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ENSURING FAIRNESS AND TRANSPARENCY IN THE MARKETS OF PRESCRIPTION DRUGS

HEARING

BEFORE THE

SUBCOMMITTEE ON CONSUMER PROTECTION, PRODUCT SAFETY, AND DATA SECURITY

OF THE

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION
UNITED STATES SENATE

ONE HUNDRED SEVENTEENTH CONGRESS

SECOND SESSION

MAY 5, 2022

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SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

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THURSDAY, MAY 5, 2022

U.S. SENATE,
SUBCOMMITTEE ON CONSUMER PROTECTION, PRODUCT SAFETY, AND DATA SECURITY,
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,
Washington, DC.

The Subcommittee met, pursuant to notice, at 10:10 a.m., in room SR–253, Russell Senate Office Building, Hon. Richard Blumenthal, Chairman of the Subcommittee, presiding.

Present: Senators Blumenthal [presiding], Cantwell, and Blackburn.

OPENING STATEMENT OF HON. RICHARD BLUMENTHAL, U.S. SENATOR FROM CONNECTICUT

Senator BLUMENTHAL. The Subcommittee on Consumer Protection, Product Safety, and Data Security will come to order. Welcome to our very distinguished panel and to the Senators who will be joining us. I want to thank particularly Senator Blackburn for her collaboration on this topic, and welcome all of you to address the anti-consumer and anti-competitive practices that increase and drive up health care costs for the American people.

Today we are specifically focused on pharmacy benefit managers, or PBMs, and how the tactics they use impact drug costs and consumer choice. This hearing is really part of a more general discussion on how to lower costs and remove barriers to care for patients, and we will continue to have hearings on that topic. If you ask the average American to tell you what a pharmacy benefit manager does or even what it is, you are probably met with a blank stare, which is understandable.

PBMs have long operated in relative obscurity with little transparency, acting as middlemen between insurer, drug companies, and pharmacies. PBMs exist to manage the drug prescription benefits for 266 million Americans. So even if you have never heard of a PBM, you have almost certainly been impacted by one.

They are hired to hire—they are hired to buy health plans to—by managing the health plans' prescription drug benefit, lower costs to the health plan by exacting rebates from drug companies and managing what drugs will be covered for patients and at what cost. Then they act as the intermediary between the health plan and the pharmacy, reimbursing the pharmacy for the prescription drugs they dispense.

PBMs stated goal is to lower health care costs for consumers through this complex system. The problem is that patients rarely see or feel the benefits. Drug prices continue to rise. Insurance costs continue to eat into incomes. And more and more often, drug—the drugs patients need are not covered by their health care plan at all. In this way, PBMs are part of a broken drugs supply chain that leads to increasing profits for drug companies, increasing profits for PBMs, and increasing drug costs for patients.

PBMs benefit from high prices. They receive rebates and administrative fees from drug companies that are often based on the initial price. It is called the list price of a drug. This means the higher the initial cost of a drug, the higher the profits for the PBM. PBMs will argue that these rebates lower the cost of your insurance, that they largely pass these rebates along to insurers who use them to lower your health care costs.

But truly, we have no idea whether this is accurate, because PBMs shroud this information in secrecy. If these rebates are lowering the cost of health care, that is news to patients. Insurance premiums and deductibles have not gone down. Instead, increasingly, they are eating into Americans' hard earned dollars and savings. PBMs are a significant part of the drug pricing problem, but drug companies shouldn't get a pass.

As Professor Feldman, one of our witnesses here today wrote in her aptly entitled article, and I am quoting here, "driving up prices is a win-win for PBMs and drug companies. Drug companies can charge more for their products, while PBMs increase their slice of the pie." The one who loses out is the patient, because even though that initial price isn't what anyone else in the drug supply chain pays, it oftentimes directly impacts what you pay.

That is because for nearly half of people with commercial insurance and nearly all Medicare beneficiaries, out-of-pocket payments are based on an initial drug price, not the reduced rate. The higher the initial price, the more you pay, and PBMs have a financial incentive to keep that initial price high. PBMs also limit choice. PBMs are the ones who decide which prescription drugs your health plan will cover and which they won't. They determine which drugs will be preferred by your insurance plan, meaning which drugs will cost you more out of pocket and which will cost you less. Increasingly, PBMs have taken to excluding drugs entirely from health plans.

More and more patients who receive a diagnosis are working with their doctors to find a prescription drug that works for them, only to be denied access to it at the pharmacy counter. This happened to April Flowers, a teenager from Texas, whose family told their story to Consumer Reports. She had taken the same medication for her seizures for years when suddenly her family learned at the pharmacy counter that her out-of-pocket costs was now $1,700. Her family made frantic calls to figure out the problem.

What they learned was that her drug was suddenly dropped with no warning. Her drug was no longer covered. They scrambled. They enlisted her doctor. With 2 days of medicine left, April got an exception. The stress, the threat to her health must have been infuriating. April's situation is shockingly common. In fact, in recent years, PBMs' refusal to cover certain drugs has skyrocketed.

Now hundreds of drugs are excluded by the biggest PBMs every year. Certain types of insulin, drugs to treat chronic conditions, and in recent years, cancer drugs are all fair game. A poll cited in the same *Consumer Reports* article found that more than a third of people with prescription drug coverage said they or someone in their home had dealt with the same issue as April within the last 12 months.

Let's be clear, PBMs are just part of a broken system. It is massively broken. It has left millions of Americans without a way to afford lifesaving medicine like insulin. Drug prices have skyrocketed, and drug companies have made record profits while engaging in anti-competitive tactics that keep cheaper drugs off the market. I pushed for reform, so have many of my colleagues.

The biggest and most important priority we have is to lower the cost of prescription drugs. And that is a health care imperative as people feel the weight of high health care costs. We cannot ignore the power of PBMs and their influence in drug pricing and eroding patient and provider choice. I hope that today's hearing will lead to action. And I turn to the Ranking Member.

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

Senator BLACKBURN. Thank you, Mr. Chairman. And good morning and welcome to all and to our witnesses that are joining us remotely today. We welcome them also. And Chairman Blumenthal, I am so pleased that we are doing this hearing about the issue of the PBMs and the impact that these arrangements have on our consumers.

And when you look at the fact that the PBMs are the middleman and over the past few decades, they have grown, really escalated with Medicare Part D. And initially the purpose was, save money for the employers and the insurance companies, try to keep the costs down. But in those 20 years since the Medicare Part D has been with us, it seems that the role of the PBM has become really quite complicated.

Three PBM middlemen accounted for nearly 80 percent of all the prescription claims in 2020, and that is not lost on us. And one of the reasons we are wanting to look at the market, the size of the market, the inefficiencies that are there—maybe there are ways to create efficiencies and save money for the system and for consumers who seem to be paying an ever higher cost.

We understand and appreciate rebates are a part of this system and are really a part of the payments that are made by the pharmaceutical companies to the—to keep certain drugs in a formulary. And we know that the PBM has a lot of control over what pharmaceutical can actually reach the consumer that is on a specific plan. And we know and are curious about some of the other rebates that are recouped from pharmacists by the PBMs.

And pharmacists tell me that this is done without transparency or accountability by the PBMs. Distorted incentives within the pharmaceutical supply chain have created a dynamic where middlemen involved in distributing and paying for prescription medicines benefit from higher list prices and higher rebates, and the consumer pays more.

Senators Grassley and Wyden published a two-year investigation into the cost of insulin. I know that each of you are familiar with this. And what they noted was how the PBMs really stood in the way of a lot of transparency in this process. They concluded that the PBMs have an "incentive for manufacturers to keep list prices high." And that is a direct quote from them. Now, this is really a 180 from what the purpose of a PBM was to be initially. In recent years, 40 states, including Tennessee, have enacted legislation to curb some PBM practices.

The bill recently passed by the Tennessee General Assembly includes reimbursement transparency and protects patients from being steered to PBM-affiliated pharmacies. This shows you how you have gotten away from a core mission with the PBM when the states jump in and say we are going to protect our citizens.

That is why we need to look at this. You have got onerous audits, claw back provisions, and patients steering into anti-competitive behaviors by PBMs that have caused small pharmacy businesses to struggle to survive. While CMS recently proposed rule to end retroactive DIR fees, which harm independent pharmacies and raise costs for seniors, they unfortunately delayed implementation until 2024.

That is unacceptable. This delay gives PBMs another year to play games that cause seniors to pay higher cost sharing and pharmacies to face huge claw backs. As they say, sunlight is the best disinfectant, and it is time for more transparency about the impact of potentially anti-competitive PBM practices on patients, small pharmacy businesses, and taxpayers.

To this end, I have introduced S. 298, the Pharmacy Benefit Managers Accountability Act. I have done that along with Senator Braun. The bill would require GAO to submit a report to HHS and Congress on PBMs and their role in the pharmaceutical supply chain. I encourage my colleagues to take a look at it and consider co-sponsoring that legislation. I would note that a few months ago the FTC asked for public input on PBMs and their impact on patients, physicians, and businesses.

I am not opposed to this line of inquiry. Last year, I sponsored a bipartisan bill with Senator Blumenthal and Chair Cantwell and others that directed the FTC to report to Congress on anti-competitive practices. But I want to emphasize that this is not a blank check for the FTC. It is not for them to move forward with any type of rulemaking that they want to pursue without the direction of us in Congress, especially given the need for more information and the important role of HHS and the states in this area.

So these are all issues for our discussion today. We look forward to hearing you. Thank you, Mr. Chairman.

Senator BLUMENTHAL. Thanks so much, Senator Blackburn. We have a great panel. Welcome to all of you. I will introduce you and then ask for your statements. David Balto, who is a Principal in the law offices of David Balto. He is an expert on health care competition and regulation, and an antitrust attorney with over 25 years of experience in both the private and public sectors.

Mr. Balto served as a trial attorney in the Department of Justice's Antitrust Division and in several senior level positions at the FTC during the Clinton Administration, including as Policy Direc-

tor for the Bureau of Competition. Craig Garthwaite, who joins us personally, is the Herman Smith Research Professor and Hospital and Health Services Management, Professor of Strategy and Director of the Program on Health Care at Northwestern University's Kellogg School of Management.

He has a Ph.D. in economics from the University of Maryland and is an expert in health care policy and the biopharmaceutical sector, and I understand is a native of Stanford, or at least has a connection there. Robin Feldman is the Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson Distinguished Professor of Law Chair, and Director of the Center for Innovation at the University of California Hastings. She is an expert in the legal junction of intellectual property, health, and medicine.

Her work illuminates how and why practices often operate to the benefit of the pharmaceutical industry over consumers, and she offers solutions. J.C. Scott, who joins us in person, is the President and CEO of the Pharmaceutical Care Management Association representing America's Pharmacy Benefit Managers. He joined PCMA in the fall of 2018 and before that held roles with Abiomed and the American Council of Life Insurance.

He also has held various staff offices in the House of Representatives. We are going to go in alphabetical order, beginning with David Balto, then Craig Garthwaite, Robin Feldman, and J.C. Scott. Mr. Balto, if you can hear us, the floor is yours.

STATEMENT OF DAVID A. BALTO, ANTITRUST ATTORNEY, DAVID A. BALTO LAW OFFICES

Mr. BALTO. Thank you. Good morning, Chairman Blumenthal, Ranking Member Blackburn, and other members of the Subcommittee. I am very grateful that you are holding this hearing and that you invited me to speak. There is increasing attention to PBMs, and it is very justifiable.

PBMs are an increasing source of cost increases in the pharmaceutical area, and they are probably the least regulated area, and they have a significant impact on health care costs that is appropriate for attention. And unfortunately, our antitrust and consumer protection enforcers, especially FTC, have given them a green light and consumers have paid dearly for that. In my written testimony, I make four basic points.

