicare & Medicaid Services (CMS) requires reporting from multiple entities, including Exchange and Medicare plans which must publicly report data on numerous administrative processes like coverage determinations and prior authorization; benefits design; generic dispensing rate (by pharmacy type); the aggregate amount and type of rebates, discounts, or price concessions that are attributable to patient utilization, those that are passed on to the plan sponsor; the total number of prescriptions that were dispensed; and the difference between the amount the health plan pays the PBM and the amount that the PBM pays retail and mail order pharmacies. Medicare Part D plans must also submit Prescription Drug Event (PDE) records, a summary of Part D claims activities for each drug dispensed. When plans submit PDEs to CMS for payment, they include any pharmacy dispensing fee. As part of the bid and reconciliation processes, PBMs (via the Part D plans) must report estimated pharmacy and manufacturer Direct and Indirect Remuneration (DIR), including rebates and other price concessions.

Part D plans and the PBMs that administer them must also implement real-time benefits tools to give patients and prescribers cost sharing and benefits information at the point of prescribing.

Beginning December 27, 2022, the Departments of Treasury, HHS, Labor, and the Office of Personnel Management required PBMs to report:

- The 50 most frequently dispensed brand prescription drugs.

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[x] Ibid. Includes information sourced from *Todd,* 275 F.3d at 212–2013.

- The 50 costliest prescription drugs by total annual spending.
- The 50 prescription drugs with the greatest increase in expenditures from the previous year.
- Prescription drug rebates, fees, and payments by drug manufacturers in each therapeutic class of drugs, as well as for each of the 25 drugs that yielded the highest amount of rebates.
- The premium and out-of-pocket cost impact of prescription drug rebates, fees, and other payments.

PBMs may report these data directly to the government or to their clients. The clients (plan sponsors, issuers, and the FEHB program carriers generally) are required to submit this information aggregated at the state/market level, rather than separately for each plan.

Beyond government reporting requirements, much of the PBMs' operational specifics are available to plan enrollees through other provisions of the ACA and Social Security Act including the Summary of Benefits and Coverage, Medicare Plan Finder, and real-time benefit tools that provide current information on prescription drug benefits.

The Securities and Exchange Commission (SEC) also requires publicly traded health plans and PBMs to report quarterly and annual financial information to the SEC.

This Act Interferes with Businesses' Ability to Provide Affordable Benefits

The Pharmacy Benefit Manager Transparency Act fails to consider employers' need for choice and flexibility when it comes to designing prescription drug benefits that meet the health and affordability needs of unique employee populations. Employers and other health plan sponsors vary dramatically in size, resources, and function and serve diverse populations. Employer health plan sponsors know more about their financial resources and plan participants than any other entity and they use that information to make choices about how to best serve their unique populations.

Health plan sponsors, including employers, are not required to use PBMs, and yet nearly all of them elect to contract with a pharmacy benefit company to administer their prescription drug benefits. Plan sponsors rely on PBM expertise to secure savings through price concessions from pharmaceutical companies (through formularies and other tools), administer medication adherence and health coaching programs, and provide overall guidance and expertise on pharmacy benefit design and coverage. Employers report about 80 percent satisfaction with the cost-saving, health-improving services provided by their PBM.

Plan sponsors should have the option of determining how they would like to pay the pharmacy benefit company they select for their services. "Spread pricing" is a risk-based contracting model in which employers choose to let the pharmacy benefit company hold the risk that plan participants may use more expensive pharmacies to acquire drugs in exchange for the option to keep the savings when a patient uses a less expensive pharmacy, as well as to take a loss when they use costlier pharmacies. Today, employers can choose spread pricing or "pass-through" contracting, in which the plan sponsor pays whatever the pharmacy charges. While larger employers typically select pass-through contracts, as they have the scale to deal with the variability of pharmacy charges, smaller employers often choose spread contracts because of the pricing predictability and savings they derive. This bill would mandate pass-through contracting with employers, prohibiting employers from designing their own PBM contractual compensation model, and could dramatically increase their administrative costs. Health plans should not be deprived of the right to make that choice.

This bill also provides states with enforcement authority that is outside the scope of the Employee Retirement Income Security Act, 1974 (ERISA), thereby eroding ERISA protections.

This Bill Includes Significant Technical Issues

A number of more technical concerns are inherent in the proposed legislation. For example, it assumes PBMs are negotiating directly with pharmacies; however, approximately 83 percent of independent pharmacies contract with powerful pharmacy services administrative organizations (PSAOs) to negotiate pharmacy network contracts and perform many fundamental administrative operations on their behalf. Further, pharmacies and PSAOs are always informed of reimbursement rates as a matter of standard operating procedure. There are no surprises. The bill also would require disclosure to a pharmacy of spread pricing, which is unnecessary as the

amount the health plan pays its pharmacy benefit company does not impact the pharmacy's reimbursement, which could be higher or lower.

The bill would also require PBM reporting if a PBM moved a drug to a lower formulary tier, or a drug had a higher cost, or resulted in lower reimbursement to a pharmacy. Under longstanding Federal law and guidance, plans are encouraged to make positive formulary changes, which benefit Exchange and Part D plan enrollees, and reduce overall program costs by encouraging generic and biosimilar substitution. Disclosing these changes to the pharmacies could impact the incentive structure, causing a decrease in substitution of lower-cost alternatives in place of expensive brand drugs, contrary to this Administration's and the Congress's stated objective to foster a competitive market for biosimilars and other prescription drugs.

This Bill Would Increase Costs and Facilitate Pharmacy Fraud

Beyond increased consumer costs due to tacit collusion, the expansion of the powers of the FTC encompassed in this bill would almost certainly increase taxpayer costs given the additional oversight and enforcement authority, expanded focus, and need to coordinate with numerous state attorneys general and other state officials.

Adding to costs for taxpayers, businesses, states, and the Commission, the private right of action in section 5(b) would allow pharmacists to turn every matter of dissatisfaction into a lawsuit, generating an exorbitant amount of litigation from pharmacies for things that are ordinary contract elements today. For example, recent Part D regulatory changes that go into effect in 2024 require PBMs to change payments to pharmacies. This bill would give pharmacies the ability to submit legal claims against PBMs for complying with Medicare rules.

Another cost increase would stem from limitations on pharmacy audits. The National Health Care Anti-Fraud Association (NHCAA) estimates billions of dollars in annual financial losses due to health care fraud.[xi] The HHS Office of the Inspector General routinely investigates and prosecutes providers, including pharmacies, for fraudulent activities and makes significant economic recoveries on behalf of Medicare and Medicaid programs. Private actors should be able to take these actions and make these recoveries, as well. The restrictions this bill seeks to place on "clawbacks" would encompass audits and recoveries, which have long been established as appropriate and necessary business practices. In addition to fraud, waste, and abuse, pharmacy audits have exposed inventory discrepancies, unwanted autorefills and shipping of medications, claim submissions for medications not dispensed or prescribed, claims submissions for medications not requested by patients, and intentional billing for one product while dispensing another. Health benefit plans are required to audit all providers, including pharmacies, and given that contracts are between PBMs and pharmacies, they delegate pharmacy audits to PBMs. PBMs utilize varying types of audits, from in-person to completely remote, and use best business practices consistent with audits across the health care industry to minimize abrasion. This bill would tie pharmacy benefit companies' hands in fighting fraud, waste, abuse, and drug diversion by preventing PBMs from recovering funds from pharmacy audits when a pharmacy claims that the recovery is unfair, deceptive, or arbitrary—a word that does not have a clear legal application in this instance.

Conclusion

PBMs have always focused on lowering drug costs for patients and health plans.

The Pharmacy Benefit Manager Transparency Act takes a biased approach against one aspect of the pharmaceutical supply and payment chain and will not lower prescription drug costs. Any true attempt at understanding the factors driving costs must include a look at the broader supply chain including PSAOs, pharmacy wholesalers, manufacturer wholesalers, employer benefit consultants, pharmacies, and others with impact on the cost of prescription drugs. PCMA agrees that policymakers need information that exposes the factors driving up prescription drug costs for consumers and continues to support the "Prescription Drug Pricing for the People Act," sponsored by Senators Grassley, Cantwell, Blackburn, Blumenthal, Braun, Capito, Lankford, Tillis, and Tuberville, which does not point fingers at a single entity, and instead examines multiple parties in the pharmaceutical supply chain to evaluate anticompetitive practices.

PCMA would be happy to provide additional information to the Committee on the value pharmacy benefit companies bring to patients, health plan sponsors, and society, and looks forward to working collaboratively with Congress and other stakeholders to build on the existing private market framework to make medications more affordable and accessible for patients.

[xi] NHCAA. *The Challenge of Health Care Fraud.* 2022 *https://www.nhcaa.org/tools-insights/about-health-care-fraud/the-challenge-of-health-care-fraud/*.

COMMUNITY ONCOLOGY ALLIANCE

Dedicated to Advocating for Community Oncology Patients and Practices

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(202) 729-8147 | communityoncology.org

January 30, 2023

The Honorable Maria Cantwell
Chair, Commerce, Science & Transportation Committee
United States Senate
511 Hart Senate Office Building
Washington, D.C. 20510

Dear Senator Cantwell:

On behalf of the Board of Directors of the Community Oncology Alliance (COA), we thank you for your leadership in introducing the *Pharmacy Benefit Manager Transparency Act* (S. 127). This legislation is an important first step in stopping unfair and deceptive tactics by the top pharmacy benefit managers (PBMs). It will address long-overdue PBM abuses that have fundamentally broken the United States health care system, leading to delays and denials of critical treatment for patients with cancer and other serious diseases; bureaucratic nightmares for providers simply trying to care for patients; the lowballing reimbursement for independent pharmacies that ultimately creates pharmacy "deserts" across the country; and, worst of all, fueling drug costs and out-of-pocket spending for all Americans.

Unchecked PBM consolidation has had an extremely negative impact on patients, physicians, employers, pharmacies, and our entire health care system. Today, the top three PBMs (CVS Caremark, Express Scripts, and OptumRx) control 80 percent of the prescription drug market in this country. The next three in size (Humana Pharmacy Solutions, MedImpact, and Prime Therapeutics) control an additional 14 percent. As such, the top PBMs have inordinate market leverage allowing them to dictate payment terms to pharmacy providers, including "clawing back" reimbursement after the point of sale and imposing all types of network and sham performance fees. Most onerous, the top PBMs increasingly mandate use of their own mail order pharmacies, resulting in medication delays and denials for patients, including patients requiring critical therapies. COA has long documented and reported on PBM abuses, including several cases we provided your office involving constituents from Washington state.

Your leadership in introducing the *Pharmacy Benefit Manager Transparency Act* is an important step in bringing much-needed transparency to the murky underworld of PBMs.

We stand ready to work with your office in getting this critical legislation signed into law.

Thank you.

Sincerely,

Miriam Atkins, MD, FACP
President

Ted Okon
Executive Director

National Alliance of Healthcare Purchaser Coalitions
Driving Health, Equity and Value

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February 16, 2023

Shannon Smith
Counsel and Senior Consumer Advisor
Senate Commerce, Science, and Transportation Committee
254 Russell Senate Office Building
Washington, DC 20510

Ms. Smith,

The National Alliance of Healthcare Purchaser Coalitions (National Alliance) is the only nonprofit, purchaser-led organization with a national and regional structure dedicated to driving health and healthcare value across the country. Our members represent private and public sector, nonprofit and Taft-Hartley organizations, and more than 45 million Americans, spending over $300 billion annually on healthcare. We are writing today to submit this statement for the record on the hearing held by the Committee on February 15, 2023 titled Bringing Transparency and Accountability to Pharmacy Benefit Managers.