First, PBMs are probably one of the least regulated areas of the drug supply chain. There is no Federal enforcement and very little State enforcement, and that has left PBMs free to engage in anticompetitive conduct. When you look at the—listen to the complaints of the community pharmacists in your state, what they are subject to in trying to deliver better services to consumers is truly—[technical problems]—tremendous power of PBMs.

Second, the—because of the lack of enforcement, the PBMs have formed a tight oligopoly, as ranking member noted. There are three elements you need for competition to exist in the market. First, you need choice. You need to be able to play competitors off against each other. Now, Mr. Scott is going to tell you there are 70 PBMs. That doesn't matter. Three firms dominate the market. The question of whether a firm has market power is the ability of a customer to say no.

And when a PBM goes to a pharmacist and says, I am going to take all these DIR fees or I am going to force you to reimburse below cost, or when a generic drug company comes to a PBM and says, please put me on the formulary and the PBM says, no, you are not offering me rebates like the branded drug manufacturer receives, that means the PBM has market power. It has the ability to act anti-competitively. What is the result? We have seen PBM profits more than double to over $20 billion a year.

Now, pause for a second. These aren't firms that are producing products. These are firms that are moving information and money and negotiating contracts, and for that, they are taking $28 billion, adding $28 billion of cost into the system. Why should consumers be paying so much for so little? And the reason that happens is because of the lack of competition. Factor two, transparency.

You have to go no further than PBMs imposing—[technical problems]—saying that they don't want any form of transparency in the market. Then third, conflicts of interest. PBMs—the purpose of PBMs is to lower drug prices, but as the ranking member noted, they make more money in rebates when prices go up. So their interest is in seeing prices increase. And that is why you see them deny access or provide inferior access to biosimilars or generic drugs or some competing drugs.

It is basically an auction for shelf space in which they say the highest cost product to the consumers is going to win the auction. And that is why prices are increasing so significantly. In my testimony, I outline how the FTC has really failed at this. And nothing is worse than a decade ago when they made the Faustian bargain to allow two of the three biggest PBMs, Express Scripts and Medco, to merge under the assumption that that increased market power would lead to lower prices for consumers.

Well, they were dead wrong. What is the result? We see skyrocketing rebates over the past decade. We see more restrictive networks and consumers being denied their pharmacies of choice as there has been a flood of PBM consolidation over those 10 years. One message I want to leave you with is consumers care a lot about their community pharmacy.

The community pharmacist is the health care provider that provides the greatest access to consumers, and that is vital, vital in underserved, rural, and inner city markets. They are the most accessible health care professional. And we saw that during the vaccine crisis over the past several years.

My testimony ends by outlining several amendments to the Federal Trade Commission Act, specifying anti-competitive practices for the Commission to dig its teeth into to prevent—to make this market competitive. And I think at the top of that list has to be the impact on pharmacies and also this rebate system that is leading to skyrocketing drug prices.

Thank you very much for the opportunity to testify.

[The prepared statement of Mr. Balto follows:]

PREPARED STATEMENT OF DAVID A. BALTO, ANTITRUST ATTORNEY, DAVID A. BALTO LAW OFFICES

Good morning, Chair Blumenthal, Ranking Member Blackburn, and Members of the subcommittee: I thank you for giving me the opportunity to testify on the con-

cerns and the need for regulation and accountability in the pharmacy benefit manager ("PBM") market. My testimony documents the tremendous competitive and consumer protection problems in the PBM market and need for stronger antitrust enforcement, oversight, regulation, and Federal legislation. For years PBMs have existed with scant regulation, and consumers have paid a heavy price in higher costs, less choice and inferior service. Congress and regulators need to reverse this permissive stance toward PBMs to lower prescription drug prices for patients.

My testimony is based on my 30 years of experience as a public interest antitrust attorney and an antitrust enforcer for both the Department of Justice and the Federal Trade Commission (FTC). From 1995 to 2001, I served as the Policy Director of the FTC's Bureau of Competition and the attorney advisor to Chairman Robert Pitofsky. Currently, I work as a public interest antitrust attorney in Washington, DC. I have represented consumer groups, public interest organizations, health plans, unions, employers, retail and specialty community pharmacy associations, and even PBMs on PBM regulatory and competitive issues. I led the consumer opposition to the proposed mergers of Anthem and Cigna and Aetna and Humana and worked with consumer groups to oppose CVS' acquisition of Aetna.

I have testified before Congress on several occasions and before fourteen state legislatures on the need for PBM reform and regulation and served as an expert witness for the State of Maine on its PBM legislation.

My testimony makes the following points:

- PBMs are one of the least regulated sectors of the healthcare system and drug supply chain. There is almost no Federal antitrust enforcement, oversight, or regulation. The lack of antitrust enforcement and regulation has created an environment in which PBMs are free to engage in anticompetitive, deceptive, and fraudulent behavior that harms patients, payors, employers, unions, and pharmacists and significantly increases drug costs.[1]
- Because lax antitrust enforcement allowed the three largest PBMs to become vertically integrated and form a tight oligopoly,[2] the PBM market lacks the essential elements for a competitive market: 1) choice, 2) transparency, and 3) a lack of conflicts of interest. PBMs leverage this lack of competition to further their own interests at the expense of patients, employers, and others in the system.
- The PBM rebate system turns competition on its head with PBMs seeking higher, not lower prices to maximize rebates and profits. *In the past decade, PBM profits have increased to $28 billion annually.*[3] PBMs are supposed to control costs, but because of the perverse incentives the rebate system creates, they frequently deny access to lower cost drugs including lower cost generics and biosimilars, to maximize rebates available from higher cost drugs.[4] That is why major consumer and patient groups and unions supported the past administration's efforts to eliminate the antikickback safe harbor for PBM rebates.[5]
- Because of their market power and vertical integration these middlemen increasingly stifle competition from this country's most accessible and trusted health care professionals—community pharmacies. PBMs create endless schemes to reduce reimbursement, claw back funds, restrict networks, and effectively force pharmacies to provide drugs below cost. *In 2020 alone, PBMs took $9,535,197,775*[6] *from independent pharmacies who serve Medicare Part D par-*

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[1] *How PBMs Make Drug Pricing Problem Worse,* David Balto, August 31, 2016, The Hill, *https://thehill.com/blogs/pundits-blog/healthcare/294025-how-pbms-make-the-drug-price-problem-worse/*.

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

[3] PBM Accountability Project, *Understanding the Evolving Business and Revenue Models of PBMs,* 2021, *https://www.pbmaccountability.org/_files/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true*

[4] Charlie Grant, *Hidden Profits in the Prescription Drug Supply Chain,* February 24, 2018, Wall Street Journal.

[5] Comments of Consumer Action, Consumer Federation of America, Consumer Reports, NETWORK Lobby for Catholic Social Justice, and Public Research Interest Group PIRG in Support of Department of Health and Human Services Office of Inspector General's ("HHS") proposed new rules to eliminate the safe harbor for rebates in Medicare Part D plans, April 8, 2019, *https://docs.wixstatic.com/ugd/1859d0_c7d2ccf1d47d4f65a8965e9bbaed989d.pdf*.

[6] Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revi-

Continued

ticipants. Community pharmacies are crucial for consumers in underserved low income and rural neighborhoods. These unfair and coercive tactics by PBMs result in inferior health care, less choice and higher costs.

- The FTC has failed to protect consumers from unfair, deceptive and egregious conduct in this market. Thus, the Committee should consider amending the FTC Act to specify unfair acts or practices and unfair methods of competition that PBMs engage in that the FTC should address and provide a clear mandate for strong enforcement. Consumers should no longer be forced to pay billions for the schemes of these middlemen.

For the PBM market to function properly for patients, employers, unions, and other stakeholders, we need strong oversight and regulation as well as greater antitrust and consumer protection enforcement. Any conversation on drug pricing reform must include a discussion on how to rein in PBMs.

THE PBM MARKET IS BROKEN

Ensuring that patients can afford lifesaving and life-managing prescription drugs is critically important to public health because better use of medicines has been shown to help patients live longer and healthier lives. Unreasonably high out-of-pocket costs for prescription drugs at the pharmacy counter threaten patient access to medicines, as some choose to stop or delay treatment because they cannot afford it.[7]

Undoubtedly, rising prescription drug prices are a serious problem for patients.[8] PBMs were supposed to be a solution to this problem, but a lack of competition, transparency and existing conflicts of interest enable PBMs to game the system and put profits before patient welfare.

PBMs represent themselves as "honest brokers" or intermediaries between drug manufacturers, health insurers, plan sponsors, and providers. Although PBMs in principle have great promise in terms of their potential to control prescription drug costs, over time their role has evolved. Now, there is a pattern of self-dealing and anticompetitive behavior. Patients pay higher prices for drugs than they should because PBMs are not fulfilling their cost-control function. Consider that two of the three largest PBMs are in the Fortune 10 and all three in the Fortune 15.[9] The Pharmaceutical Care Management Association ("PCMA"), the PBM trade association, frequently says that PBMs are "the only actors in the pharmaceutical supply chain whose fundamental role is to negotiate lower drug prices for patients," but PBMs are not "fulfilling their primary mission to lower prescription drug costs for consumers and health plan sponsors."[10] *Instead, consumers are funding profits of more than $28 billion annually for network intermediaries that make no products and provide no health care, but rather basically serve primarily to transfer data and money.*

Let me be clear, the PBM market is broken because it lacks the essential elements for a competitive market, namely: (1) choice, (2) transparency and (3) a lack of conflicts of interest.[11]

First, there is a lack of choice. The PBM industry is a tight oligopoly, which results in reduced consumer choice. According to the Council of Economic Advisors (CEA), three PBMs—CVS Caremark, Optum Rx, and Express Scripts—control over 80 percent of the market, "which allows them to exercise undue market power

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sions in Response to the COVID–19 Public Health Emergency, CMS 4192–F, *https://public-inspection.federalregister.gov/2022-09375.pdf.*

[7] Press Release, Kaiser Family Foundation, *Poll: Nearly 1 in 4 Americans Taking Prescription Drugs Say It's Difficult to Afford Their Medicines, including Larger Shares Among Those with Health Issues, with Low Incomes and Nearing Medicare Age* (Mar. 1, 2019), *https://www.kff.org/health-costs/press-release/poll-nearly-1-in-4-americans-taking-prescription-drugs-say-its-difficult-to-afford-medicines-including-larger-shares-with-low-incomes/.*

[8] Leigh Purvis and Stephen W. Schondelmeyer, *Brand Name Drug Prices Increase More Than Twice As Fast As Inflation in 2018.* AARP Public Policy Institute, November 2019, *https://press.aarp.org/Brand-Name-Drug-Price-Increases-2018-Rx-Price-Watch?intcmp=AE0POL-TOENG-TOGL.*

[9] Fortune Rankings, *https://fortune.com/fortune500/2021/search/.*

[10] J.C. Scott, *FTC's Inquiry of PBMs Won't Lower Prescription Drug Costs,* The Hill, April 18, 2022, *https://thehill.com/blogs/congress-blog/3272225-ftcs-inquiry-of-pbms-wont-lower-prescription-drug-costs/*

[11] *"Protecting Consumers and Promoting Health Insurance Competition,"* Testimony of David Balto, Before House Judiciary Committee, Subcommittee on Courts and Competition Policy, October 8, 2009, at *http://www.dcantitrustlaw.com/assets/content/documents/CAP/protecting%20consumers.pdf.*

against manufacturers and against health plans and beneficiaries."[12] *Indeed, the three largest PBMs have a higher gross margin than any other players involved in the drug supply chain,*[13] *and in recent years, more of the increase in spending on brand medicines has gone to payers, including PBMs and health plans, than to drug manufacturers.*[14] PBM profits have more than doubled in the past decade. It is hard to see what value these middlemen have added to our healthcare system in return for the skyrocketing profits.[15]

Second, the PBM market lacks transparency. PBM operations are cloaked in secrecy, and they fight efforts to require transparency tooth and nail. There is no better example of their efforts to hide information than "PBM gag clauses" which PBMs long used to prevent pharmacists from telling consumers about available lower-cost alternative medications. While Congress finally prohibited PBMs from imposing such clauses for federally funded patients (*i.e.,* Medicare beneficiaries), in many states, PBMs still utilize such clauses to ensure continued receipt of substantial profits on the backs of consumers. *There is simply no pro-consumer reason to deny consumers the necessary information to receive drugs at the lowest cost. None.*

PBMs establish tremendous roadblocks to prevent payors from knowing the amount of rebates they secure. Even sophisticated buyers are unable to secure specific drug by drug rebate information. PBMs prevent payors from being able to audit rebate information. As the Council of Economic Advisors observed, the PBM market lacks transparency as "[t]he size of manufacturer rebates and the percentage of the rebate passed on to health plans and patients are secret."[16] Without adequate transparency, plan sponsors cannot determine if the PBMs are fully passing on any savings, or whether their formulary choices really benefit the plan and subscribers.

Legislation requiring transparency or imposing a fiduciary duty might be one solution. Yet PBMs regularly fight against any such legislative proposals. For example, the PBMs fought against a 2014 Department of Labor consideration of transparency even though the proposal was supported by HR Policy Association, the AFL–CIO and Consumers Union.[17]

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[12] CEA White Paper, *supra* note 2. The Top Pharmacy Managers of 2021, the big get even bigger, Drug Channels, April 2022, *https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html.* I expect the witness from PCMA will note that there are dozens of PBMs. But these firms are not competitors at least from the perspective of competition law and economic policy. Under the antitrust laws, a "competitor" in a relevant market is a firm that can constrain prices. *FTC v. Staples, Inc.,* 970 F. Supp. 1066, 1078 (D.D.C. 1997) ("The pricing evidence indicates a low cross-elasticity of demand between consumable office products sold by Staples or Office Depot and those same products sold by other sellers of office supplies. This same evidence indicates that non-superstore sellers of office supplies are not able to effectively constrain the superstores prices, because a significant number of superstore customers do not turn to a non-superstore alternative when faced with higher prices in the one firm markets.") None of these much smaller PBMs have either the incentive or ability to constrain the anticompetitive conduct of the three dominant PBMs.

[13] Charley Grant, *Hidden Profits in the Prescription Drug Supply Chain,* February 24, 2018, Wall Street Journal, *https://www.wsj.com/articles/hidden-profits-in-the-prescription-drug-supply-chain-1519484401#:~≦text=Drug%20distributors%20converted%2046%25%20of,benefit%20from%20higher%20drug%20prices.*

[14] Brownlee A., *The Pharmaceutical Supply Chain,* 2013–2020, Berkeley Research Group, January 2022, *https://www.thinkbrg.com/insihts/publications/pharmaceutical-supply-chain-2013–2020/;* Van Nuys K, Ribero R, Ryan M., *Estimation of the Share of Net Expenditures on Insulin Captured by U.S. Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans from 2014 to 2018,* JAMA Health Forum, 2021, *https://doi.org/10.1001/jamahealthforum.2021.3409.*

[15] PBM Accountability Project, Understanding the Evolving Business and Revenue Models of PBMs, 2021, *https://www.pbmaccountability.org/_files/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true*

[16] CEA White Paper *supra* note 2.

[17] PCMA Testimony to the ERISA Advisory Council, William J. Kilberg, June 19, 2014 *https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/about-us/erisa-advisory-council/2014-pbm-compensation-and-fee-disclosure-kilberg-06–19.pdf;* Consumers Union Testimony, June 12, 2014, *https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/about-us/erisa-advisory-council/2014-pbm-compensation-and-fee-disclosure-quincy-06–19.pdf.* I expect that Professor Graithwaite will suggest that that PBM transparency may be harmful because it may lead to collusion. I firmly disagree with that suggestion. First even Professor Graithwaite seems to admit the PBM market may not be competitive. TESTIMONY OF CRAIG L. GARTHWAITE, Ph.D., Before the House Committee on Education and Labor Subcommittee on Health, Employment, Labor, and Pensions On "Making Health Care More Affordable: Lowering Drug Prices and Increasing Transparency," September 26, 2019, at 21, *https://edlabor.house.gov/imo/media/doc/GarthwaiteTestimony0926191.pdf.* Second, although there may be a theoretical argument that excessive transparency can lead to collusion, I think that is rather unlikely in this market. It assumes that buyers will disclose the precise amount of rebates to rival manufacturers. I rep-

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Third, PBMs create and exploit numerous conflicts of interest. PBM rebate schemes create a clear conflict between the PBM and the payor. The payor prefers the lowest cost drug. But to maximize its profits PBMs often prefer the drug with the highest list price. And they often will prevent lower cost drugs such as generics and biosimilars from receiving preferred access on their formularies.

Conflicts of interest also abound because PBMs are vertically integrated with health insurers, mail order operations, specialty pharmacies, and in the case of CVS, the largest retail and specialty pharmacy chain, and the dominant long term care pharmacy. All three PBMs own their own specialty pharmacies, which they favor, discriminating against rival pharmacies. These PBMs steer patients to their own pharmacies as a requirement for patients to access their full prescription benefit. And all three PBMs are owned by or affiliated with the three largest insurance companies—United, Aetna and Cigna. *How can they offer fair contracts to their clients when they have a vested interest in driving traffic to their own pharmacies? Who sets the standards and audits the affiliated pharmacies, and do they have to meet the same standards as the independent pharmacies? Are affiliated pharmacies charged the DIR fees that independent pharmacies pay and have exceeded billions of dollars annually? The fox is guarding the henhouse, and Congress needs to ensure that patients are not paying the price in less choice, inferior service and higher prices.*

A Broken Market Leads to Escalating Drug Costs and Rapidly Increasing PBM Profits.

The most significant conflict that leads to escalating drug costs involves PBMs' incentives to maximize the rebates paid by manufacturers to get preferred access on their drug formularies. PBMs were formed to act as honest brokers to negotiate with drug manufacturers for lower prices for payors, but when PBMs share in the rebates that they negotiate, it creates an incentive for them to want higher, not lower, list prices. According to a recent Senate Finance Committee Report, "PBMs have an incentive for manufacturers to keep list prices high, since the rebates, discounts, and fees PBMs negotiate are based on a percentage of a drug's list price—and PBMs may retain at least a portion of what they negotiate." [18] PBMs have gone so far as to require additional payments in the event of any reduction in manufacturer list prices.[19]

PBMs' Demand for Rebates Results in Patients Not Having Access to the Most Efficacious and Affordable Medicines that they Need.

PBMs base formulary access decisions on the amount of the rebates, which encourages drug manufacturers to focus on offering higher rebates to secure that preferred status. Focusing on rebates gives PBMs incentives to put higher-cost drugs on their formularies, because the rebates are based on a percentage of a drug's list price. In essence, PBMs are 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. 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.

As important as cost is the adverse impact on patient health. PBM rebate schemes interfere with doctor-patient relationships, and harm patients' health when they cannot get the drugs they need. PBMs may exclude new innovative drugs that may be less expensive and more effective, in favor of higher rebates.[20] On many occasions PBMs may require patients to go through cumbersome and health-threatening step therapy programs in order to secure the more efficacious drug. As Robin Feldman, a professor at UC Hastings College of Law, puts it, "the system contains odd and perverse incentives, with the result that higher–priced drugs can receive

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resent payors and based on my experience I doubt that would occur. Moreover, in my 15 years as an antitrust enforcer including working as the FTC Policy Director, I cannot recall a single case where transparency led to the type of collusion the Professor suggests.

[18] Senate Finance Committee. *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug,* 2021, *https://www.finance.senate.gov/imo/media/doc/Grassely-Wyden%20Report%20(FINAL%201).pdf.*

[19] Sagonowsky, E., UnitedHealthcare demands drug rebates even if pharma cuts list prices: analyst, February 2019, *https://www.fiercepharma.com/pharma/letter-to-pharmas-unitedhealthcare-seeks-to-protect-drgug-rebates-from-price-reductions.*

[20] Mariana Socal and Gerard Anderson, *Favorable Formulary Placement of Branded Drugs in Medicare Prescription Drug Plans When Generics Are Available,* JAMA, March 18, 2018, *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2728446.*

more favorable health-plan coverage, channeling patients toward more expensive drugs."[21] Uninsured patients face higher prices and insured patients pay higher coinsurance or pre-deductible out-of-pocket costs when list prices rise.[22]

PBMs use Their Market Dominance to Harm Community Pharmacies.

As detailed below, PBMs engage in a long list of egregious, unfair and abusive practices that harm community pharmacies. Community pharmacies simply have no reasonable bargaining power with PBMs who extend contracts on a "take it or leave it" basis. You simply have to look no further than pharmacy direct and indirect remuneration fees. As noted above, the PBMs pulled in over $9 billion dollars in these fees in 2022 alone. The foundation for these fees are the inflated price points that were established by PBMs themselves. The fact that these fees skyrocketed from practically nothing to over $9 billion demonstrates the PBMs market dominance. They reap additional fees beyond the $9 billion by way of inflated coinsurance payments by seniors. There is simply no pro-consumer reason to inflate Medicare Part D beneficiaries' coinsurance costs at the point of sale. Never have seniors received a rebate from PBMs for overpayment of their coinsurance.

Lax Antitrust Enforcement of the PBM Industry Has Led to Widespread Anticompetitive Conduct

The U.S. antitrust agencies have effectively placed PBMs in a regulatory free zone. The Department of Justice Antitrust Division ("DOJ") and the FTC have failed to take any meaningful enforcement actions, while permitting massive consolidation and anti-consumer practices. In the case of the PBMs' "gagging" of pharmacists, preventing them from telling consumers of lower-priced alternatives. The FTC knew about this conduct yet did not act.

As authors from the Institute for Local Self Reliance have observed:

> The FTC was designed to be a forward-thinking agency that would use its investigatory and rule-making authority to stamp out unfair methods of competition and protect the less powerful from fraud and abuse. But the FTC has been quick to dismiss concerns about the impact of concentration on small independent businesses. The agency has presided over an increasingly consolidated economy and has repeatedly embraced vertical integration despite evidence that such industry structures invite self-dealing and inflict harm on small businesses and the communities they serve.[23]

Ten years ago, the FTC faced a critical decision—whether to approve the merger of two of the three largest PBMs—Express Scripts and Medco. Despite the fact the merger violated the Merger Guidelines, and there was strong opposition by employers, unions, pharmacists and consumer groups, and dozens of Congresspersons raising significant competitive concerns, the FTC approved the merger. The Commission statement is illustrative of its misguided views.[24] The Commission suggested that there were ten competitors in the market, yet by this point its list looks more like a list of fossils—a record of firms that have since been acquired or exited the market. The Commission also suggested the concerns of pharmacies were unfounded because they "negotiate" contracts with PBMs, but no one with any business sense would suggest those are anything more than take it or leave it arrangements. The merging parties suggested that the country needed the merger so the merged firm could force down drug prices. The FTC bought into this Faustian bargain, but the real result was skyrocketing prescription drug prices, rebates, and massive profit increases.