Employer experience demonstrates that PBMs too often engage in opaque and anti-competitive business practices that are geared to improve their own bottom line at the expense of plan sponsors, and employees and their families. We are very concerned about the recently introduced legislation, The Pharmacy Benefit Manager Transparency Act (S. 127). This bill does not offer any solutions for the root causes of these issues. The National Alliance and the broad employer community remains committed to working with policymakers to enact legislation that would address the problems employers face when working with PBMs.

The PBMTA does not require PBMs to be transparent about secret agreements with pharmaceutical manufacturers, which may be affecting drug prices, formulary placement, and other critically important aspects of prescription drug benefits. Further, while the bill calls for a study on PBM practices, it fails to outlaw direct payments related to drug formulary placement. Patients deserve immediate relief from these practices. Moreover, a study is not needed and will only cause patients to suffer unnecessarily high prices and lack of access to competing products for additional years.

We believe Congress should enact legislation to fundamentally reform PBM business practices and the drug supply chain. For the plan sponsor community to support a bill aimed at PBM reform, such legislation must:

- Require PBMs to provide plan sponsors with timely reports on the costs, fees and rebate information associated with their PBM contracts.
- Prohibit PBMs from engaging in spread pricing or charging a plan sponsor, health insurance plan, or patient more for a drug than the PBM paid to acquire the drug.
- Require the PBM to pass on 100% of any rebates or discounts to the plan sponsor.
- Require PBMs to act as fiduciaries under ERISA.
- Require PBMs to disclose to plan sponsors any bona fide fee arrangements.
- Prohibit PBMs from altering a plan sponsor's formulary in exchange for remuneration from a third party.

Employers need relief from high drug prices and they need them now. It is critically important to take the employer-purchaser voice into consideration when crafting legislation aimed at reducing drug prices and cracking down on the anti-competitive behaviors of some of the stakeholders in this industry. PBMs claim to use their size and expertise to leverage deep discounts from drug manufacturers on behalf of healthcare purchasers and consumers. However, employers have known for years that even if PBMs are getting discounts from manufacturers, they are not passing those savings on to employers. Congress needs to act so families with employer-sponsored insurance can afford their necessary medications, and so employers have transparency into PBMs' practices.

Sincerely,

Mike Thompson President and CEO
National Alliance of Healthcare Purchaser Coalitions

February 16, 2023

The Honorable Maria Cantwell
Senator of Washington
511 Hart Senate Office Building
Washington, DC 20510

The Honorable Chuck Grassley
Senator of Iowa
135 Hart Senate Office Building
Washington, DC 20510

Dear Senators Cantwell and Grassley,

On behalf of the over 2.2 million members of the Association of Mature American Citizens - AMAC, I write in support of S. 127, The Pharmacy Benefit Manager Transparency Act 2023. This bipartisan legislation will help drive down consumer costs for seniors by holding pharmacy benefit managers (PBM) accountable for the use of anti-competitive business practices.

As an organization representing mature Americans, we are concerned with the PBM issue as it pertains to our members, many of whom are negatively affected by the increasing costs of prescription drugs. An overwhelming majority of seniors report that they are currently taking prescription medication. A recent Kaiser Family Foundation poll found that 75 percent of Americans aged 50-64 and nearly 90 percent of respondents over 65 report taking prescription medications.

Pharmacy benefit managers were created to manage drug benefits for insurance plans and lower consumer costs, but over the years, these middlemen have expanded beyond their original purpose. AMAC has been very vocal on behalf of our members about the layers of anti-competitive business practices used by PBMs, including reducing market competition for drugs, using spread pricing to increase profits without lowering costs, using clawbacks to hurt independent pharmacies, and shifting patients to costlier drugs. None of these practices are in the best interest of the patient.

The Pharmacy Benefit Manager Transparency Act 2023 would prevent anti-competitive practices and require PBMs to be more transparent. The purpose of this legislation is to hold PBMs accountable to the rule of law if they continue these business practices in bad faith. We hope that as the bill makes its way through the Senate Commerce Committee to see the language is modified to ensure that vertically integrated PBMs do not take advantage of the exceptions clause to increase rebates and continue to use anti-competitive business practices.

AMAC is committed to ensuring senior citizens' interests are protected and thanks you, Senators Cantwell and Grassley, for introducing this critical and timely bipartisan bill.

Sincerely,

Bob Carlstrom
President
AMAC Action

PBM ACCOUNTABILITY PROJECT

February 16, 2023

The Honorable Maria Cantwell
511 Hart Senate Office Building
Washington, DC 20510

The Honorable Charles Grassley
135 Hart Senate Office Building
Washington, DC 20510

Dear Chair Cantwell and Senator Grassley,

The PBM Accountability Project is working to ensure that patients, employers and unions are not overpaying for prescription medicines. Meanwhile, middlemen pharmacy benefit managers (PBMs) continue to find new ways to rake in profits at the expense of patients and plan sponsors. This is why we are so thankful for your leadership in taking on predatory PBM pricing behavior that is harming American consumers and employers.

We write in support of the recently introduced Pharmacy Benefit Manager Transparency Act (S.127) that aims to curtail harmful PBM practices. We appreciate that the bill aims to prohibit exploitation of independent pharmacists through a number of harmful practices, including spread pricing and reimbursement clawbacks.

Stated simply, there is an undisputed need to rein in predatory PBM practices evident in the millions of prescription drug claims processed every day. Only three, vertically integrated PBMs control more than 80% of drug purchasing for private and public sector health programs. Such market domination enables PBMs to engage in anti-competitive practices throughout the prescription drug supply chain. The vertical integration of PBMs has allowed them to profit at the expense of patients and plan sponsors. We therefore also welcome the Prescription Pricing for the People Act (S.113) that directs the Federal Trade Commission (FTC) to issue a report within one year addressing the legal and regulatory obstacles to FTC enforcement of antitrust and consumer protection laws pertaining to PBMs. It is time for improved transparency and tackling of anti-competitive PBM behavior.

The Pharmacy Benefit Manager Transparency Act is a major first step in the right direction. The Act's requirements will shed critical light on two of many arbitrage tactics deployed by PBMs to divert value extracted from supply chain participants, and ultimately consumers, into outsized PBM gross profit margins. These tactics include PBM reporting on prohibited clawbacks from pharmacist compensation and PBM-retained spread pricing revenues. Research conducted by the PBM Accountability Project reveals that more than 42% of PBM gross profit margins are derived from unreported pricing practices like these that will finally be made transparent by the Act.

The Act will also highlight differentials in reimbursement rates, pricing concessions and other remuneration that PBMs provide independent pharmacies compared to those they offer to PBM-owned, controlled or affiliated pharmacies. Required reporting will provide legislators and regulators valuable insight into how vertically integrated PBM giants are able to weaponize market domination to expand market share through anti-competitive tactics. Such information

PBM ACCOUNTABILITY PROJECT

will be critical for restoring competitive conditions in the prescription drug marketplace and protecting consumers, as well as independent pharmacists, from predatory pricing behavior.

This is the beginning of an important process of uncovering PBM arbitrage in prescription drug markets that has too long festered in a "black box," where obscure PBM pricing schemes have enabled PBMs to divert value from consumers, putting costs of prescription medicines increasingly out of reach of patients who need them. Transparency of PBM-intermediated transactions is needed throughout the prescription drug supply chain. S.127 will shine an important light on PBM manipulation of pharmacy pricing and reimbursements. Similar light will need to be shined, as well, on PBM strategies for extracting manufacturer-derived revenues, for example, and on the drug price-increasing impact of Group Purchasing Organizations (GPOs) owned by each of the dominant three PBMs. Of note, two of the GPOs are headquartered off-shore and beyond easy scrutiny by federal regulators.

The Act will help pull back the shroud of opacity that obscures a broad range of unregulated and largely unreported predatory PBM pricing behavior. We applaud your leadership in taking on anti-competitive PBM practices that are ultimately paid for by America's patients and health plan sponsors. The PBM Accountability Project stands ready to support you in taking this important step and additional steps that must follow to restore sustainable affordability of prescription drugs for all Americans.

Sincerely,

Doug Dority
Chairman
PBM Accountability Project

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CROHN'S & COLITIS FOUNDATION

February 17, 2023

The Honorable Maria Cantwell
511 Hart Senate Office Building
Washington, DC 20510

The Honorable Marsha Blackburn
357 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Michael Braun
404 Russell Senate Office Building
Washington, DC 20510

The Honorable James Lankford
316 Hart Senate Office Building
Washington, DC 20510

The Honorable Tommy Tuberville
142 Russell Senate Office Building
Washington, DC 20510

The Honorable Charles Grassley
135 Hart Senate Office Building
Washington, DC 20510

The Honorable Richard Blumenthal
706 Hart Senate Office Building
Washington, DC 20510

The Honorable Shelly Moore Capito
172 Russell Senate Office Building
Washington, DC 20510

The Honorable Thom Tillis
113 Dirksen Senate Office Building
Washington, DC 20510

Dear Senators:

The Crohn's & Colitis Foundation is pleased to endorse the Pharmacy Benefit Manager Transparency Act of 2023 (S. 127). The Crohn's & Colitis Foundation is a non-profit, volunteer-fueled organization dedicated to finding cures for Crohn's disease and ulcerative colitis, and improving the quality of life of children and adults affected by these diseases. Crohn's disease and ulcerative colitis are chronic, degenerative autoimmune diseases collectively known as inflammatory bowel disease (IBD). If not properly treated, IBD causes pain and a diminished quality of life, and can eventually lead to malnutrition, cognitive impairment, repeated hospitalizations, multiple surgeries, or event death.

IBD patients have benefitted greatly from the introduction of biologic medications that promote and extend disease remission. Biologic therapies offer a distinct advantage in IBD treatment because their mechanisms of action are more precisely targeted to the factors responsible for IBD. For example, unlike corticosteroids (which affect the whole body and may produce major side effects) biologic agents act very selectively. Unfortunately, these medications are quite expensive, and biosimilars have been slow to come to the market.

In response to these high costs, pharmacy benefit managers (PBMs) have adopted a wide range of tactics that have perversely impacted access to biologics and biosimilars. The largest PBMs control around 80 percent of the market for prescription drugs and have enormous influence over which medicines are prescribed to patients, which pharmacies patients can access, and how much patients will pay at the pharmacy counter. Hidden rebate schemes have complicated market entry and often result in patients paying much more for medications than they cost the PBM. Yet, PBMs are one of the least understood or regulated sectors of the health care system.

IBD patients deserve to understand why PBMs are making the decisions that they do, and whether these decisions are financially motivated, or based on science. They should also share in any cost savings achieved by PBMs. The Pharmacy Benefit Manager Transparency Act would make great strides in revealing the true motives and operating practices of PBMs.

I thank you for your leadership on this important issue and look forward to working with you to help ensure that the Pharmacy Benefit Manager Transparency becomes law.

Sincerely,

Erin McKeon
Associate Director, Federal Advocacy

NATIONAL ASSOCIATION OF SPECIALTY PHARMACY

March 1, 2023

Senator Maria Cantwell
Chair, Senate Committee on Commerce, Science and Transportation
254 Russell Senate Building
Washington DC, 20510

Senator Ted Cruz
Ranking Member, Senate Committee on Commerce, Science and Transportation
254 Russell Senate Building
Washington DC, 20510

BY ELECTRONIC DELIVERY

RE: Bringing Transparency and Accountability to Pharmacy Benefit Managers Hearing Testimony

Dear Chairperson Cantwell and Ranking Member Cruz:

I write today on behalf of the National Association of Specialty Pharmacy (NASP) to express support for the Senate Committee on Commerce, Science and Transportation's focus on preventing unfair pharmacy benefit manager (PBM) practices, especially anticompetitive business practices that lead to narrow pharmacy networks.