The PBMs did secure the market power that the antitrust laws are meant to protect against. Rather than use that market power to effectively lower drug prices they used it to massively increase rebates and rebate schemes. As the following two charts demonstrate, PBMs have taken a majority of any reductions in pharma-

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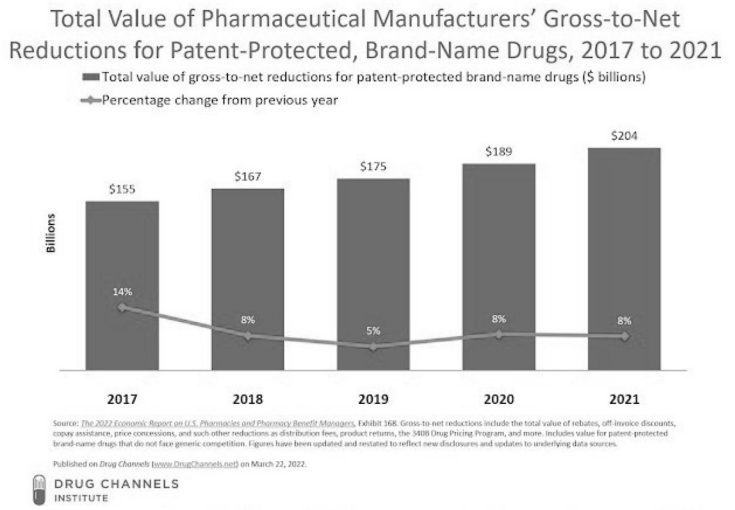
[21] Robin Feldman, *Why Prescription Drug Prices Have Skyrocketed?,* Washington Post, November 26, 2018, *https://www.washingtonpost.com/outlook/2018/11/26/why-prescription-drug-prices-have-skyrocketed/*.

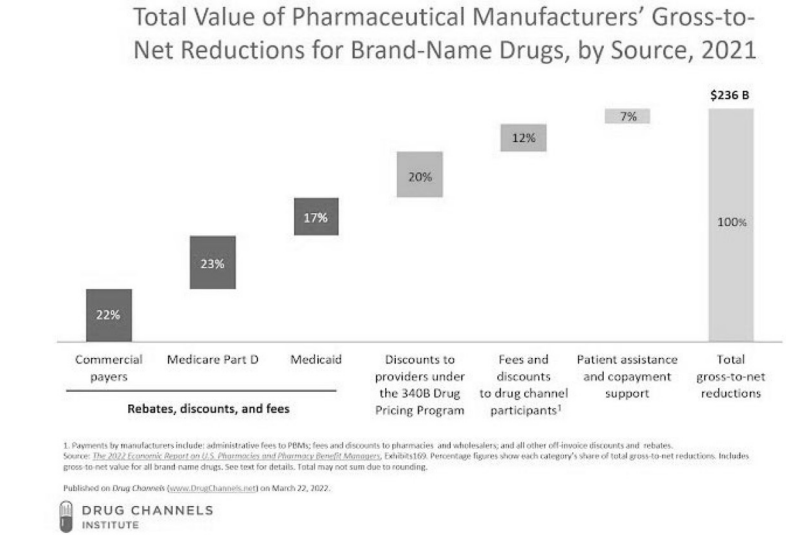
[22] *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs,* U.S. Department of Health and Human Services ("HHS"), May 14, 2018, pg. 17.

[23] Stacey Mitchell and Zach Freed, *How the FTC Protected the Market Power of Pharmacy Benefit Managers,* February 19, 2021, Pro Market, *https://www.promarket.org/2021/02/19/ftc-market-power-pharmacy-benefit-managers/*.

[24] Statement of Commission Concerning Proposed Acquisition Medco Health Solutions and Express Scripts, Inc., FTC File No. 111–0210, April 2, 2012, *https://www.ftc.gov/sites/default/files/documents/public_statements/statement-commission-concerning-proposed-acquisition-medco-health-solutions-express-scripts-inc./120402expressmedcostatement.pdf.*

ceutical drug costs in the form of rebates and fees over the past five years and they are pocketing an increasing portion in profits.





In other words, drug manufacturers are attempting to lower costs through rebates, but an increasing portion of those rebates are being pocketed by the PBMs. They can do that because of the lack of competition, transparency and the conflicts of interest in the system.

Contrast the FTC decision to "hope" creating mega-middlemen would benefit consumers with the DOJ decision five years later to block the Aetna-Humana and Cigna-Anthem mergers. The insurance companies presented many of the same arguments as ESI-Medco—there were lots of competitors, there was little risk of monopsony power because healthcare providers could protect themselves, and the mergers were needed to lower healthcare costs. But the DOJ saw that approving the mergers

were a poor bargain for consumers and properly challenged them. Consumers and providers today benefit from competition between the four firms.[25]

Unfortunately, the FTC decision to green light the ESI-Medco merger led to a flood of additional PBM mergers as the major PBMs devoured their smaller rivals and specialty pharmacies. None of these transactions were challenged by the FTC, yet the underlying structural factors were far worse.

The lack of FTC merger enforcement is only the tip of the iceberg of misguided efforts. States have recognized the rampant consumer protection concerns and proposed legislation to regulate PBMs. When states tried to regulate deceptive and anti-consumer conduct of PBMs, the FTC staff sided with the PBMs, suggesting that "economic theory" teaches that PBM-pharmacy and PBM-drug manufacturer relationships result in lower prices and that regulation would harm consumers.[26] For example, the FTC has consistently opposed PBM transparency even though both Republican and Democratic Administrations have been strong advocates for healthcare transparency. In many cases, the FTC staff has relied on an outdated 2005 FTC mail order study, which Commissioner Julie Brill acknowledged was "antiquated."[27] Ultimately, many states rejected the FTC advocacy and adopted state regulations, but the broad statements in the FTC's own advocacy hamper the ability of states or Federal regulators to engage in meaningful PBM regulation.

One of the reasons the FTC advocacy and nonenforcement has missed the mark is that it has focused on the wrong set of consumers—payors rather than patients. With the vertical integration of the three largest PBMs with an insurer, a lowering of cost to the insurer through a sharing of rebates and other revenue does not directly equate to lower prices for patients taking prescription drugs. Under the current system, vulnerable patients are left to pay artificially high prices when their cost sharing is tied to the undiscounted list price of a medicine, rather than the lower net price the PBMs and insurers pay. And uninsured patients are in an even worse predicament. That is why consumer groups and unions supported reform of PBM rebates in the prior Administration.

The lack of enforcement has harmed pharmacies, and this has a direct impact on consumers. I know as a consumer advocate that consumers place tremendous value on their access to community pharmacies. Community pharmacists are consistently ranked as our most trusted health care professionals. And community pharmacies are often the most accessible form of health care services in underserved rural or inner-city markets. Community pharmacies provide essential advice and health care monitoring especially for patients taking specialty drugs. Yet despite receiving hundreds of complaints from community pharmacies for the egregious and deceptive actions by PBMs, the FTC has never brought an enforcement action. Not even one.

Just one example of egregious non-enforcement involves the numerous allegations that large PBMs are engaging in predatory pricing activities through the use of retrospective Direct and Indirect Remuneration ("DIR") and related fees. In practice, these fees depress reimbursement rates to pharmacies. In some cases, PBMs "claw back" more than the pharmacy initially received for the prescription, resulting in a net loss to the pharmacy.[28] In fact, PBM claw backs of pharmacy revenue has been increasing each year, causing significant financial strain on these small businesses.[29] The FTC, however, has not prevented PBMs from engaging in these predatory acts. Congress should ask what the basis for these fees is and how they benefit consumers, and why they have increased so dramatically.

Moreover, PBMs have engaged in a variety of practices that fundamentally can be defined as theft from the pharmacies, ultimately to the detriment of patients. For example, in 2018, the Ohio State Auditor audited its Medicaid Prescription Drug Program and found that the difference between what independent pharmacies are paid and what PBMs report back to the plans, commonly referred to as the "spread," had been growing. However, this growth in savings failed to translate into lower

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[25] Unfortunately, the DOJ allowed CVS to acquire Aetna, Inc. and Cigna, Inc. to acquire Express Scripts, Inc. in 2019.

[26] FTC Press Release, *FTC Staff: Mississippi Bill That Would Give State Pharmacy Board Authority Over PBMS Likely Would Increase Prices,* March 22, 2011, *https://www.ftc.gov/news-events/news/press-releases/2011/03/ftc-staff-mississippi-bill-would-give-state-pharmacy-board-authority-over-pbms-likely-increase.*

[27] *See* Commissioner Brill's Letter to the ERISA Advisory Council, August 19, 2014, available at *https://www.ftc.gov/system/files/documents/public_statements/579031/140819erisaletter.pdf.*

[28] *Markian Hawryluk, The Last Drugstore: Rural America is Losing Its Pharmacies, WASH. POST (Nov. 10, 2021), https://www.washingtonpost.com/business/2021/11/10/drugstore-shortage-rural-america/.*

[29] *Id.*

costs for the state.[30] The Auditor further described that the spreads, which resulted in reimbursement cuts to local providers, actually turned into PBM profits.[31] The Ohio Pharmacist Association explained that "[b]eing that PBMs also own their own pharmacies, this essentially amounts to one pharmacy company reaching into the pockets of competitors, pulling out cash, and putting it right into their own. Regardless of the intent, this warped incentive has absolutely no place in a fair, competitive marketplace."[32] Again, the FTC has failed to act despite numerous examples of this type of behavior.

And, because antitrust agencies have allowed PBMs to vertically integrate with insurers, mail order operations, and pharmacies, PBMs have financial incentives, and the necessary market power, to steer patients to their affiliated services.[33] Since PBMs have their own pharmacies (indeed the largest pharmacy chain CVS owns the second largest PBM) PBMs frequently access rival pharmacy patient data and provide it to their pharmacy affiliate in an effort to steer patients away from rivals. Patients may be forced into PBM-owned mail order or 1–800 specialty pharmacy operations that provide an inferior level of service to competing community pharmacies and specialized pharmacies like AIDS Healthcare Foundation pharmacies.[34] Or the PBMs may engage in egregious auditing practices to harm rival pharmacies.

PBMs "offer" independent pharmacies "take it or leave it" contracts, where a pharmacy must choose between accepting unfavorable reimbursement terms, or exclusion from the PBM's network (and patient population). In some cases, pharmacies are coerced into agreeing to below-cost reimbursement. This unsustainable choice has forced many pharmacies to close their doors.[35] This has caused what has been characterized as "pharmacy deserts" and has disproportionately harmed rural and urban African American and Hispanic populations that now lack pharmacies because PBMs have driven the independents out of business, but these PBMs do not put new pharmacies in these locations and instead they steer patients to mail order or long distance driving.[36] This is a significant problem for these vulnerable patients because no group of healthcare providers is as accessible, service oriented and dedicated as community pharmacies.[37] A community pharmacist is there to serve the patients and make sure they get the right prescription at the lowest cost. That is why consumer and patient groups have consistently supported the advocacy efforts of community pharmacies and their requests for PBM reform. The FTC has heard these concerns but has chosen not to take any action to prevent PBM predatory behavior designed to eliminate pharmacy competition. Patients lose when community pharmacies are handcuffed in the competitive battle.

And, when state legislatures try to pass basic reform laws to protect independent pharmacies and consumers from predatory practices of PBMs, the PBMs, without fail, bring lawsuits to challenge such statutes based on ERISA (the Employee Re-

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[30] *See Pharmacy Middlemen Made $223.7 Million From Ohio Medicaid,* Kaitlin Schroeder, June 23, 2018, Dayton Daily News, *https://www.daytondailynews.com/news/pharmacy-middlemen-made-223-from-ohio-medicaid/JsPLtbs3wfKoBmaGbF9GrK/*

[31] *Id.*

[32] Ohio Pharmacist Association Press Release, *Ohio Auditor releases stunning Medicaid PBM audit report, https://www.ohiopharmacists.org/aws/OPA/pt/sd/news_article/184063/_PARENT/layout_interior_details/false.*

[33] Vertical Integration Isn't Great for Health Care Consumers or Purchasers, PURCHASER BUSINESS GROUP ON HEALTH (Aug. 23, 2021) available at *https://www.pbgh.org/despite-claims-vertical-integration-isnt-great-for-health-care-consumers-or-purchasers/.*

[34] Dr. Michael Wohlfeiler of the AIDS Healthcare Foundation testified in the CVS-Aetna Tunney Act proceeding that the merger could endanger HIV and AIDS patients because the merged firm could steer its "patients to leave HIV and AIDS specific treatment providers for providers that are unequipped to treat those conditions." *United States v. CVS Health Corp.,* 407 F. Supp. 3d 45, 57 (D.D.C. 2019). AHF has created an extraordinarily successful model for delivery of care to HIV/AIDS patients, a one stop shop model in which AHF functions as a testing, linkage, specialist, health insurer, pharmacy, and price care facility. Patient steering to cookie-cutter models results in fragmentation of care, inferior quality of care, and severance of trusted provider relationships, which is very problematic for vulnerable patients with chronic conditions like HIV.