NASP represents the entire spectrum of specialty pharmacy industry stakeholders, including the nation's leading specialty pharmacies and practicing pharmacists; nurses; technicians; pharmacy students; non-clinical healthcare professionals and executives; pharmacy benefit managers (PBMs); pharmaceutical manufacturers; group purchasing organizations; wholesalers and distributors; integrated delivery systems and health plans; patient advocacy organizations; independent accreditation organizations; and technology, logistics and data management companies. With more than 170corporate members and 3000 individual members, NASP is the unified voice of specialty pharmacy in the United States.

What is Specialty Pharmacy

Specialty pharmacies support patients who have complex health conditions like rheumatoid arthritis, multiple sclerosis, hemophilia, cancer, organ transplantation and rare diseases. Specialty pharmacies operate as independent pharmacies, academic medical center and hospital-health system based pharmacies, regional and national chain pharmacies, grocery store owned specialty pharmacies, health plan-owned specialty pharmacies and home infusion pharmacies. The medications a specialty pharmacy dispenses are typically expensive. Historically, there are limited generic or biosimilar alternatives to brand specialty drugs.

Specialty prescription medications are not routinely dispensed at a typical retail pharmacy because the medications are focused on a limited number of patients and require significant patient education and monitoring on utilization and adherence. Typical retail pharmacies are not designed to provide the intense and time-consuming patient care services that specialty medications require. Though many specialty medications are taken orally, still many need to be injected or infused. The services a specialty pharmacy provides include patient training in how to administer the medications, comprehensive treatment assessment, ongoing patient monitoring, side effect management and mitigation, and frequent communication and care coordination with caregivers, physicians and other healthcare providers. A specialty pharmacy's expert services drive patient adherence, proper management of medication dosing and side effects, and ensure costly and complex drug therapies and treatment regimens are used correctly and not wasted.

Concerns with Market Dominance and Impact on Specialty Pharmacy

While the number of specialty medications only comprises 2.2 percent of the total number of prescriptions dispensed in the United States, these medications represent approximately 50 percent of overall drug spend in the U.S., which by the end of 2021, was estimated to be about $600 billion. Distribution for most specialty medications is limited, with payers working to keep them even smaller. The market is heavily dominated by the largest PBMs and the health insurers that own those PBMs.

While the specialty market has grown, so has vertical integration in the market. The three largest PBMs—CVS Caremark (subsidiary of CVS Health, Inc.; 2019 revenue: $141.5 billion), Express Scripts (subsidiary of Cigna, Corp.; 2019 revenue: $96.4 billion), and OptumRx (subsidiary of UnitedHealth Group; 2019 revenue: $74.3 billion)—account for more than 80% of the PBM market.[1],[2] Vertically-integrated insurers have more incentive to fill a specialty drug through their PBM-owned specialty pharmacy. The largest PBMs have their own or an affiliation with three of the four largest specialty pharmacies in the United States: CVS Specialty (owned by CVS Health, Inc.), Accredo / Freedom Fertility (owned by Express Scripts), and Optum Specialty Pharmacy (owned by OptumRx).[3]

Over the years, anticompetitive market practices, including unfair contract terms, inappropriate pharmacy performance evaluations tied to metrics unrelated to the business of specialty pharmacy, and an escalation in DIR clawback fees and spread pricing have led to a significant narrowing of pharmacy networks. Efforts by Congress are needed to address such anticompetitive practices.

<u>Efforts by PBMs to Limit the Specialty Pharmacy Network</u>

[1] https://www.acpjournals.org/doi/abs/10.7326/M17-2506?journalCode=aim
[2] https://docs.house.gov/meetings/JU/JU05/20151117/104193/HHRG-114-JU05-Wstate-BaltoD-20151117.pdf
[3] https://www.drugchannels.net/2020/04/the-top-15-specialty-pharmacies-of-2019.html

In many instances, specialty pharmacies have witnessed increased efforts by PBMs to limit the participation of non-affiliated specialty pharmacies in a given pharmacy network. Tactics such as demanding impossible terms for participation and non-negotiable reimbursement rates that do not cover the cost of the drug alone – let alone the patient management and product support services needed to go with the drug - are all too common. Impossible terms can include requiring a specialty pharmacy to stock non-specialty drugs that are outside the needs of its patient base and mandating that a pharmacy set up additional physical locations despite the PBM knowing that most specialty pharmacies have a hub and spoke model where they successfully ship medications to patients as opposed to operating multiple physical facilities. Specialty pharmacies must repeatedly work through state and federal laws and fight to get into provider networks. Examples of anti-competitive actions vertically integrated PBMs take to limit pharmacy network participation include the following:

- **Reimbursing affiliated pharmacies at a rate higher than non-affiliated pharmacies**— PBM's offer drug reimbursement rates below the purchase price of specialty pharmacies. For example, many of the current Pharmacy Services Administration Organization contracts contain a take it or leave reimbursement rate that is below acquisition cost. This ability is driven by the PBM in its effort to favor its own specialty pharmacy that has either a better reimbursement rate given its size or can sustain the loss also because of its size and dominance in the marketplace. Unless addressed, such practices are intended to negatively impact specialty pharmacy participation in plan networks by making reimbursement too low to effectively operate and support patient care.

- **Pharmacy DIR Fees—**pharmacy direct and indirect renumeration fees, called pharmacy DIR fees, are monies received by PBMs that include concessions pharmacies are forced by PBMs to pay long after the pharmacy dispenses medications to a patient. These fees are not used by PBMs or their affiliated health plans to reduce the cost of the drugs for patients. Pharmacy DIR fees only result in profit for PBMs/payers, forcing pharmacies to fill prescriptions below cost. Specialty pharmacies pay millions of dollars in DIR fees per year, with these fees assessed six months or longer after the pharmacy has dispensed the drug to a beneficiary and with no transparency as to what the fees represent. The net negative effect on market participation and competitiveness has been significant.

  While we are encouraged by attempts to address pharmacy DIR in the *Pharmacy Benefit Manager Transparency Act of 2023* that is being considered by the Committee, we are concerned that there is language in the bill that would allow the practice of pharmacy DIR fees when the DIR fees collected by a PBM are passed onto the plan. Such an exception will continue to benefit the three largest PBMs who are vertically integrated. **Therefore, we encourage the Chair and the Committee to advocate for the removal of this DIR exception from the legislation: so long as "the pharmacy benefit manager, affiliate, subsidiary, or agent passes along or returns 100 percent of any price concession to a health plan or payer, including any rebate, discount, or other price concession."**

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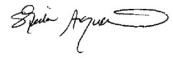
- **Contracting specialty pharmacies as retail pharmacies—** PBMs typically contract specialty pharmacies as a retail pharmacy. The challenge is that specialty pharmacy is not a retail pharmacy and offers distinctly different drugs and services than a typical retail pharmacy. Because PBMs also typically own their own mail order pharmacy, they will not offer a specialty pharmacy a contract that allows for delivery of medications to patients via home delivery. While contracted as a retail pharmacy despite its difference in business model, a PBM can accuse the pharmacy of not meeting retail requirements, and when this occurs, a specialty pharmacy can be removed from the network. This same threat does not exist for a PBM-owned specialty pharmacy that equally dispenses the same amount of drug directly through home delivery. Many of NASP's members have received notice or have been thrown out of network for violating the "mail order" clause of the retail contract.

Conclusion

NASP is pleased that the Senate Committee on Commerce, Science and Transportation is discussing the need to examine PBM anticompetitive practices closely. We look forward to working with you to ensure there is oversight over anti-market practices that are gravely limiting patient access to specialty pharmacies today.

NASP appreciates the opportunity to provide written comments for Committee's consideration. If we can provide additional information, please contact me at Sheila.arquette@naspnet.org or (703) 842-0122.

Respectfully submitted,



Sheila M. Arquette, R.Ph.
President and Chief Executive Officer

NATIONAL MULTIPLE SCLEROSIS SOCIETY
March 1, 2023

Hon. MARIA CANTWELL,
Chair,
Senate Committee on Commerce,
Science, and Transportation,
Washington, DC.

Hon. TED CRUZ,
Ranking Member,
Senate Committee on Commerce,
Science, and Transportation,
Washington, DC.

Dear Chairwoman Cantwell and Ranking Member Cruz:

On behalf of the National Multiple Sclerosis Society (Society), thank you for holding the hearing entitled *"Bringing Transparency and Accountability to Pharmacy Benefit Managers"*. We appreciate this hearing's focus on examining the role that pharmacy benefit managers (PBMs) play in the American healthcare system. People with MS need more information to make educated choices about their health insurance and the medications they need to live their best lives. Unfortunately, PBMs currently operate in the middle of the pharmaceutical distribution chain and very little information is available for patients and regulators to utilize in healthcare decision-making. The Society is pleased to endorse S.127, *the Pharmacy Benefit Manager Transparency Act* and support its goal to bring more transparency into PBM business practices and prohibit unfair or deceptive practices that drive up costs for patients.

Multiple Sclerosis (MS) is an unpredictable, often disabling, disease of the central nervous system, which interrupts the flow of information within the brain and between the brain and the body. Symptoms range from numbness and tingling to blindness and paralysis. The progression, severity, and specific symptoms of MS in any one person cannot yet be predicted, but advances in research and treatment are moving us closer to a world free of MS. The Society works to cure MS while empowering people affected by MS to live their best lives. To fulfill this mission, we fund cutting-edge research, drive change through advocacy, facilitate professional education, collaborate with MS organizations around the world, and provide services designed to help people affected by MS move their lives forward.

MS is a highly expensive disease. The average total cost of living with MS is $88,487 per year.[i] The total estimated cost to the U.S. economy is $85.4 billion per year, and the direct medical cost to live with MS is an average of $65,612 more than a person who does not live with MS.[ii] Evidence demonstrates that early and ongoing treatment with a MS disease-modifying therapy (DMT) is the best way to manage the disease course, prevent the accumulation of disability, and protect the brain from damage due to MS.[iii] There are now more than twenty DMTs on the market, including generic options, and these medications have transformed the treatment of MS over the last 29 years. Unfortunately, these DMTs are incredibly expensive. The annual cost for individuals on an MS DMT ranges from $57,202 to $92,719, depending on an individual's age and gender[iv] and people with MS stay on these medications for years.

The full range of MS DMTs represent various mechanisms of action and routes of administration with varying efficacy, side effects, and safety profiles. No single agent is 'best' for all people living with MS[v] and, as MS presents differently in each person, every person's response to a DMT will vary. It is common for people with MS to move through several different DMTs throughout their life as they may "break-through" on a medication, or have disease activity, and need to try a different DMT.

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[i] Bebo, Bruce et. al. The Economic Burden of Multiple Sclerosis in the United States: Estimate of Direct and Indirect Costs. Neurology May 2022, 98 (18) e1810-e1817; DOI: 10.1212/WNL.0000000000200150. *https://n.neurology.org/content/98/18/e1810* (accessed May 4, 2022).