[35] Markian Hawryluk, *The Last Drugstore: Rural America is Losing Its Pharmacies,* WASH. POST (Nov. 10, 2021), *https://www.washingtonpost.com/business/2021/11/10/drugstore-shortage-rural-america/.*

[36] *Id.,* Stacy Mitchell and Charlie Thaxton, *The Rebirth of Independent Pharmacies Could Cure Rural Ills,* The American Conservative, November 5, 2019, *https://www.theamericanconservative.com/articles/the-rebirth-of-independent-pharmacies/.*

[37] *See,* Stacy Mitchell, *Small Pharmacies Beat Big Chains at Delivering Vaccines. Don't Look So Shocked,* Washington Post, February 5, 2021, *https://www.washingtonpost.com/outlook/small-pharmacies-beat-big-chains-at-delivering-vaccines-dont-look-so-shocked/2021/02/05/6bb307ec-671b-11eb-886d-5264d4ceb46d_story.html.*

tirement Income Security Act of 1974) pre-emption. Recently, such PBM reform passed by the State of Arkansas, which guaranteed that Arkansas pharmacists would be reimbursed by PBMs for the dispensing of drugs at least the amount of their wholesale cost, was challenged by the PCMA. This lawsuit culminated in a unanimous decision by the U.S. Supreme Court that such PBM reform legislation aimed at protecting independent pharmacies in the wake of PBM oppression is not pre-empted by ERISA. *See Rutledge v. PCMA,* 141 Sp. Ct. 474 (2020). While consumers hold out hope that such state protections could open a fair playing field for pharmacies, PBMs have found ways to circumvent such laws resulting in more invasive pharmacy audits, network exclusions and increased pharmacy terminations.

Legislative Action to Prevent PBM Abuse

We are at a crucial turning point on PBMs. It is increasingly evident that these middlemen are significantly increasing drug costs and reducing access because of clear market failures and a lack of meaningful regulation. We can ill afford middlemen that extract $28 billion in profits or $9 billion in DIR fees and increasingly deny consumers access to the lowest price and most efficacious drugs and the most effective pharmacy services.

This Committee should consider amending the FTC Act to specify certain practices that harm consumers and competition as "unfair or deceptive acts or practices" and "unfair methods of competition." Congress established the FTC to use a broad range of powers including enforcement and regulation to prevent and proscribe practices that were harmful to the marketplace. In doing so, Congress established a flexible standard in which it has occasionally proscribed certain practices as an "unfair or deceptive act or practice."

This Committee should evaluate what practices should be considered for potential enforcement. Some of the practices that should be considered include:

- Failing to pass on all rebates and clawbacks to payors and patients;
- Basing PBM compensation on the price of a drug;
- Schemes that prevent lower priced drugs from being included on a formulary or being placed in a disadvantageous position;
- Discrimination in reimbursement to pharmacies;
- Forcing pharmacies to dispense below acquisition cost;
- Failing to disclose DIR and other associated fees; and
- Discriminatory practices against community pharmacies.

The FTC should be given broad rule making power to address these practices. In addition, the Commission should be instructed to use its 6b power to study past PBM mergers including the ESI-Medco merger. Congress should use all its powers to insure this is a major priority for the FTC.

Concluding Thoughts

The dominant PBMs play a significant role in driving up prescription drug prices, reducing patient choice of medicines that they need, and lessening competition among pharmacies. Patients care deeply about rising healthcare costs, including out-of-pocket costs for prescription drugs, as well as ensuring they can access the medicines that they need. If PBMs continue to evade FTC scrutiny, they will continue to engage in egregious conduct that is fraudulent, deceptive, and anticompetitive. What health plans and employers should fundamentally be purchasing is the service of an honest broker to secure the lowest prices and best services from both pharmaceutical manufacturers and pharmacies. When PBMs exist in a regulatory-free environment, the result is misaligned incentives and inherent conflicts of interest. Fraud, deception, anticompetitive conduct, higher prices, and reduced choice harms payors, including the government and taxpayers, and, most importantly, patients, who rely on access to lifesaving and life-managing prescription drugs.

I look forward to answering any questions.

Senator BLUMENTHAL. Thank you so much, Mr. Balto. And now, Mr. Garthwaite.

STATEMENT OF CRAIG L. GARTHWAITE, PH.D., PROFESSOR OF STRATEGY, HERMAN SMITH RESEARCH PROFESSOR IN HOSPITAL AND HEALTH SERVICES MANAGEMENT, DIRECTOR OF PROGRAM ON HEALTHCARE AT KELLOGG (HCAK), KELLOGG SCHOOL OF MANAGEMENT, NORTHWESTERN UNIVERSITY

Mr. GARTHWAITE. Thank you, Chairman Blumenthal and Ranking Member Blackburn for inviting me today. As we discussed, the high and rising price of pharmaceuticals attracts a deservedly large amount of attention from policymakers, the press, and citizens across the United States.

Many point to these high prices as evidence of a clearly broken market. However, it is not clear that is obviously true. High pharmaceutical prices represent a fundamental tradeoff that sits at the center of the U.S. health care market. New drugs are developed through a risky and expensive process where we ask private firms to provide enormous amounts of capital at risk to fund scientific progress.

Evidence of the progress in this field abounds as we now treat huge numbers of diseases that previously would have been death sentences. In order to generate the incentives to make these investments, we provide innovative firms with time limited periods of market exclusivity where they have the ability to charge higher prices. These higher prices do decrease access to medications today.

However, we tradeoff that lack of access today in order to get new drugs in the future. In this way, the system provides access in the future to people who have no treatments available at any price today. And while there are many potential current concerns about our existing pharmaceutical system, a critical point is that the high prices today need to generate sufficient returns to generate new products in the future.

If instead, these firms are captured or dissipated by other people in the pharmaceutical supply chain, our existing system may not provide the optimal incentives. Understanding whether firms are capturing this value requires more context about prices in the pharmaceutical supply chain. In the U.S., there are many prices associated with prescription drugs, as we have talked about already.

Of particular importance in today's hearing is that there is a publicly available list price that is set by the manufacturer. Payers, such as insurers or large employers, then employ pharmacy benefit managers to, among other things, negotiate rebates or discounts from this list price. And that leads us to the focus of the hearing today, these PBMs or pharmacy benefit managers.

As Chairman Blumenthal noted, most Americans have no clue what a PBM is, but they are central to everything about pharmaceutical distribution and insurance in the United States. They take their relatively obscure position in the market, but they control everything about our access to drugs. In return for those activities, PBMs do earn revenue through a variety of means.

A primary concern, then, is whether they capture too much value through those means. And given the high concentration in the market that David Balto spoke about, and increasing amounts of

vertical integration, it is logical people should be concerned about a possibility of where the market is providing an efficient outcome.

One primary area of concern are these list prices and rebates in the system, which directly cause higher consumer cost sharing payments. Given PBMs often receive their payments as a function of the list price, the pitch—the push for high list prices is seen as abuse by PBMs of the market. But like many things in health care, the reality is likely far more complex.

Plan sponsors, these insurers and these large employers, use the system of rebates and high cost sharing as a way to decrease the premiums for their insurance products. This is done to make the products more competitive and to help them gain share in the market. The result of that is that we are witnessing, through rebates and cost sharing, a reintroduction of the concept of medical underwriting in health insurance that was taken away by the Affordable Care Act.

Through a combination of predictable cost sharing payments and high premiums, individuals with chronic conditions such as diabetes and those with expensive acute conditions such as cancer are paying more for insurance so healthy people can pay less. It is important to note this does not appear to be driven independently by the PBMs. Instead, it is driven by the demands of their clients.

PBMs have long offered contracts to these plan sponsors where rebates were passed along to the customer at the point of sale. Plan sponsors have routinely ignored these contracts in favor of capturing high rebates. That fact should influence policy. If we are worried about high list prices leading to high cost sharing, we should attack that directly through Congressional action.

That said, there are also features of the markets where PBMs do appear to be exploiting a lack of transparency. For example, we are now seeing increasingly administrative fees that are a function of the list price. Those are often not apparent to the plan's sponsor. They do not have insight into the amount of money that is going between the manufacturer of the pharmaceutical and the pharmacy benefit manager.

And given that those fees are a function of the list price, you may be concerned that PBMs are taking advantage of that lack of transparency. In my testimony, I identify ways in which we can try and improve transparency to allow more complete contract negotiations between plan sponsors and PBMs. It should be clear that PBMs do play a valuable role in the market. They are counterpoint to the market power of innovative pharmaceutical firms. It is important we provide them with the tools to negotiate these lower prices.

That said, any compensation they get should reflect their unique contribution to the market. As a closing point, I will agree with what the chairman and the ranking member said, we just lack insight in many ways into the PBM market.

And so, Ranking Member Blackburn, I am heartened to hear that you have a bill to have the GAO look more into this because without more information about how PBMs interact with manufacturers and PBMs interact with the plan sponsors that they are giving rebates to, we simply are not going to be able to develop good policy in this area. Thank you very much.

[The prepared statement of Mr. Garthwaite follows:]

PREPARED STATEMENT OF CRAIG L. GARTHWAITE, PH.D., PROFESSOR OF STRATEGY, HERMAN SMITH RESEARCH PROFESSOR IN HOSPITAL AND HEALTH SERVICES MANAGEMENT, DIRECTOR OF PROGRAM ON HEALTHCARE AT KELLOGG (HCAK), KELLOGG SCHOOL OF MANAGEMENT, NORTHWESTERN UNIVERSITY

In contrast to other developed countries, the United States relies more heavily on private markets to finance and provide healthcare services. This use of economic markets is not a policy accident and instead reflects an intentional belief that market-based healthcare provides many advantages. A large and diverse country such as the United States has a wide variety of preferences and meaningful differences in the willingness to pay for quality. In this setting, the central planning inherent to regulated prices is unlikely to maximize welfare, and an economic market is the superior method of allocating goods and services. This is even more true once we consider the variety of economic actors necessary for the development of innovative new healthcare products and services. It is hard to imagine what omniscient actor could balance the forces necessary to promote value creating innovations more efficiently than the market.

Therefore, despite many contentions to the contrary, a market-based system remains the best mechanism for providing the appropriate incentives for long term welfare maximization in the U.S. healthcare market. However, relying on the market for the provision of such a vital set of goods and services requires both recognizing that healthcare markets, like any other market, can fail and that all markets require vigilant protection of the structures and institutions necessary to promote robust and vigorous competition.

Concerns about the appropriate role for markets in healthcare are perhaps most frequently discussed in the world of pharmaceuticals. These discussions are motivated by high and rising pharmaceutical prices. While many claim these high prices provide prima facie evidence of a market failure, in reality they are the result of the complex and delicate balancing of incentives that sits at the center of the U.S. healthcare market.