[ii] Bebo, Bruce et. al. The Economic Burden of Multiple Sclerosis in the United States: Estimate of Direct and Indirect Costs. Neurology May 2022, 98 (18) e1810-e1817; DOI: 10.1212/WNL.0000000000200150. *https://n.neurology.org/content/98/18/e1810* (accessed May 4, 2022).

[iii] Costello, K. *et al.,* MS Coalition. "The Use of Disease Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. September 2019. *https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf* (accessed May 20, 2022)

[iv] Bebo, Bruce et. al. The Economic Burden of Multiple Sclerosis in the United States: Estimate of Direct and Indirect Costs. Neurology May 2022, 98 (18) e1810-e1817; DOI: 10.1212/WNL.0000000000200150. *https://n.neurology.org/content/98/18/e1810* (accessed May 4, 2022).

[v] MS Coalition. The Use of Disease Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. *http://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT_Consensus_MS_Coalition_color.* Accessed December 26, 2018.

The Role of PBMs in the U.S. Healthcare system and trajectory of MS DMT prices

PBMs have played an increasingly important—but often hidden—role in the U.S healthcare system. PBMs manage prescription drug benefits for health insurers, Medicare Part D drug plans, large employers, and other payors. While initially created in the 1960s to help control the cost of prescription drugs, their role has evolved and today they are powerful, but hidden, players in the American healthcare system. PBMs play a fundamental role in determining the cost of prescription drugs for payors, influencing the access to medication that people with MS and other patients need, and determining how much pharmacies are paid for these medications.

When the first MS DMT came to market in 1993, the price range was $8,000 to $11,000 for one year of treatment. The price of MS therapies has dramatically risen since that time. The annual median price for MS DMTs has increased nearly $34,000 in less than 10 years. As of January 2023 (see appendix I), the median annual price of brand MS DMTs is close to $98,000. While not identical, most brand MS DMTs have seen similar pricing trajectories which are not sustainable for people with MS or the U.S. healthcare system. Cost increases have also impacted MS symptom management medications. For example, H.P. ActharGel (Acthar), approved in 1952, is used as a short-term treatment for acute exacerbations of MS. For years, this medication was priced at less than $40 per vial. However, today, a vial of Acthar is priced at around $40,000-approximately 140,000 percent more expensive than when it was approved 68 years ago.[vi] The price increases and additional out-of-pocket costs associated with these medications present real hurdles and barriers to people affected by MS.

PBMs role in formulary development and restrictions to access

PBMs play a significant role in the access that people with MS have to their DMTs and symptom management. As costs have increased, health plans and PBMs employ increasingly strict utilization management practices to minimize the use and cost liability for these therapies. These practices present significant hurdles for prescribers and real barriers for people with MS. While PBMs often cite part of their role as keeping pharmaceutical and health costs down, there are documented examples that PBM practices can add costs to the healthcare system overall and inhibit patient care. For example, physicians in the United States complete an average of 33 prior authorization requests every week, taking an average of 14.4 hours to process.[vii]

Too often, formularies designed by PBMs, and health insurers are driven not by medical practice, but by rebates in the system. For example, according to a 2020 staff report from the House Committee on Oversight and Reform, Teva Pharmaceuticals exerted pressure on PBMs by tying contractual rebates on Copaxone 20 mg/ml to adding Copaxone 40 mg/ml to their formularies.[viii]

There is often little transparency into how formularies or step therapy protocols are developed, especially for MS DMTs, where there are no publicly available algorithms describing how to progress through the different MS DMTs. In 2019, in response to a Society funded survey, people with MS reported that the greatest challenge in getting DMTs comes from insurance companies.[ix] Through the years, people with MS and their healthcare providers have described egregious step therapy practices and prior authorization delays that have resulted in MS exacerbations, worsening health, and increased costs to the healthcare system. Examples of these practices include requiring three to five DMTs to fail a person with MS prior to accessing the individual's medication of choice, requiring someone to use a DMT they already know does not work for them, and requiring people with needle phobia to use self-injectable medications even though oral medications are available. Rather than "getting the right medication to the right person" as the industry describes, these practices result in nonadherence and dangerous delays to people getting on the

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[vi] H.P. Acthar Gel Prics, Coupons and Patient Assistance Programs. *https://www.drugs.com/price-guide/h-p-acthar-ge*l. (Accessed March 1, 2023).

[vii] 2019 AMA Prior Authorization (PA) Survey. American Medical Association. June 2020. *www.ama-assn.org/system/files/2020-06/prior-authorization-survey-2019.pdf*

[viii] Drug Pricing Investigation Teva-Copaxone. Staff Report Committee on Oversight and Reform. U.S. House of Representatives. September 2020. *https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Teva%20Staff%20Report%2009-30-2020.pdf* (Accessed May 3, 2020).

[ix] National MS Society. Quantifying the Effect of the High Cost of DMTs. Market Research Report. August 2019. *https://nms2cdn.azureedge.net/cmssite/nationalmssociety/media/msnationalfiles/advocacy/nmss-research-report-full-access-to-ms-medications.pdf.* (Accessed February 15, 2023).

DMTs that will work for them. With every delay, people with MS risk disease activity and underlying progression from which they may not recover.

Additionally, increasing vertical integration of PBMs and payors, rebating, and other business-related practices often result in formulary placement of medications that often steers individuals towards more expensive medications, while generics and biosimilars are available. For example, PBMs often place generic drugs and biosimilars in higher formulary tiers alongside brand medications, thus negating the cost savings to the health system and the patient. We have seen this practice in the MS space, as MS generics, due to higher cost than regular generic medications, are covered more like specialty medications, resulting in higher cost sharing for people with MS. Likewise, a PBM may prefer a higher cost drug because it will increase their revenue so, despite lower cost alternatives being available, a higher cost product receives favorable formulary placement. We believe that the choice of therapy for people with MS should be between the patient and their healthcare provider, and the profit margin of the PBM should not be relevant in the decision.

Policy Changes To Promote Transparency and Accountability are Needed

There is increased pressure on people with MS and other chronic health conditions to make good choices about the cost of their care and prescription drug medications, yet there is very little true transparency throughout the healthcare system, and people often have very little information about price and cost to guide these decisions. We believe that S.127, *the Pharmacy Benefit Manager Transparency Act* is a good first step to increase transparency to help people affected by MS understand why formularies are designed the way they are, prohibit unfair PBM business practices, incentivize those practices that are fair and promote transparency, protect patients, and have an enforcement mechanism that will bring about change.

The Society's full set of policy recommendations for PBM reform is outlined below. We realize that some of these recommendations fall outside this Committee's jurisdiction, but we urge you to pass S.127 out of Committee and work with your colleagues to advance PBM reform this Congress to ensure all patients have access to the life-changing therapies they need to live their best lives.

- Ensures transparency by requiring disclosure of specific costs, prices, reimbursements, fees, mark ups, discounts and aggregate payments received with respect to their PBM service.
- Prohibits unfair and deceptive pricing models including spread-pricing and arbitrary claw backs of payments.
- Requires pass-through pricing models.
- Requires oversight and reporting on PBM behavior and allows FTC to take legal action when a PBM is found in violation of the law.
- Allows for patients to have a choice of the pharmacy where they receive their medications.
- Allows patients to receive the benefits from rebated savings and pay the lesser amount of copay/co-insurance, the amount charged by the PBM to the pharmacy, or the cost of the drug.
- Includes a substantial monetary penalty for those PBMs who act in violation of the law.

Thank you again for holding this important hearing. If you have any questions about or comments or recommendations, please contact Leslie Ritter, AVP of Federal Government Relations at *Leslie.Ritter@nmss.org.*

Sincerely,

BARI TALENTE, ESQ.,
Executive Vice President,
Advocacy and Healthcare Access,
National Multiple Sclerosis Society.

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. MARIA CANTWELL TO DR. RYAN OFTEBRO

Question 1. I have heard from pharmacists who are afraid to speak out against PBMs for fear of retaliation. Are you concerned that by speaking out you may be opening yourself up to arbitrary and detrimental actions on the part of PBMs?

Answer. Yes, I am very concerned about retaliation from PBMs. Elimination from the network by even one of the three major PBMs would be catastrophic to our practice. Within days of my testimony to the Committee, we received notification of large

on-site audits from two major PBMs. While we periodically receive desk audits on single claims, it is highly unusual (and very burdensome) to receive two major on-site audits in the same week.

Question 2. During the hearing, you were asked to describe anticompetitive tactics used by PBMs. Do you have additional examples you can provide? How have those tactics affected your pharmacy business?

Answer. Yes, our pharmacy has experienced many additional examples of PBM anticompetitive tactics, such as:

No mailing clauses—many of the major PBMs have contract clauses that expressly forbid pharmacies from mailing to patients, even if the pharmacy chooses not to charge a mailing fee. PBMs will routinely conduct audits on claims by zip code. If a pharmacy fills a prescription for a patient that is outside an arbitrary radius determined by the PBM, the pharmacy must produce a patient signature indicating that the prescription was picked up in person. Failing to do so will result in the recoupment of payment for the prescription.

Withholding contracts—Major PBMs are now withholding contracts from new pharmacy locations. When we opened a new location last fall, inside a clinic serving chronically homeless and highly vulnerable populations, we were told that we must demonstrate that we have been in business for at least 6 months before we could apply for a contract. Another large PBM told us that the wait would be 12 months, however we could shorten the time-frame with a $2000 fee. We were simply adding a location to an existing business within their network, however they refused to accommodate us. When the three largest PBMs control 80 percent of the market, it is impossible to establish a sustainable business without access to these contracts for any period of time.

Anti-competitive rates—Our pharmacies are seeing contract rates from major PBMs that are well below our cost to purchase, despite the fact that we are able to purchase drugs through our buying group at extremely competitive rates. The PBM reimbursement rates reflect prices that are not available anywhere in the legitimate market, without even accounting for retroactive fees.

Take it or leave it contracts—We have made numerous attempts to negotiate rates and other undesirable terms with PBMs and the answer is consistently no. We recently opened a new location and requested to contract with one of the large PBMs. They provided reimbursement rates that were well below any pharmacy's net acquisition costs. We respectfully requested a contract of NADAC (National Drug Acquisition Cost) and they refused. They said if we changed our minds we could sign the original contract they provided. On the single occasion a PBM has responded to our request to renegotiate rates, we were given a fraction of a percentage increase for one year, which had negligible impact on the overall rate, which was still well below our cost to purchase.

Underpay, then offer to buy pharmacy—We frequently receive solicitations from vertically integrated pharmacy chains to purchase our pharmacy. In their letters, they cite the economic pressures of PBM reimbursements, including DIR fees which come from the very same vertically integrated entity, as reasons to sell.

Deceptive communications to patients/pharmacies/physicians—We frequently hear from patients that they receive calls and letters from their PBM indicating that we are not in network and they need to transfer to the PBM owned pharmacy, when we in fact are in network. This often now happens as a text that is received by the patient immediately after filling a prescription, attempting to steer them to their own pharmacy for their next fill, including deceptive language and a link to click to initiate the transfer. We also receive transfer requests from PBM owned pharmacies that patients report never having initiated. Doctor's offices have also shared with us that they consistently receive prescription requests from vertically integrated pharmacies (not used by the patient) attempting to steer fills from our pharmacy and others. It seems that the only way the vertically integrated pharmacy would have this data would be from the vertically integrated PBM.