This delicate balance is necessary because market failures at the center of the innovative process for developing new drugs requires some degree of market intervention in the first place. This failure results from that fact that the scientific advancements generated by firms developing innovative pharmaceutical products are essentially a public good, *i.e.,* the knowledge is effectively non-rival and non-excludable.[1] Rational firms realize they will be unlikely to capture a sufficient amount of the value generated by the large, fixed, and sunk investments necessary to bring a product to market. This results in an economic phenomenon known as "hold up" whereby firms, absent some form of government intervention, are unwilling to make value creating investments in the first place.

To address this initial market failure, governments offer various forms of intellectual property protection. Through patents or other forms of market exclusivity, governments arm firms with time limited periods of enhanced market power that allow them to capture a larger portion of the value created by their innovative products. During this limited time period, higher prices than would otherwise exist curtail some access to valuable medicines. This reduced access is deliberately traded off for the development of new products in the future.[2] These new products, however, provide access to patients for whom there would otherwise be no available treatments.

In this way, policies governing the development of pharmaceutical products involve trading off the *static inefficiency* of reduced access to products today in order to create the *dynamic efficiency* of the increased development of new products. To the extent the value created by the new products exceeds the welfare losses resulting from the high prices (and decreased quantity), the granting of these periods of market exclusivity is welfare enhancing. This could be true even if the prices today are quite high.

This tradeoff is a source of much of the controversy surrounding prescription drug prices because it involves some number of readily identifiable individuals who are

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[1] The degree to which this is fully a public good depends on how much information can be gleaned from the actual product, the regulatory filings, and the published research. For example, small molecule products can be more easily reverse engineered and therefore absent intellectual property protections are relatively easier to copy. Biologic products, however, have a more complex production process and therefore copying the technology is easier than making the product *de novo* but harder than for a small molecule product.

[2] In considering this tradeoff it is important to consider the role of health insurance in mitigating decreased quantity resulting from high prices. To the extent that insurance mitigates some of this quantity decline it is possible that the welfare loss are smaller than would be expected. See D. Lackdawalla and N. Sood, "Health Insurance as a Two-Part Pricing Contract," *Journal of Public* Economics, 2013, 102: 1–12.

unable to access existing and potentially life-saving medications.[3] Unsurprisingly, this particular form of a lack of access garners large amounts of press and political attention. However, it is critical to remember a perhaps far greater access problem for patients suffering from conditions for which no treatment options exist at all.[4] For these individuals, there is no price at which they can purchase a treatment. These patients will gain access in the future only as a result of the dynamic incentives created by intellectual property protection. As we consider the optimality of policies governing the pharmaceutical market, we must balance the oft-discussed need for access to existing products with the less-discussed lack of access from the absence of effective treatments.

A central parameter of this tradeoff of static and dynamic incentives is the relationship between the elevated prices paid for prescription drugs today and the incentives of innovative firms to develop new products in the future. Economic research has clearly documented a relationship between increased market size and investments in research and development.[5] Therefore, to the extent high prices signal expected economic returns for the providers of the risk-based capital necessary for innovation then the prices could represent a welfare enhancing policy choice. However, if the revenue generated by high drug prices is instead captured by other parts of the value chain there are valid concerns that our current policies are not providing an optimal level of innovation to outweigh the welfare losses from the price related reduced access.

Determining the optimality of this tradeoff in today's market requires a more careful understanding of the pharmaceutical supply chain. In particular, it is important to understand how various firms capture a share of the value created by innovative pharmaceutical products. provides a broad overview of this supply chain and the flow of funds across firms at its various stages. Perhaps most important for today's hearing is the relationship between manufacturers, payers, and pharmacy benefit mangers (PBM), which is depicted in the figure's upper right corner.

While largely unknown to customers, PBMs are the private firms that effectively manage all aspects of insurance coverage for pharmaceuticals. Despite their relative lack of attention, these firms occupy a central role in nearly every facet of the pharmaceutical distribution and insurance market. At a high level, PBMs sign contracts with plan sponsors (*e.g.,* risk bearing health insurers or employers) to undertake activities such as negotiating drug prices, establishing pharmacy networks, processing pharmaceutical claims, and developing drug formularies.

In return for these activities, PBMs earn revenue through a variety of means. These include, but are not limited to, direct per member per month (PMPM) fees paid by plan sponsors, the ability to keep a negotiated share of the rebate (*i.e.,* the discount from the manufacturer that the PBM is able to negotiate), spread pricing (*i.e.,* the difference between what a PBM is paid by a plan sponsor for a drug and what they pay to the pharmacy to fill the prescription), and various administrative fees from manufacturers.

The primary role of PBMs is to help manage the static inefficiency resulting from high prices. Historically, these firms emerged to implement some degree of managed care and negotiation to the pharmaceutical benefit offered by plan sponsors. In particular, they allowed relatively small insurers to pool together and negotiate as a group against manufacturers.[6] By constructing formularies, PBMs negotiate lower prices and can increase access to products and potentially to insurance overall. Of course, such activities limit revenues to pharmaceutical manufacturers and have

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[3] Garthwaite, Craig, and Benedic Ippolito. 2019. "Drug pricing conversations must take the cost of innovation into consideration." STAT. January 11.

[4] This is particularly true because the impact of high prices on quantity is far more complicated in a world of widely available health insurance. Those who are insured may not suffer as much decreased access as they would in a market without third party payment. However, those for whom drugs do not exist certainly will not access a treatment at any price.

[5] D. Acemoglu and J. Linn. 2004. "Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry," *The Quarterly Journal of Economics,* 119(3): 1049–1090; A. Finkelstein, "Static and Dynamic Effects of Health Policy: Evidence from the Vaccine Industry," *Quarterly Journal of Economics,* 119(2): 527–564; Dubois *et al.,* 2015"Market size and pharmaceutical innovation," *RAND Journal of Economics,* 46(4): 844–871; and Dranove, Garthwaite and Hermosilla, 2020. "Pharmaceutical Profits and the Scientific Novelty of Innovation," *NBER Working Paper #27093.*

[6] Z. Brot-Goldberg, C. Che, and B. Handel, "Pharmacy Benefit Managers and Vertical Relationships in Drug Supply: State of Current Research," *NBER Working Paper #29959,* April 2022.

been shown to blunt incentives to develop new products.[7] This demonstrates the importance of the role of PBMs in the tradeoff central to drug development.

It is important to note that if the construction of formularies represents the preferences of consumers for access to new products, a reduction in innovative activity is not necessarily a problem. After all, our goal is to maximize welfare not innovation. However, if the reduction of revenues to manufacturers comes instead from PBMs capturing an inappropriately large fraction of spending as profits—there could be concerns about whether the pharmaceutical market is operating in a way that maximizes welfare. In particular, concerns about whether the welfare losses from the lack of access today are sufficiently offset by incentives to develop new products in the future. These concerns are central to today's hearing investigating the PBM market.

Concerns about this possibility stem from features of the existing market. For example, the PBM market is dominated by three large firms—Caremark, Express Scripts and OptumRX. Figure 2 contains the market share of each of these firms in 2021 and shows that these firms comprise approximately 80 percent of all volume in this market. Beyond concentration, there have also been changes in the vertical structure of this industry over time as each of these PBMs is now part of a larger firm that also owns health insurers, specialty pharmacies, and medical providers. The degree of vertical integration can be seen in Figure 3.[8] These concerns are magnified by the relative opacity of the process by which pharmaceutical prices are determined. While none of these market features (*i.e.,* the high concentration, increased vertical integration, or opaque pricing) provide clear evidence of a potential problem they are areas that should be investigated. This is likely why this market has attracted the attention of a variety of regulators and policymakers.

Given these concerns, I will concentrate my testimony today on the relationships between plan sponsors (*i.e.,* third party payers such as insurers and employers), PBMs, and manufacturers. In particular, I will focus on the degree to which features of these relationships may allow PBMs to capture more value than might be appropriate or whether negative features of the market instead reflect the actions and incentives of firms in other parts of the value chain.

A consistent point to consider throughout my testimony is that any analysis of this market is meaningfully hampered by a lack of information about numerous features of the contractual arrangements between the various types of firms. While it is easy to identify potential areas of concern, without more information about the nature of these arrangements it is difficult to truly understand the validity of such concerns. Therefore, Congressional action in this area should be initially focused on creating more insight for regulators into these areas. That said, I will also highlight several policy options that exist to more directly confront potentially undesirable features of the current pharmaceutical market without generating unintended consequences.

I. Pricing, Rebates, and Cost Sharing in the U.S. Pharmaceutical Market

In the U.S., there are many prices associated with pharmaceutical products. Of particular importance to today's hearing, pharmaceutical products have a publicly available list price that is set by the manufacturer. Payers then employ PBMs to, among other things, negotiate rebates (*i.e.,* discounts from list prices) on the pharmaceuticals purchased by their enrollees.

PBMs are able to secure the discounts based on their ability to shift customers across competing therapeutic substitutes. For example, if there are two brand-name statin medications that treat high cholesterol, the PBM can place the product from a manufacturer offering a lower net price on a more preferential tier of its formulary, thus lowering the out-of-pocket payments from an individual enrollee when they purchase the drug. This should result in this product selling higher quantity, albeit at a lower price. In extreme cases, a PBM could entirely exclude a product from its formulary if the manufacturer is unwilling to provide a sufficiently low net price (*i.e.,* they are unwilling to pay the PBM a sufficiently large rebate). The use of exclusion lists has grown in recent years. Figure 4 shows the number of products that are excluded by the largest PBMs. It is this ability to credibly threaten to move volume across products that results in larger discounts from the list price.

The increased use of strict formularies and exclusion lists has contributed to a growing spread between the list and the net (*i.e.,* post rebate) price. Figure 5 depicts

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[7] L. Agha, S. Kim, and D. Li, "Insurance Design and Pharmaceutical Innovation," *forthcoming American Economic Review: Insights.*

[8] In earlier testimony, I discussed the potential benefits and concerns of this vertical integration. This testimony is available at: *https://www.judiciary.senate.gov/download/garthwaite-testimony.*

these prices from 2014—2020 and documents a large spread between the publicly known and often discussed list prices and the actual prices received by manufacturers. This figure demonstrates that any discussion of list prices provides an, at best, incomplete picture of the returns to innovative manufacturers in this market.

The spread between list and net prices has resulted in a large amount of total rebates in the system. Figure 6 shows that in 2016, pharmaceutical manufacturers paid total rebates of approximately $127 billion—an increase of 108 percent ($66 billion) since 2011. The recent rise is larger in both absolute and relative terms than the history of this market. From 2007 to 2011, the total magnitude of these rebates increased only 42 percent, for a total increase of $18 billion.

While the increasing magnitude of rebates in the system is often discussed in a negative light, it is not necessarily a problem. After all, higher rebates could simply reflect more sophisticated or effective bargaining by PBMs. The ultimate question is which parties in the supply chain capture the value of those rebates and what features of the market determines the ability of those firms to capture that amount of value. The split of the rebate between the PBM and the payer is dictated by a contract that is the result of a bilateral negotiation between those firms. The specifics of this contract depends on the relative bargaining power of the two parties. Figure 7 contains estimates of the existing contractual structure in the commercial market with respect to rebates over time based on whether plan sponsors are large or small employers. From 2014–2018, there has been a marked increase in employers with PBM contracts that entitle them to receive 100 percent of the rebates. By that year a majority of both types of employers were using such contracts.

Unsurprisingly, PBMs often point to increasing rebates as evidence of their effectiveness. It is not clear this is accurate. After all, a large rebate can come from a higher list price, a lower net price, or a combination of both. If rebates are only the result of higher list prices then the actual price paid in the market (and the return to manufacturers) has not necessarily changed. It is tempting to think that in that situation the high list prices have little economic effect. However, even in contracts where 100 percent of the rebate flows to the plan sponsor, higher list prices can negatively impact other market participants.