Specialty steering—Our pharmacy treats a large population of people living with HIV. We had a major PBM communicate to us that they were moving all medications to treat HIV to specialty, and that we would be removed from the network for these medications unless we became specialty accredited, which involved leaving our PSAO (the entity that assists pharmacies with contracting) and sign a direct contract with the PBM, pay the PBM thousands of dollars in fees and achieve third party accreditation. We were required to do all of this BEFORE they would let us see a specialty contract. Upon completing the re-

quirements, we were given a much lower reimbursing contract, with rates well below our cost to purchase HIV medications. The same PBM has continued to arbitrarily move HIV medications on and off their specialty list for their own economic advantage. Additionally, this specialty requirement was not applied to other network pharmacies in our area, only ours. We believe we were targeted in an attempt to steer these patients to the PBMs own pharmacy.

Question 3. As an owner of an independent pharmacy, have you ever bid on a contract to provide pharmacy services to a health plan? Do you know whether your contract bid faced competition from a pharmacy owned by a PBM? Would those situations raise any anticompetitive concerns? If so, please describe those concerns.

Answer. Yes. For many years we had a direct contract to provide pharmacy services to a large Labor Union in Washington state. The trustees for the Union and their benefits consultant put the contract for the PBM services as well as for the pharmacy services out to bid. The incumbent PBM had all of our data and was able to utilize that data to win the contract for both the PBM and the pharmacy services (PBM owned pharmacy).

Question 4. In his written testimony, Dr. Mulligan referred to a research paper he prepared, "The Value of Pharmacy Benefit Management," (July 2022). In that paper, Dr. Mulligan stated that mail pharmacies, many of which are sponsored by PBMs, "can reduce patient costs and increase patient convenience, both of which encourage utilization[;]" and "increase medication adherence." Assuming that mail pharmacies can increase patient convenience and medication adherence, does your pharmacy provide medications by mail? If not, why?

Answer. We have been contractually prohibited from mailing to patients by several major PBMs. Where this practice is not prohibited, we happily offer mailing. Many patients prefer to have our pharmacy mail their prescriptions over their mail order benefit, as they report much higher customer service levels, and they report receiving medications much faster when mailed from a local pharmacy than the PBM owned pharmacies that are typically out of state.

Question 5. You described in your testimony how a PBM moving a generic cholesterol medication from the lowest copay tier to the second-highest tier increased patients' copay to almost ten times what they paid before. Did the PBM offer an explanation for why it changed this drug's copay tier? Do these price hikes for consumers cause consumers to take medications less than they need to, or stop taking them altogether, because they've become too expensive?

Answer. The PBM in this example offered no explanation to the pharmacy, and as far as we know, offered no explanation to patients why they were suddenly being required to pay nearly 10 times the cost of the medication. Feedback from patients indicated that this was clearly an economic burden that was requiring them to make difficult decisions. These were Medicare part D beneficiaries, many of them on fixed incomes. These patients would be inappropriately incentivized to ration medications, resulting in sub-therapeutic doses, or having to choose between paying for their medications and their other bills, groceries, etc.

We also frequently see PBMs require a brand medication to be filled when a cheaper generic is available. The PBMs rationale for this practice has to do with rebates they extract from the brand manufacturer, which they argue makes the brand medication more cost effective for the plan. Unfortunately, many patients do not receive this benefit, as they are frequently still required to pay a higher brand co-pay instead of the less expensive generic co-pay.

Response to Written Question Submitted by Hon. Maria Cantwell to Dr. Debra Patt

Question. In your opinion, do PBMs tend to prioritize cost savings over the judgement and experience of medical professionals? Can you provide any additional examples of the impact PBM cost-cutting measures have had on your patients and their care?

Answer. (No responses from witness).

Response to Written Questions Submitted by Hon. Shelley Moore Capito to Dr. Debra Patt

Bringing transparency to the practices of pharmacy benefit managers and copay accumulator programs is something that patients have long been calling for. My state was one the first to prohibit copay accumulator programs and is one of the unfortunately low number of states to do so. By banning copay accumulators, we

ensure that patients aren't blindsided when picking up their prescriptions, and the results have been beneficial for West Virginians.

Question 1. Dr. Patt, can you explain the involvement of PBMs in "accumulator adjustment" and why states like mine are banning the practice?

Answer. (Did not receive a response).

Question 2. Dr. Patt, why hasn't the Federal Government pursued a copay accumulator ban in line with what states are already doing?

Answer. (Did not receive a response).

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. MARIA CANTWELL TO DR. ERIN TRISH

Question 1. There seems to be a problem with the incentives that motivate PBMs' decision-making. As an example, PBMs may contract with insurance companies to keep a percentage of the rebates, which are based on list prices. Does this create an incentive for manufacturers to maintain high list prices or inflate list prices for drugs if they want to be approved by PBMs?

Answer. If PBMs and other supply chain intermediaries are paid as a share of the list price of a drug (or a share of the negotiated rebate), that produces an incentive for those intermediaries to prefer drugs with higher list prices and larger rebates over low-list-price, low-rebate drugs. For example, take the case of authorized generics, which are exact copies of brand name drugs that are marketed without the brand name on their label. In several instances in recent years, manufacturers have introduced authorized generics at significantly reduced list prices, even years before expected generic competition. For example, this strategy has been used for hepatitis C treatments (Harvoni and Epclusa) in 2018 and insulin (Humalog and Novolog) in 2019 and 2020, respectively. However, one study found that only 3–4 percent of Medicare Part D beneficiaries were enrolled in plans that covered only these authorized generics, despite their having 50 percent+ lower list prices, even though covering them would have resulted in lower out-of-pocket spending for beneficiaries. This type of evidence demonstrates the incentives for high-list-price, high-rebate drugs in practice.

Question 2. Do you believe greater transparency in pricing would do more than just protect consumers—that it would also spur increased innovation in drug research and development? Does the current structure of the market incent PBMs to focus on profits over innovation? How might incentives be structured to improve transparency and ensure a level of competition that leads to cost savings and innovation?

Answer. Schaeffer Center research indicates that, in 2015, for every $100 spent on prescription drugs at retail pharmacies, $41 went to intermediaries in the distribution system, including PBMs. More recent Schaeffer Center research has shown that the portion of insulin spending retained by intermediaries increased from 30 percent of spending in 2014 to 53 percent of spending in 2018. Consequently, a smaller share of expenditures is accruing to manufacturers over time, with likely effects on innovation and investments in research and development. Policy that instead rewards manufacturers for demonstrated real-world value of their products, rather than contracting incentives, could better promote innovation and value.

Question 3. Does the practice of claw backs help us understand who has market power in the prescription drug market?

Answer. Pharmacy price concessions—or clawbacks—in Medicare Part D increased over 1000 percent from 2010 to 2020, totaling $9.5B in 2020, or nearly 5 percent of total Part D spending. Additional research is needed to determine the extent to which this trend reflects market power of PBMs vs. pharmacies, but the growth is nonetheless striking.

Question 4. In your opinion, how difficult would it be for PBMs to comply with the transparency requirements of this legislation?

Answer. I cannot speak to the specific difficulty of compliance with the transparency requirements of S. 127. However, given my understanding of the industry, it seems reasonable that PBMs should be able to produce the parameters subject to transparency requirements—such as the spread or difference between the amount paid to the pharmacy and the amount charged to the health plan for a given drug. PBMs surely collect these measures already, to be used internally for business purposes; any additional effort to comply would therefore not involve new data collection or calculation, but only new reporting of those measures to outside parties. Moreover, it is my understanding that some of the transparency requirements—such as the aggregate total amount of reimbursements the PBM clawed back from phar-

macies—are similar to existing metrics that are required to be reported in certain business lines, such as pharmacy "DIR" fees in Medicare Part D.

Question 5. When a consumer sees the out-of-pocket price of their prescription skyrocket, are they able to get a full explanation from their doctor, insurer, or pharmacist? Does any market actor have visibility and control over the complete drug pricing process?

Answer. I am not in a position to be able to answer this definitively in all instances, but my understanding is that it is generally not possible for any one player in the prescription drug market to have complete visibility and control over the drug pricing process. Indeed, even PBMs, which sit at the nexus of negotiations between manufacturers, health plans/employers, and pharmacies do not have complete insight into this because, for example, they generally do not know the pharmacy's drug acquisition costs.

Question 6. It has been asserted that PBMs provide value to insurance plans because the pharmacy market is highly concentrated with just three major pharmacies controlling 60 percent of the market, and PBMs provide the power of a "buyer's club" to help insurance companies overcome this imbalance and get the lowest possible prices so they can keep their rates low for consumers. Yet, the top three PBMs control 80 percent of the PBM market. Does this line of reasoning indicate that insurance companies would be better off negotiating with pharmacies than they would be negotiating with PBMs, since PBMs appear to have even more market power than the pharmacies do? Is it possible that many insurance companies have no choice but to work with PBMs, since PBMs dominate the market that insurance companies do business in?

Answer. The notion of PBMs benefitting consumers via the "buyer's club" model is inconsistent with empirical evidence. Take Costco as an example. Schaeffer Center research demonstrates that—when compared with the "buyer's club" prices available at Costco pharmacies for common generic drugs—Medicare Part D plans overpaid on 43 percent of prescriptions in 2018, totaling $2.6 billion in overspending in that year alone. That is, this evidence suggests that the inefficiencies introduced by the typical PBM and insurance market model do not deliver savings to consumers on par with the buyer's club market, at least for common generic drugs.

Additionally, each of the large PBMs operate a specialty pharmacy, while some PBMs are also affiliated with retail pharmacy chains (*e.g.,* CVS). So, even if plans were to negotiate with pharmacies directly, market power in the PBM market could still be extended to the pharmacy market via this vertical integration.

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. TED CRUZ TO DR. ERIN TRISH

Medicare Part D Rebate Rule

Dr. Trish, in 2019, the Department of Health and Human Services proposed a rule to eliminate an existing safe harbor within Medicare Part D and Medicaid that allowed PBMs to negotiate rebates paid by drug manufacturers to health plans and PBMs. CBO and the CMS's Office of the Actuary estimated that eliminating this rebate negotiating ability alone would increase Federal spending by about $170 billion over 10 years and result in an estimated 25 percent increase in Medicare premiums.

Question 1. Do you agree with these economic findings? And does any of the economic modeling used by CBO and CMS apply to an economic analysis of the PBM Transparency Act (S. 127)? Why or why not?

Answer. The 2019 proposed rule would have removed the safe harbor exemption for rebates applied after the point-of-sale and established a new safe harbor that would enable pharmaceutical manufacturers to offer reduced prices when they are applied at the point-of-sale. In effect, this would allow beneficiary cost-sharing to be calculated using manufacturer net, rather than list, prices.

The projected increase in Federal spending referenced above therefore reflects two primary factors. The first is that the rule change would have lowered aggregate beneficiary out-of-pocket spending, because beneficiary cost-sharing under the standard benefit design in Medicare Part D is effectively tied to the list price of drugs. As rebates have grown in Part D—from 11.7 percent of spending in 2013 to 27.0 percent of spending in 2020—list prices are increasingly inflated relative to the manufacturer's net price of drugs. This dynamic has caused the Part D benefit to become less generous as a share of net drug costs, as patients pay more out of pocket. The 2019 proposed rule would have restored the generosity of the Part D benefit by tying cost-sharing to net rather than list prices. This, in turn, would have increased

Federal spending by increasing Part D subsidies because these subsidies are set by statute as a percentage of program spending. Thus, the change would have increased plan generosity and reduced beneficiary out-of-pocket spending, increasing program costs and therefore subsidies.

The second is driven by assumptions about how manufacturers and other actors would respond to such a policy change in terms of the magnitude of rebates. The CBO and CMS OACT estimates described above reflect an assumption that manufacturer rebates would be reduced by 15 percent in Medicare Part D. I am not privy to how CBO and CMS OACT arrived at those assumptions, but alternative assumptions—such as those modeled in an analysis conducted by Milliman prepared for the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services—projected potential *federal savings* from the rule. In the Federal Register, DHHS noted that they engaged multiple analyses from OACT and actuarial firms precisely because "it is difficult to predict manufacturer and Part D plan behavior in response to this regulation."

My understanding of the PBM Transparency Act (S. 127) is that it would essentially create two compliance options (in addition to the transparency and other requirements). Pharmacy benefit mangers (PBMs) would be prohibited from engaging in spread pricing or arbitrarily, unfairly, or deceptively imposing clawbacks; *or,* they could continue with these practices if they pass all rebates to health plans or payers and comply with additional disclosure requirements.

First, CBO would likely need to make assumptions regarding how the market would distribute across these two compliance options. Second, the provisions here are different than the so-called rebate rule for a number of reasons, including the markets to which they would apply. While the modeling of the rebate rule may inform CBO's estimates, I expect other CBO analyses may also be equally if not more relevant. For example, in 2019, CBO scored the Lower Health Care Costs Act. Section 306 would have required PBMs operating in commercial health care markets to (in short) provide information on costs, aggregate rebates, and fees; fully pass rebates, fees, discounts, or other remuneration to plan sponsors; and prohibit spread pricing. CBO estimated these provisions would reduce average premiums in the private insurance market and decrease the deficit by $1.7 billion over the 2019–2029 period.

PBM Transparency Act Effect on Consumers

During the hearing, Dr. Mulligan testified that the requirements in the PBM Transparency Act (S. 127) could increase consumer health premiums in the aggregate by about $10 billion.

Question 1. Do you agree or disagree with Dr. Mulligan? Why or Why not?

Answer. I have not seen an estimate of nor independently estimated the impact of the complete provisions of the PBM Transparency Act (S. 127) on consumer health insurance premiums, so I cannot directly answer this question. However, as noted above, in 2019 CBO estimated that the provisions of Section 306 in the Lower Health Care Costs Act would have reduced average premiums in the private insurance market (by about 0.2 percent in the first full year of implementation, and by 0.02 percent by 2029). There are differences in the provisions of these two bills—including the markets to which they would apply—so this should not necessarily be construed as a direct estimate of the likely effects of S. 127 on premiums, but is informative nonetheless.

Question 2. Relatedly, Dr. Mulligan also testified that the requirements in S. 127, including the disclosure requirements, could increase PBM consolidation with greater benefit to larger, vertically integrated PBMs with higher barriers to entry for potential competitors and smaller PBMs potentially being forced to close their doors. Do you agree or disagree with Dr. Mulligan? Why or Why not?

Answer. In general, it is likely that larger organizations, including PBMs, could more readily shoulder increased costs of compliance than smaller competitors. On the other hand, to the extent that vertical integration is benefitting firms more than consumers, it is possible that disclosure requirements could shed light on these practices, in turn benefitting smaller competitors. For example, transparency requirements such as those requiring that PBMs that control or are affiliated with a pharmacy to provide a description of differences between what they reimburse or charge affiliated or nonaffiliated pharmacies would, by definition, not be imposed on smaller PBMs that are not affiliated with a pharmacy, but would provide insight into whether such vertical integration may raise competitive concerns.

PBM Transparency Act Disclosure Requirements

Dr. Trish, in your testimony you noted that prescription drug markets are complicated and a mystery for Americans and, "where there is mystery, there is mar-

gin." Transparency can be an important tool to drive competition, but certain transparency requirements could also, as the FTC and DOJ have previously warned, cause unintended consequences.

Question 1. Do you agree with Dr. Mulligan's assessment that the disclosure requirements in S. 127 require the disclosure of proprietary information? If not, why not?

Answer. I can't provide a specific interpretation of whether the provisions of S. 127 would require the disclosure of proprietary information. However, I think the warning of Harvard Professors Anna Sinaiko and Meredith Rosenthal in the New England Journal of Medicine is relevant: "How long are payers and policymakers willing to wait to see whether market-based transparency initiatives will work before moving to other, potentially more onerous, polices, such as increased regulation?"

Question 2. Would collusion in the prescription drug market become more likely when disclosing proprietary information in highly concentrated markets like health care?

Answer. I do not believe so. Recent policy efforts have marked a shift toward increased price disclosure in health care markets, such as increased hospital price transparency and insurer price transparency, both of which require disclosure of prices net of negotiated discounts off of charges or list prices.

It is also worth noting that one of the often-cited empirical examples related to these concerns about disclosure leading to potential price increases is a study of the early 1990s Danish ready-mix concrete industry. As Prof. Per B. Overgaard—one of the study's authors—noted: "I'm sure there are some similarities between pricing of various health care services and ready-made concrete in Denmark in the early 1990s, but I'm also sure there might be huge differences."

Question 3. What would the likely effect of the transparency/disclosure requirements in S. 127 have on the profits of other actors in the prescription drug supply chain, including drug manufacturers, wholesalers, retailers, PSAOs, and pharmacies?

Answer. I can't speak to the specific provisions of S. 127, but in general it is very difficult for buyers to make efficient purchasing decisions when they do not know the prices they are facing. To the extent that transparency or disclosure requirements provide buyers with a clearer picture of the prices they are facing, they can make better buying decisions.

Question 4. Could the specific disclosure requirements in S. 127 hinder competition in the industry in other ways, such as putting smaller PBMs at a competitive disadvantage?

Answer. As described above, it is possible that disclosure policies could differentially affect smaller versus larger and more vertically-integrated competitors, but that could go in either direction.

It is also worth noting an example of the ways that increased transparency in this market can benefit consumers. Information on PBM reimbursement to pharmacies is generally unavailable to researchers, but a short-lived 2013 Federal survey called National Average Retail Price (NARP) provided six months of visibility into these average pharmacy reimbursements. Schaeffer Center research used that survey to compare these average pharmacy reimbursements with patient copayments, finding that 23 percent of the prescriptions in a large sample of commercial claims involved a patient copayment that exceeded the cost to the PBM, or a so-called copay "clawback." This evidence contradicted testimony from a PBM representative that PBMs did not support the practice of collecting patients' copay in excess of the cash price of the drug and that, if such practice happened, they were "outliers." Without the transparency provided by the NARP data, such a study would not have been possible.

FTC PBM Investigation

In your testimony, you note that further investigation is warranted to better understand the myriad ways the current system harms consumers and reduces innovation—especially innovation that will lower costs for everyone. The FTC is currently studying PBM competition and the impacts on consumers.

Question 1. Might that data from the FTC be beneficial in crafting legislative solutions to lowering drug prices?

Answer. Yes. It is also possible that additional investigation—such as through additional FTC, GAO, Congressional, academic, or other studies—could be useful in crafting future legislative solutions to improve value in prescription drug markets. I believe the value of such studies would be greater if they could be based on information and data that are not currently publicly available.

Rebate Influence on Drug List Prices

In your testimony, you argue that rebates drive a wedge between a drug's list price and its net price and that increasing rebates are one of the key drivers of increasing list prices over time with an estimate from the Schaeffer Center that for $1 increase in estimated rebates, list prices increased $1.17 between 2015 and 2018.

Question 1. Why do you believe the rebate is the cause of the increased list price instead of the increased list price driving the PBMs to negotiate a larger rebate? Could it be a combination of both? Why or why not?

Answer. It is possible, but if the need for greater rebates is induced by high list prices (rather than the other way around), why would PBMs use formularies that exclude low-list-price, low-rebate drugs in favor of identical drugs with higher list prices and rebates? For example, take the case of authorized generics, which are exact copies of brand name drugs that are marketed without the brand name on their label. In several instances in recent years, manufacturers have introduced authorized generics at significantly reduced list prices, even years before expected generic competition. For example, this strategy has been used for hepatitis C treatments (Harvoni and Epclusa) in 2018 and insulin (Humalog and Novolog) in 2019 and 2020, respectively. However, one study found that only 3–4 percent of Medicare Part D beneficiaries were enrolled in plans that covered only these authorized generics, despite their having 50 percent+ lower list prices, even though covering them would have resulted in lower out-of-pocket spending for beneficiaries. This type of evidence demonstrates the incentives for high-list-price, high-rebate drugs in practice.

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. TED CRUZ TO DR. CASEY B. MULLIGAN

Rebate Influence on Drug List Prices

In her testimony, Dr. Trish argues that rebates drive a wedge between a drug's list price and its net price and that increasing rebates are one of the key drivers of increasing list prices over time with an estimate from the Schaeffer Center that for $1 increase in estimated rebates, list prices increased $1.17 between 2015 and 2018.

Question 1. Do you agree with Dr. Trish's argument? Why or Why not?

Answer. Government-mandated rebates have a significant list-price increasing effect, but Dr. Trish's testimony about the $1.17 is incorrect and misleading if it is to be understood as a reference to rebates negotiated by plans or by PBMs on plans' behalf.

Government-mandated rebates, such as the Medicaid Drug Rebate Program, specify that the government (or plans on their behalf) purchase prescription drugs from manufacturers at a percentage of the list price in the commercial market. Such programs present manufacturers with the opportunity to get more government funds merely by increasing their list prices because the net price they receive from Medicaid is proportional to the list price by statute. The resulting list price increases could be much more than the amount of the rebate. Duggan and Scott-Morton (2006) found, in fact, very large list-price effects of mandated rebates.

Negotiated rebates, by contrast, are an outcome of market competition and help magnify it. As such they reduce net prices, which is the difference between list price and the rebate, and the marginal prices that are an important disincentive for utilization. This pricing pattern is obvious as unique drugs begin to see new competitors enter, inducing the incumbent manufactures to begin paying significant rebates and receive lower net prices. Although not apparent from Dr. Trish's testimony, other Schaeffer Center studies have documented this competition-pricing pattern (Lakdawalla and Li, Association of Drug Rebates and Competition With Out-of-Pocket Coinsurance in Medicare Part D, 2014 to 2018 2021).

In contrast to a scheme in which new entry merely reduced incumbent list prices with no rebate, the rebates are part of a pro-competitive partnership between manufacturers and plans to encourage utilization. Competition on rebates also saves consumers money, and cuts into manufacturer profits, relative to competition on list prices alone. As explained in my testimony, this is why volume discounts are not unique to the drug industry. Although not apparent from Dr. Trish's testimony, other Schaeffer Center studies have also documented the pro-competitive role of insurer negotiations with drug manufacturers in sharply reducing net and marginal prices and encouraging utilization (Lakdawalla and Philipson 2012, Lakdawalla and Sood 2013).

The Office of the Actuary of the Centers for Medicare and Medicaid Services concluded that negotiated rebates reduce net prices (84 FR 2356). The paragraph in Dr. Trish's testimony does not specifically cite PBMs or negotiated rebates, but rather uses the more general term "rebates." The paragraph's position between others that do cite PBMs and/or negotiated rebates may give the false impression that the $1.17 finding is a study of rebates negotiated by PBMs. In fact, the Schaeffer study, which acknowledges the substantial "measurement error" inherent in its attempt to infer rebates from company financial reports, pools many different types of rebates, including the government-mandated rebates with economics known to be opposite of negotiated rebates.