In particular, high list prices can have direct and economically meaningful impacts on consumer out-of-pocket payments. This relationship between cost sharing and list prices results from the desire to maintain the confidentiality of negotiated prices. Such confidentiality provides stronger incentives for larger discounts. For this reason, the size of rebates paid to each PBM is kept strictly confidential, up to and including onerous audit restrictions in the contracts that limit the ability of the payer to monitor the financial activities of the PBM.[9]

To maintain this confidentiality, consumers whose cost sharing for pharmaceutical products is tied to prices (either because of a deductible or percentage based coinsurance) make these cost sharing payments as a function of the list rather than the net price.[10] Thus, any inefficiencies that create incentives for higher list prices (even if those are entirely offset by rebates) affect consumer out of pocket spending.[11] In the presence of liquidity constraints, this cost sharing could meaningfully reduce access to drugs in ways that magnify the static inefficiency of high drug prices. For this reason, high cost-sharing is not simply a financial inconvenience for consumers. Recent evidence has shown that increased cost sharing for consumers results in the decreased use of prescription drugs and increased mortality.[12]

The importance of cost sharing for prescription drugs has grown over time. Consider the evidence in Figure 8, which contains the average annual out of pocket payment for Medicare patients purchasing insulin. According to these data, in 2018 nearly 30 percent of Medicare patients purchasing insulin were paying more than $5,000 per year out of pocket. This is a marked increase from 2010 where less than 5 percent of those customers had that level of cost sharing.

Insulin is not the only place where we see high cost-sharing. Overall, prescription drugs enjoy far less insurance coverage than other parts of healthcare. Figure 9 shows that insured patients are exposed to only 3 percent of their hospital spending. In contrast, patients directly pay 15 percent of their prescription drug spending out of pocket.

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[9] Weinberg, Neil, and Robert Langreth. 2017. "Inside the 'Scorpion Room' Where Drug Price Secrets Are Guarded." Bloomberg. May 4.

[10] This is mainly an issue for consumers enrolled in certain high-deductible health plans, as well as Medicare beneficiaries.

[11] While the number of consumers with this type of cost-sharing has grown, it should be noted that customers in the pharmaceutical market are largely shielded from list prices.

[12] A. Chandra, E. Flack, and Z. Obermeyer, "The Health Costs of Cost-Sharing," *NBER Working Paper #28439,* February 2021.

Given the negative health and financial effects of high cost-sharing, it is at first puzzling why such high cost-sharing persists in the market. Cost sharing is intended to be a form of utilization management that attempts to overcome the potential moral hazard arising from patients that are fully insured for their pharmaceutical purchases. This moral hazard could occur both through the overconsumption of products where the price exceeds value or more often from purchasing products that have less expensive therapeutic substitutes. Both of these would be negative features of an insurance product that cost sharing was intended to mitigate.

The ability to use cost-sharing to move patients across products is a key tool that PBMs use to negotiate lower net prices from manufacturers. However, we increasingly see high cost-sharing on products that are unlikely to be overconsumed (*e.g.,* insulin and oral oncology products) or in areas where there are no therapeutic substitutes. This suggests this high cost-sharing serves goals other than simply utilization management.

It is not obvious that cost-sharing at the levels we observe is an independent strategic choice PBMs undertake to maximize their profits. After all, if plan sponsors desired less onerous cost-sharing they certainly could instruct their PBMs to construct such a formulary. In fact, in recent testimony before Senate Finance Committee, Cigna's Chief Clinical Officer noted that formularies which pass rebates along to customers at the point of sale have existed for many years but have failed to gain traction with plan sponsors.[13]

Instead of signing contracts that pass rebates to customers, plan sponsors increasingly demand higher rebates from PBMs—even when those rebates are not associated with lower prices.[14] Such rebates come from surging list prices and contribute to higher cost sharing payments by patients. It appears that this is because the combination of large rebate payments and high cost-sharing for expensive products provides a mechanism for plan sponsors to offer lower premiums to healthy patients and higher expected costs to sick patients requiring expensive medications.

Consider the stylized example in 0 where a consumer in the deductible period pays the full list price of the drug. This customer does not benefit from any of the negotiation efforts of the PBM. Both the PBM and plan sponsor, however, can profit from the consumer's purchase of a prescription drug because these firms still collect a rebate when one of their patients buys a pharmaceutical product. This is true even when the product is entirely paid for by the patient. A similar logic exists when a patient makes a very large cost sharing payment because of coinsurance. Sponsors are then able to use those extra rebate dollars to lower premiums or decrease the cost of employer provided healthcare. In this way, high cost sharing combined with large rebates reintroduces medical underwriting and unwinds the community rating of health insurance premiums.

This stylized example is not simply an academic exercise. In a recent Senate Finance Committee report on insulin pricing, the Eli Lilly CFO for Diabetes noted that PBMs reacted negatively to a potential lower list price product because their customers (*i.e.,* plan sponsors) reported that "such adjustment may impair market competitiveness (*i.e.,* rebate levels on lower gross price levels translating to higher plan premiums." [15]

Understanding these dynamics is important in considering the causal role of PBMs with respect to increasing list prices and rebates. It suggests that much of the furor at PBMs over increasing list prices, rebates, and cost sharing may be aimed at the wrong target. If such contractual features are being dictated by PBM clients (*i.e.,* plan sponsors) than regulators should more carefully consider the incentives of those plan sponsors when constructing policy in this area. Furthermore, as I discuss below, if the concern about high list prices is primarily motivated by the effect on cost sharing there are policies that can be considered which more directly address this cost sharing.

II. Lack of Transparency in Financial Relationships in the Value Chain

While a large portion of plan sponsors have signed contracts that allow them to collect all of the rebates associated with prescription drug purchases by their customers, there are still many contracts where the PBM receives a percentage of the rebate as compensation. In addition, PBMs collect other fees that I discuss below which are also a function of the list price. Some have proposed that this provides

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[13] *https://www.finance.senate.gov/imo/media/doc/Cigna%20ExpressScripts%20Testimony%20of%20Steven%20Miller%20MD.pdf*

[14] *https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf.*

[15] *https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf*

a perverse incentive for the PBM to prefer higher list priced products where there is a large rebate compared to even lower prices products with a smaller rebate.

The concern about PBMs being attracted to higher-priced drugs can be best demonstrated by a simple example. Consider a drug that currently has a list price of $100. The manufacturer proposes to the PBM a 20 percent list price increase—resulting in a new list price of $120, which is initially paid by the payer (*i.e.,* employer or fully funded insurer). The manufacturer also proposes to increase the rebate paid to the PBM by $15, resulting in a net price increase of only 5 percent (*i.e.,* the number that is reported in charts such the one shown in Exhibit 6). However, the PBM is only required by its contract to transfer 50 percent of rebates to the payer, meaning it keeps $7.50 of the rebate and the payer gets $7.50. Therefore, the payer spends $12.50 more, with $5 going to the manufacturer and $7.50 for the PBM.

Ultimately, the unanswered question is whether the $7.50 collected by the PBM in this example represents "too much" surplus or instead is the appropriate payment for its negotiating activities. In a well-functioning competitive market, we would expect that if the $7.50 the PBM captures from the example above represents too much of the surplus, the PBM would ultimately face competition from another firm offering a better contract to the payer. Such a contract would propose to decrease the total spending to the payer. However, this requires a market with multiple PBMs actively competing for contracts, a situation that may not exist in the current concentrated PBM market. Price competition between PBMs also may not emerge if the existing firms realize there are large barriers to entry and that incumbent firms would be better off not actively engaging in price wars to gain share.

Strong competition is even less likely to emerge if payers are unaware of the full scope of surplus created by their prescriptions. As discussed above, many large firms hire sophisticated benefit consultants and increasingly demand fully transparent contracts that provide them a complete picture of all "rebate" dollars. In theory, this provides information about the surplus created by their prescriptions. That said, there are reasons to be concerned that despite these efforts at disclosure, payers remain unaware of all of the funds (particularly those not labeled as rebates) flowing between the PBM and the manufacturer. For example, in addition to rebates, PBMs also receive various administrative fees and other payments from manufacturers—fees that are often a function of the list price of a drug.

The PBM and the manufacturer determine which of these payments are classified as "rebates" (and therefore covered by the price transparency and rebate sharing requirements), and what is instead an "administrative fee" (that does not need to be disclosed or shared).[16] These fees are not trivial—for some contracts they can account for 25–30 percent of the money moving between the manufacturer and the PBM.[17] Furthermore, since these fees are often structured as a function of the list price there is little economic distinction between an "administrative fee" and a "rebate." Describing this system, the Senate Finance Committee report on insulin pricing said "[a]lthough Part D plans are required to report rebates to CMS, they are not required to report administrative fees collected and retained by PBMs 'if the fees are for bona fide services and are at fair market value.' This basic lack of transparency in the Medicare program has been an area of concern to HHS OIG, as has the competing interests that PBMs and manufacturers find themselves in due to the administrative fees being based on the WAC price."[18] Figure 11 documents the increase in such fees over time in this market.

If we consider the simple example above, the situation for the payer could be even worse if, instead of offering a "rebate" of $15, the manufacturer offers a $15 "administrative fee" to the PBM. In that case, the payer would bear the full cost (*i.e.,* $20) of the list price increase, and the PBM and manufacturer would split the surplus. Ultimately, manufacturers are agnostic between describing payments to the PBM as "fees" or "rebates"—they simply care about the total amount of money they collect and distribute as a result of these negotiations.[19] Given the existing structure of contracts and cost sharing, other members of the value chain are far less agnostic about the labeling of these fund transfers.

To further complicate matters, sophisticated payers hoping to gather more information about the flow of funds between the PBM and manufacturers that results

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[16] Eickelberg, Henry C. 2015. "The Prescription Drug Supply Chain 'Black Box': How it Works and Why You Should Care." American Health Policy Institute. December.

[17] Dross, David. 2017. "Will Point-of-Sale Rebates Disrupt the PBM Business?" Mercer. July 31.

[18] *https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf, page 81.*

[19] To the extent manufacturers have preferences about this labeling it is likely related to the intersection with cost sharing discussed above. Note that high cost sharing impacts manufacturer revenue by reducing demand for pharmaceutical products.

from their prescriptions often face meaningful restrictions on the ability to audit their PBM-payer contracts.[20] These can include the exclusion of particular auditors that are deemed to hold views that are hostile to PBMs, requirements that audits be held at the headquarters of the PBM, unwillingness to provide contracts with manufacturers, restricted access to claims data, and strict limitations on the number of years that can be audited.[21] While many of these restrictions can be cast as attempts to maintain rebate confidentiality, they also increase the amount of asymmetric information between PBMs and payers about the amount of available surplus. Such information asymmetries can affect the efficiency of bargaining between these two groups.

As a result of these concerns, some have proposed policies where PBMs are not allowed to have contracts in which they are compensated based on the size of the rebate or the list price of a product. While this would certainly eliminate any perverse incentives for large rebates, it would also diminish the incentives for PBMs to push for large discounts. If the primary motivation for such policies is an underlying concern about the competitiveness of the PBM market, eliminating the ability for firms to sign incentive compatible contracts could have meaningful unintended consequences

In a similar vein, the Department of Health and Human Services previously proposed to instead address this problem by eliminating the safe harbor for rebates in the Medicare program. While this policy has been abandoned, other efforts underway have the same goal of ending confidential rebates based on the price of the drug and shift the market to a series of up-front price discounts and flat fees negotiated between PBMs and manufacturers.[22] This would effectively end the confidentiality of negotiated prices while also not decreasing the amount of surplus captured by PBMs—after all, a PBM with market power can calculate a flat fee as easily as the current percentage based-rebate system.