Lacking the data necessary to eliminate all transactions that involve government-mandated rebates, the study authors are only able to eliminate some of them. The results of doing so are informative: the headline 1.17 estimate shown in their Table 2 falls 25 percent. In the analogous Table A4, merely eliminating some of the mandated transactions reduces the point estimate to 0.64 and the confidence interval down to 0.44. We can guess that eliminating all of the mandated transactions would reduce the estimates still further. Even without that, the study's estimate of 0.64 is well within the range of 0.51–0.81 that I find in my analysis of rebates and net prices in insulin markets that was part of Table 1 of my submission of *Restrict the Middleman? Quantitative Models of PBM Regulations and their Consequences* into the record.

If Dr. Trish's testimony about 1.17-to-1 were to be understood as a statement about negotiated rebates, it would seem that manufacturers would want the rebates because they purportedly increase net prices too. Instead, manufacturers have vigorously lobbied government to limit or even ban negotiated rebates (see footnote 2 of my testimony and the references therein), which is exactly what we expect when negotiated rebates have the effect of magnifying competition among manufacturers. Manufacturers—including but not limited to Abbott Labs, AbbVie, Amgen, Bristol-Meyers Squibb, Gilead, and Pfizer—have also generously funded the Schaeffer Center, as is acknowledged in their latest annual report.

While negotiated rebates clearly reduce net prices, in some instances they reduce list prices too. As explained in *Restrict the Middleman?,* there is a tendency for rebates to reduce list prices because the rebates are tied to sales targets for the manufacturer paying the rebate. The additional sales frustrate competing manufacturers, forcing them to pay lower net prices too and sometimes also limiting their ability to raise list price. In other instances, especially with a convex demand curve, negotiated rebates may increase list prices even while they reduce net prices.

Dr. Trish and the authors of the Schaeffer Center study also confuse correlation with causation. They estimate that list prices and rebates change in the same direction, but then discuss the results as if the rebates caused the list price changes (ergo, eliminating rebates would change the list prices back to where they were). They have not considered, among other things, that list-price increases caused the rebate increases. That is, list-price increases initiated by manufacturers induce plans and PBMs to obtain greater rebates as market pressures discourage them from agreeing to much addition to the net price.

For example, as of the beginning of their sample period, Medicaid enrollment had just surged. Duggan and Scott-Morton's (2006) findings suggest that significant list-price increases would follow. The same model that I used to estimate the effects of S. 127 predicts that the result of such list-price increases would be negotiated rebates that increase almost one-for-one. That is, a near one-for-one effect of list prices on negotiated rebates is perfectly consistent with a much smaller—even negative—effect of rebates on list prices. The study authors are mistaken to assert that their "finding that increased rebates are positively associated with increased list prices supports the notion that PBMs' demand for rebates is at least partly responsible for increased list prices."

Question 2. How does this data comport with your findings that S. 127 could increase consumer drug prices?

Answer. The economics of S. 127 is only indirectly related to any commentary on negotiated manufacturer rebates, including Dr. Trish's, because the economically important provisions in S. 127 are:

- restrictions on pharmacy-company discounts (Sec. 2(a)),
- PBM disclosure requirements (Secs. 2(b), 4), and
- expanding the authority of the Federal Trade Commission (Sec. 6).

As explained in my testimony, the first two provisions would undermine competition in the drug-supply chain. The third provision affects pharmaceutical economics through the interpretation and enforcement of the first two.

Sec 2(b)(1) of S. 127 does prohibit PBMs from retaining any price concessions. This provision does not prohibit rebates, although it would interfere to some degree with the capability and incentives of plans and PBMs to manage the drug benefit including the negotiation of volume discounts. Sec. 2(b)(1) may not apply to PBMs depending on how they choose to comply with the other sections of S. 127.

S. 127 is even further from the issue of government-mandated rebates, which are driving the $1.17 estimate that Dr. Trish highlighted in her testimony. The economic model I use to estimate the effects of S. 127—exposited in *Restrict the Middleman?*—has not yet been used to analyze government-mandated rebates.

A rigorous and coherent economic framework for PBM regulatory impact analysis, which neither Dr. Trish nor the Schaeffer Center have offered, would link negotiated manufacturer rebates to pharmacy discounts and disclosure requirements. As such, Dr. Trish's $1.17 headline could be an indirect test of such a framework, at least if the $1.17 were purged of the effect of government-mandated rebates. The Schaeffer Center study steps part way in this direction in its Table A4, cutting the point estimate in about half to 0.64. 0.64 is well within the range of 0.51–0.81 that I find in my analysis of rebates and net prices in insulin markets that was part of Table 1 of *Restrict the Middleman?*.

Overall, Dr. Trish's testimony gives the false impression that my findings are inconsistent with the statistics cited in her testimony, including but not limited to the $1.17. To the contrary, all those statistics support the quantitative economic model I use to analysze regulation of rebates, pharmacy DIR, disclosure requirements, and other aspects of PBM transactions. Indeed, the findings of some of the Schaeffer Center studies are integral to my approach, both qualitatively and quantitatively.

To the extent that Dr. Trish reaches different conclusions than I do, the discrepancy derives from her unjustified and improper departure from the economic profession's standard approach to "tax incidence," which refers to the distribution of the burden of a tax or regulation among the various market participants. Her unexplained departure is a ubiquitous theme in most of the questions and responses from the Ranking Member and other members (see below).

According to economics, it is not enough to look merely at the legal obligations created by the regulation. Imposing a regulation on sellers, for example, may primarily harm buyers. Economics reaches conclusions about incidence by considering the alternative actions available to each participant that might allow them to mitigate their cost of compliance. Those alternative actions affect other market participants. In the case of a regulated seller, it may be able to raise the price or reduce the quality of the product and thereby largely maintain its profits. Meanwhile, the buyers are stuck with a higher price or lower quality. In this example, the buyers bear most of the burden of a regulation even though it imposes no legal obligation on them. Buyers are harmed because they are *situated in the same market as* someone who has a legal obligation created by the regulation while the buyers have comparatively few alternatives to mitigate the harm.

A general principle in tax incidence is that the parties with less valuable alternatives bear most of the burden of costs imposed on the market. In the case of drug-supply-chain regulation, compliance obligations are created with no new money necessarily being injected into the system. The regulatory costs will tend to disproportionately fall on those with less valuable alternatives, which tends to be the patients and plan members. Indeed, S. 127 would impede one of the only alternatives—benefit management—that patients and plans have to mitigate the costs of manufacturers' and pharmacy-companies' market power.

The point is that Dr. Trish promulgates incidence conclusions—about who purportedly "profits" and who is "harmed"—without going through the calculus of alternatives. What alternatives would PBMs, pharmacy companies, plans, patients, and manufactures have without, say, pharmacy price concessions? How would each of them be affected by the fact that the other market participants are pursuing their next-best alternatives? Until these are considered—typically with a model of how the market as a whole works—there is no valid economic basis for any of her incidence conclusions.

Question 3. In the Medicare Part D context, Dr. Trish also noted that PBMs deflect blame for their rebate practices by pointing out they pass them to health plans who may lower premiums but increase out-of-pocket costs on consumers. Do you agree with Dr. Trish's argument? Why or why not?

Answer. Dr. Trish's paragraph about rebate "blame" makes two distinct claims. One is that the "ultimate result" of negotiated rebates is to increase out-of-pocket costs. Because the ultimate result plays out in the marketplace, and Dr. Trish has not offered any market-level analysis, she has no valid basis for that incorrect claim. The second claim, also incorrect and hardly relevant to the economics of rebates, is

that any plan acknowledging a tradeoff between premiums and cost sharing is doing "the opposite of what insurance is supposed to do."

Negotiated rebate transactions are volume discounts. Plans and PBMs get the full rebate—and the lowest possible net price—only if utilization targets are attained. The low net price by itself reduces plan expenses, which is savings that it can split between reducing premiums and reducing cost sharing for plan members. Even if all of the savings went to premiums, that still would reduce cost sharing generally because the low premiums help attract and retain members who would otherwise not have drug insurance or would have less generous coverage.

Because they are backed by financial incentives, the utilization targets by themselves reduce cost sharing to the extent that low cost sharing is a tool the plan can use to encourage utilization. Cost sharing is typically used this way, even in Medicare Part D where cost sharing is regulated. Especially, plans' part of the rebate bargain is often to put the drug in a lower cost tier or to at least include the drug in its formulary, which prevents plan members from having to pay the full list price. These are actions that significantly reduce cost sharing, yet are not mentioned in Dr. Trish's testimony or in Schaeffer Center studies of rebates.

Even if rebate transactions on a particular drug increased patient cost sharing for that drug, it likely reduces patient cost sharing for other drugs or, in an integrated plan, for non-drug medical claims. One reason is that many plans, each of which is covering many pharmaceutical products if not other medical services, are subject to actuarial-value regulations. A silver ACA plan, for example, is supposed to finance no more than 20 percent of benefits through patient cost sharing. If a plan's transaction with a particular provider resulted in greater cost sharing for a particular type of claim originating with that provider, then the plan would likely reduce cost sharing on other types of claims or from other providers in order to comply with the 20 percent requirement.

A fundamental weakness in Dr. Trish's discussion of rebates is that it fails to mention that rebates are part of a larger incentive contract, let alone situated in a multiproduct sale (drug insurance) and situated in a larger market context.

Regarding Dr. Trish's second claim, insurance involves a tradeoff between risk sharing and moral hazard, which refers to possible discrepancies between the patient's financial stake and influence on claim outcomes, as well as the challenge of attracting and retaining voluntary consumers. From an economic point of view, a plan designer is "supposed to" understand that generous cost sharing provisions go together with higher premiums. There is real value from having the patient be a financial partner through cost sharing. Dr. Trish is incorrect that insurance plans are supposed to minimize cost sharing without regard for the other costs of doing so. In the real world, plans do regard those other costs; see, *e.g.,* Einav, Finkelstein, and Polyakova (2018).

PBM Business Practices and "Market Distortions"

Dr. Trish also outlined what she called "market distortions" in the form of copay "clawbacks," direct and indirect remuneration, and use of spreading pricing which negatively impacts pharmacies, including "$9.5 billion price concessions," which increase PBM profits and avoiding scrutiny.

Question 1. Do you agree with Dr. Trish that these practices are "market distortions" that should be addressed? Why or why not?

Answer. No, they are more accurately described as pro-competitive practices that reduce the costs of the fundamental market distortions in pharmaceutical markets, namely market power of pharmacy companies and, especially, of drug manufacturers. (Their market power itself relates to other fundamental economic factors, such as the high cost of drug development and the difficulty of securing intellectual property rights). To label pro-competitive responses as "market distortions" without connecting them to the root cause is to, metaphorically, confuse the treatment with the disease itself. It is also unclear what is the basis for Dr. Trish's labeling any practice as a "market distortion" when she has offered no economic model of how the market as a whole works.

Putting the labels aside, pharmacy price concessions are voluntarily given by pharmacy companies. The pharmacy company giving the concession gets something in return, such as preferred placement in the plan network and, ultimately, more traffic in its retail stores than would occur without making the concessions. As retailers are well aware, traffic in the stores can be particularly valuable when it drives sales of other products and services.

While a pharmacy company benefits from its own voluntary price concessions, it is harmed (lower profits) by its competitors' price concessions. The net result of these two effects is less profits for pharmacy companies overall and a greater vol-

ume of retail pharmacy services. This is a classic example of how market competition benefits consumers while it increases the economic pie.

Using regulation to curtail pharmacy price concessions would be anti-competitive. It would redistribute from consumers to pharmacy companies, while reducing the volume of retail pharmacy services. I estimate for each $1 that such regulation would increase pharmacy profits, costs of more than $6 would be imposed on patients, plans, manufacturers, and ultimately taxpayers (page 6 of my testimony). Whether giving up $6 to deliver $1 to pharmacy companies is a worthy policy goal is partly a value judgment for elected officials to decide.

Just as no disease treatment is free, benefit management-activities that alleviate the costs of the market's fundamental distortions have costs themselves. It takes personnel, capital, and information-infrastructure to manage benefits or to run just about any other type of buyers' club. On average, these costs are far less than the benefits to patients and plans and to the entire economy. At the same time, management costs—both those incurred by PBMs and the benefit-management restrictions experienced by patients—are likely high at the margin, because this is what limits the scope of a PBM or any buyers' club. These are all reasons why my quantitative economic model of benefit management not only acknowledges various market frictions and imperfections including market power, coordination costs, tax distortions, and incomplete innovation incentives but makes them central to the analysis.

Estimating or even signing the effect of pharmacy contracts on PBM profits requires a market-level analysis, which Dr. Trish has not offered. I conclude that PBM profits especially depend on entry barriers into the business of benefit management, which S. 127 would increase. That is, S. 127 would make benefit management more expensive for patients and plans, and potentially increase the profits of the largest PBMs, because regulation generally places a disproportionate burden on the smaller of the regulated businesses and S. 127 particularly puts more burden on the PBMs that are not vertically integrated with plans and pharmacies.

PBM Transparency Act Disclosure Requirements

You made it clear in your testimony of the unintended consequences associated with the disclosure requirements in S. 127. Transparency requirements are often good for consumers.

Question 1. What transparency requirements could Congress consider in this context to avoid the consequences you outline but also fuel greater competition in the prescription drug market?

Answer. The U.S. Department of Justice and the Federal Trade Commission (1996) have concluded that disclosure requirements in healthcare are more beneficial, or less harmful, when the data are more aggregated and delayed in order to avoid disclosing proprietary information. In addition, Congress should consider what is happening with real-world PBMs for whom "transparency" is their business model. Does their lack of success suggest significant costs of that approach that are not commensurate with the expected benefits?

Ultimately competition comes from real-world competitors, or at least from sellers who fear that high prices will increase the number competing. A transparent monopolist is still a monopolist. In this vein, Congress could consider the effect of disclosure requirements on entry and exit by drug manufacturers, PBMs, and pharmacy companies. Regulation that favors large incumbents over small new entrants reduces competition even if the regulation is mandating transparency.

In the Trump Administration, we saw firsthand that deregulation, rather than regulation, resulted in lower drug prices because it brought more producers and more products into the industry. By May 9, 2017, Scott Gottlieb was nominated and confirmed to head the Food and Drug Administration (FDA). He immediately told Congress that his FDA would prioritize competition (U.S. House of Representatives, Committee on Appropriations, Agriculture Subcommittee 2017). He delivered, with approvals at a higher rate during his tenure as compared with either the 2 years before it or the 2 years after it. Before Gottlieb's leadership, the FDA averaged 54 generic approvals per month (1,286 for the 24 months). The average was 73 per month during Gottlieb's tenure (through April 2019) and 61 in the subsequent 24 months. FDA approvals of new drugs, new biologics, and new biosimilars were also high during his tenure (Mulligan 2023).

Drug market performance reflected the additional competition stemming from deregulation. Incumbent manufacturers saw their stock prices drop in 2017 as traders realized that their regulatory protection was over. Even without an inflation adjustment, retail prescription drug prices fell in 2018 for the first time in 46 years after a long string of increasing faster than inflation.

The Biden Administration is bringing costly regulations, and ultimately higher drug prices, back again. Early in its tenure, it reinstated the FDA's Unapproved

Drug Initiative (86 FR 28605) under which FDA used its enforcement power to grant selected generic drug manufacturers monopolies on decades-old drugs merely because the manufacturer executed FDA paperwork. President Trump had ended this practice (85 FR 75331) because, unsurprisingly, it was sharply increasing the prices of generic drugs as soon as competitors were removed by FDA order.

Copay Clawback and Price Controls

During the hearing, you stated that prohibitions of copay clawbacks would amount to price controls.

Question 1. Please explain your reasoning for comparing a copay clawback prohibition to a price control.

Answer. At the hearing, Senator Welch asked the witnesses about the clawback of pharmacy fees (DIR) months after the drugs are dispensed according to how the pharmacy met various performance metrics specified in their contracts with plans and PBMs. During the hearing, I pointed out that prohibiting those fees would be a price control. Such a prohibition is a price control because it prohibits contracts that pay pharmacies on the basis of performance metrics that would be unknown until months after the drugs are dispensed. Under the prohibition, a pharmacy that performed poorly on such metrics would have to be paid the same as a pharmacy that performed well.

A copay clawback is different from pharmacy DIR clawback. A copay clawback refers to the practice of using some of the patient funds paid at the pharmacy to finance part of the insurance and benefit-management overhead other than the cost of acquiring the drug. Prohibiting copay clawbacks would be a price control because it would cap prices charged patients below the pharmacy drug-acquisition costs without regard for any of the other costs of having insurance and benefit-management services. Those costs would have to be paid through premiums or some other revenue source.

With many price controls, their advocates recommend them on the basis of purported "fairness" even though their unintended consequences would often be understood as unfortunate, wasteful and unfair. This is why the Executive Branch requires, at least in principle, a "particularly demanding burden of proof" of a price-control benefit that justifies the regulatory cost (Office of Management and Budget 2003).

PBM Rebate Pass Through

During her response to a question posed by Sen. Rosen, Dr. Trish argued that rebates are not being passed on to consumers.

Question 1. Do you agree with Dr. Trish's argument? Why or Why not?

Answer. At the hearing, both Senator Rosen and Dr. Trish were clear that they understood "passed on to consumers" narrowly in terms of the amount paid "at the pharmacy counter" (a.k.a., "out of pocket" or "cost sharing"). They ignored any savings that consumers get through lower premiums. This is a major omission because CBO, OACT, and I, among others, find that rebates help keep drug-plan premiums low by providing a revenue source beyond premiums and cost sharing.

My disagreement with Dr. Trish is not just about her narrow definition of "consumers." Because she does not discuss rebates as part of a larger incentive contract and situated in a multiproduct sale (drug insurance), she cannot acknowledge the ways that rebates substantially reduce the amount paid at the pharmacy counter.

Real-world rebates are tied to sales targets for the manufacturer paying the rebate. Because they are backed by financial incentives, the utilization targets by themselves reduce cost sharing. Especially, plans' part of the rebate bargain is often to put the drug in a lower cost tier or to at least include the drug in its formulary, which prevents plan members from having to pay the full list price. These are actions that significantly reduce cost sharing, yet are not mentioned in Dr. Trish's testimony or in Schaeffer Center studies of rebates.

Even if rebate transactions on a particular drug increased patient cost sharing for that drug, it likely reduces patient cost sharing for other drugs or, in an integrated plan, for non-drug medical claims. One reason is that many plans, each of which is covering many pharmaceutical products if not other medical services, are subject to actuarial-value regulations. A silver ACA plan, for example, is supposed to finance no more than 20 percent of benefits through patient cost sharing. If a plan's transaction with a particular provider resulted in greater cost sharing for a particular type of claims originating with that provider, then the plan would likely reduce cost sharing on other types of claims or from other providers in order to comply with the 20 percent requirement.

Question 2. S. 127 contemplates a 100 percent pass through of a rebate to the consumer. Would consumers benefit and pay a lower price from this requirement? Why or Why not?

Answer. Between drug-plan premiums and out-of-pocket expenses, consumers would likely pay more as a result of S. 127's Sec. 2(b)(1) that requires "pass[ing] along or return[ing] 100 percent of any price concession to a health plan or payer. . .."

Sec. 2(b)(1) apparently allows plans to retain rebates for either reducing premiums or financing other expenses. Whether the consumer, more broadly than "at the counter," benefits depends on what happens to the other expenses. S. 127's Sec. 2(b)(1) would take away a revenue source for PBMs without encouraging any new companies to get into the PBM business. Without more genuine competition among PBMs, that leaves only three possibilities. One is that PBMs opt to comply with Sec 2(a) rather than 2(b), which is their option, thereby increasing retail pharmacy expenses for patients and plans. A second possibility is that PBMs would collect their fees in another way that proves more costly to patients and plans. The third possibility is that PBMs do less benefit management, which means that plans pay more for drugs and retail pharmacy services.

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. TED BUDD TO DR. CASEY B. MULLIGAN

Question 1. Dr. Mulligan, could you explain why you think adding rebate data to the analysis of rising drug costs would be tapping into propriety information?

Answer. One of the major intended (and procompetitive) results of a managed insurance benefit is to maintain different prices of products produced by monopolistic or oligopolistic healthcare providers. Because the systems for doing so are intellectual property that is rarely protected by patent or copyright, disclosure of proprietary information about those systems would remove much of the financial incentive to invest in advancing them because competitors could use the disclosed information to more rapidly imitate. Unlike other areas of healthcare where the product is a chemical, procedure, or device, much of the product of benefit management is the pricing and other contract provisions.

Question 2. Dr. Mulligan, the Federal Trade Commission is currently conducting a study to "scrutinize the impact of vertically integrated pharmacy benefit managers on the access and affordability of prescription drugs." [1] There are three major Pharmacy Benefit Managers that control 80 percent of the market. This appears to be market consolidation.

Can you explain why you think this helps lower prescription drug costs?

Answer. Pharmacy benefit management, as compared to no (or less) pharmacy benefit management, reduces drug costs. This is the conclusion I presented at the hearing.

A consolidated market for benefit management, as compared to vigorous competition in benefit management, increases drug costs both by increasing the price of benefit management and by reducing the amount of benefit management. The question of consolidated benefit management, which is the question you are asking now, was addressed in the *Restrict the Middleman?* report I submitted into the record on the day of the hearing. There I conclude that less benefit management competition means higher drug prices. See especially Table 5.

[Perhaps your question is asking about the drug-cost effect of the forthcoming FTC study rather than the drug-cost effect of PBM consolidation. Without seeing the study or knowing how it is received in Washington, I cannot assess the drug-cost effect of that study.]

Question 3. Dr Mulligan, in your testimony you mentioned that requiring disclosures of product benefit management pricing could remove financial incentives to negotiate lower prices and lead to firms imitating one another.

Can you explain why mandating pricing disclosures could potentially reduce competition and undercut the effectiveness of selective pricing by health plans?

Answer. One of the major intended (and procompetitive) results of a managed insurance benefit is to maintain different prices of products produced by monopolistic or oligopolistic healthcare providers. Because the systems for doing so are intellectual property that is rarely protected by patent or copyright, disclosure of proprietary information about those systems would remove much of the financial incentive to invest in advancing them because competitors could use the disclosed information

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[1] *https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry*

to more rapidly imitate. Unlike other areas of healthcare where the product is a chemical, procedure, or device, much of the product of benefit management is the pricing and other contract provisions.

Consider an example in the spirit of U.S. Department of Justice and the Federal Trade Commission (1996). Three branded drug therapies compete. Absent mandated disclosures, one pays a 20 percent rebate, a second pays 30 percent, and a third pays 40 percent. The second and third understand that they are rebating more than another competitor but are unaware that the gap from the more expensive competitor is a full 10 percentage points. As full disclosure reveals the gaps, the second reduces its rebate to 21 percent while the third reduces to 22 percent. In other words, full disclosure reduces the average rebate from 30 percent to 21 percent.

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