It is perhaps not surprising that policies from both parties are coalescing on attempting to end rebates. Frustrated by rising drug prices, people are looking for a scapegoat and a system of shrouded prices by large firms fits a convenient narrative. That said, it would be extremely unwise to limit the ability of PBMs to negotiate large discounts. Instead of ending the current system of confidential rebates, I've proposed (along with Fiona Scott Morton) that we move to a system where all payments currently paid between the manufacturer and the PBM flow first to the payer before being split between the payer and the PBM.[23] PBMs and payers would be free to negotiate any split of the rebates, fees, and other funds that are paid by the manufacturer—including contracts that compensate a PBM as a percentage of the savings that they generate. Importantly, under this policy these contracts would emerge from a negotiation between two parties with equal information about the amount of money at stake. There are variety of ways to implement the move to such a system. One possible solution would be for regulators to end the safe harbor for payments between manufacturers and PBMs and instead create a separate safe harbor for payments between manufacturers and payers. I'd note that if the current PBM market is truly competitive, this proposed policy solution should have little effect on the distribution of surplus.

III. Congress Should Address Cost Sharing and Price Negotiations More Directly

While the optimality of the existing PBM market remains unclear, it is becoming apparent that Congress should enact some meaningful reforms in this area. I offer some suggestions for such policies below.

As a starting point, there is a clear case for a reform to Medicare Part D's reinsurance program. Currently, this program blunts the incentives of firms to negotiate price discounts for the most expensive drugs and increases consumer cost sharing. Figure 12 shows the distribution of spending responsibilities under Part D. During the deductible period, the beneficiary is responsible for all the spending. Then, during the initial coverage phase, enrollees are responsible for 25 percent of their drug spending and the plans are responsible for the remaining 75 percent of spending. If individuals spend through the initial coverage period, they find themselves in the

[20] Weinberg, Neil, and Robert Langreth. 2017. "Inside the 'Scorpion Room' Where Drug Price Secrets Are Guarded." Bloomberg. May 4.

[21] Advisory Council on Employee Welfare and Pension Benefit Plans. 2014. "PBM Compensation and Fee Disclosure." Report to the United States Secretary of Labor.

[22] U.S. Department of Health and Human Services. 2019. "Trump Administration Proposes to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients." January 31.

[23] Garthwaite, Craig, and Fiona Scott Morton. 2017. "Perverse Market Incentives Encourage High Prescription Drug Prices." ProMarket Blog. November 1.

coverage gap where they are responsible for 25 percent of spending, the plan is responsible for 5 percent, and manufacturers are required to give a discount of 70 percent. If an individual spends more than the catastrophic coverage threshold (approximately $8,000 in 2019), then the government is responsible for 80 percent of all additional costs, plans are responsible for 15 percent, and beneficiaries are responsible for the final 5 percent. Given the lack of a lifetime limit on out-of-pocket spending by enrollees, this benefit structure is part of the reason why beneficiaries find themselves on the hook for exceptionally high cost-sharing for prescription drugs.

Furthermore, for high priced products the private firms empowered to negotiate on behalf of Medicare are largely shielded by reinsurance from the costs of most price increases—limiting the ability of the market to lower these drug prices. Perhaps more concerning, PBMs operating in both the commercial and the Part D markets may face different incentives for rebates across these different markets and could use the confidential nature of rebates to unnecessarily increase government Part D spending. Initially, reinsurance was not a dominant feature of Part D. This has changed. Figure 13 shows the average national plan bid across Part D firms by its component parts—the direct subsidy from the government, the base premium from the enrollee, and the expected reinsurance payment. These data show that from 2007 to 2018, the reinsurance component of Part D spending has grown from a relatively minor part of the program (25 percent of the plan bid) to the dominant source of payments to firms under Part D (60 percent of the plan bid).

This level of reinsurance shields plans from the costs of the most expensive specialty drugs—a category of products that represents a growing share of overall prescription drug spending. While such a large amount of reinsurance may have been necessary to attract plans to the newly established Part D market, it is highly unlikely this remains true today. Part D is now an established market where firms have sufficient data to make reasonable projections about potential risk. Therefore, I propose that Congress either remove catastrophic reinsurance entirely from Part D (and force plans to pay 100 percent of the cost of these expensive products) or at a minimum switch the cost sharing so that the plan is responsible for 80 percent of the spending above the catastrophic limit and the government is responsible for 20 percent.[24] This would provide the appropriate incentives for firms to strongly negotiate for larger rebates and lower prices within Part D.

Beyond changing the incentives to negotiate prices, it is clear we should find policy solutions to pass along more of the negotiated discounts to consumers. However, it is critical that any policy solution saves the proverbial baby while throwing out the bathwater by maintaining the ability of PBMs to effectively negotiate larger rebates with manufacturers. Therefore, I propose that PBMs be required to base cost-sharing payments on a number that more closely approximates the net price of the product even if it is not the exact net price associated with that purchase. For example, this number could be the average net price across PBMs for that product, the average net price for the therapeutic class, or the minimum price paid in the market, *i.e.,* the Medicaid best price. Assuming PBMs have sufficient ability to modify their formularies, any of these options should still expose the patient to enough of the cost of the product to address moral hazard concerns while not exposing consumers to artificially high prices that unwind the generosity and efficiency of the insurance contract.

Some have complained that policies that pass along rebates to consumers at the point of sale would lead to higher premiums. This fact is almost certainly true. However, this is not necessarily a problem. Our current system of using cost sharing by patients requiring expensive products to lower the premiums paid by healthier patients subverts many popular policy goals regarding the treatment of pre-existing conditions in the health insurance market. In addition, these higher premiums would reflect, in part, a more complete insurance product. It is not immediately clear consumers are fully aware of the financial exposure they have to expensive medications, and therefore we should not think that increasing the completeness of insurance in this setting is clearly a negative outcome.

IV. More Information is Needed Before Implementing New Policies Aimed at PBMs

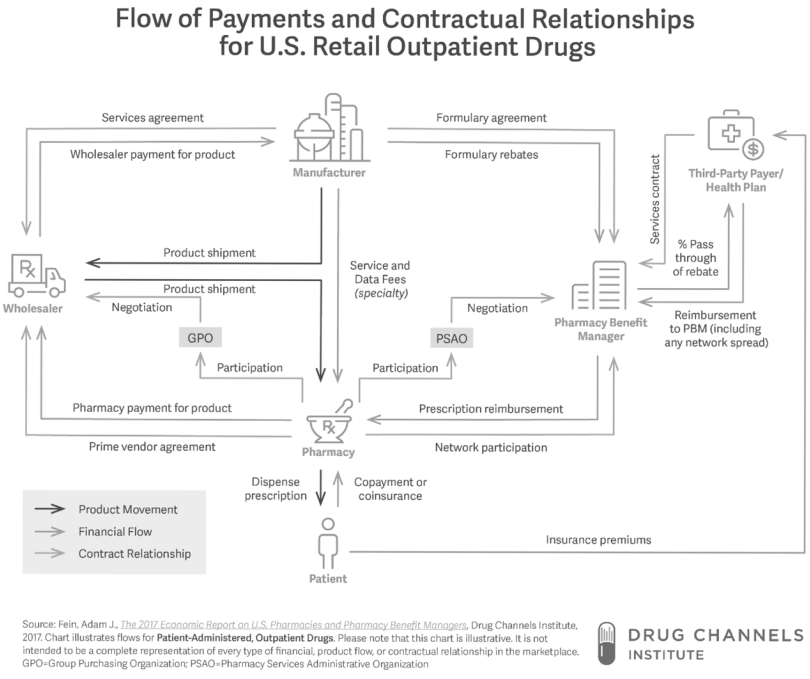
The role of various entities in the supply chain is clearly complicated. Pharmaceuticals move through a relatively lengthy supply chain inhabited by private firms with differing incentives, information, and market power. Given their central role in both negotiating prices and establishing formularies, it is tempting to blame

[24] As I discuss below, very large consumer cost sharing (such as the 5 percent of spending that patients must pay under Part D) can decrease the efficiency of insurance.

PBMs for every negative feature of the system we observe. And it is possible that such blame may ultimately be valid. However, it is also apparent that we simply lack the information necessary to determine the degree to which these aspects of the market are actually caused by the independent motivations of PBMs to maximize profits versus how much they reflect the incentives of other firms in the value chain. For example, as mentioned above PBMs have offered contracts where rebates are passed along to customers at the point of sale and plans sponsors have largely avoided those plans. This suggests a more complicated story is necessary to explain the current market dynamics.

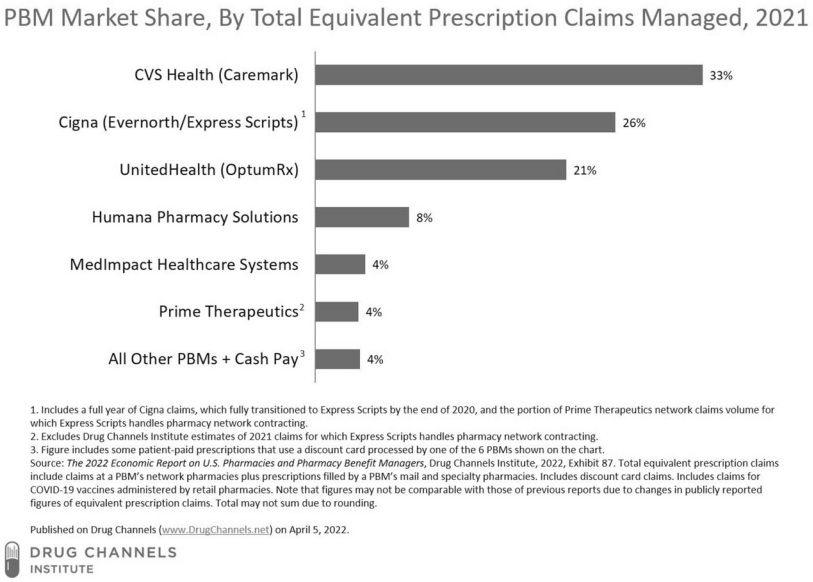
Given the uncertainty in this area, it is incumbent on policymakers and regulators to gather more information before attempting to develop and implement solutions. Certainly, the recent Senate Finance Committee investigation into insulin pricing shed some important light on the relationships between PBMs and manufacturers. In that document we learned more about the role of administrative fees and the views of PBMs about the motivations of their customers, *i.e.,* the plan sponsors. However, that report fell short on investigating the relationship between PBMs and plan sponsors. More information about those contracts and whether the actions of PBMs vary based on the contractual relationship with the plan sponsor would be useful for understanding the degree to which potentially undesirable features of the market are the result of the structure of the PBM market or other features of the supply chain.

Figure 1



Source: Drugchannels.net, available at: *http://www.drugchannels.net/p/about-blog.html*

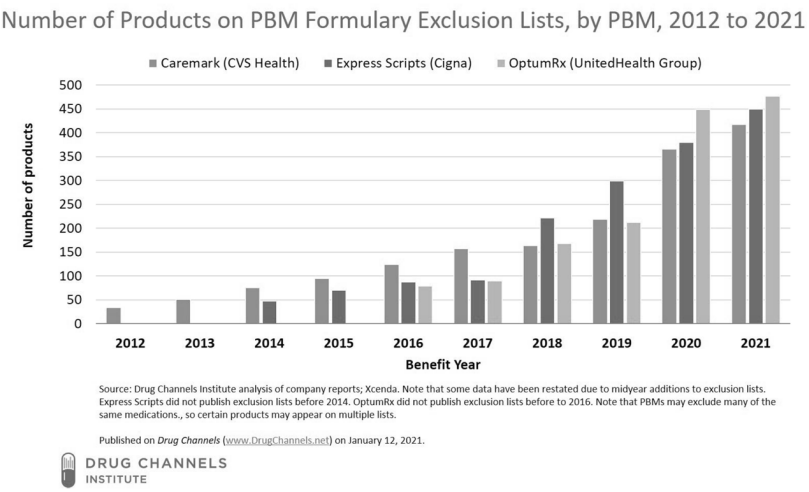
Figure 2



Source: *https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html*

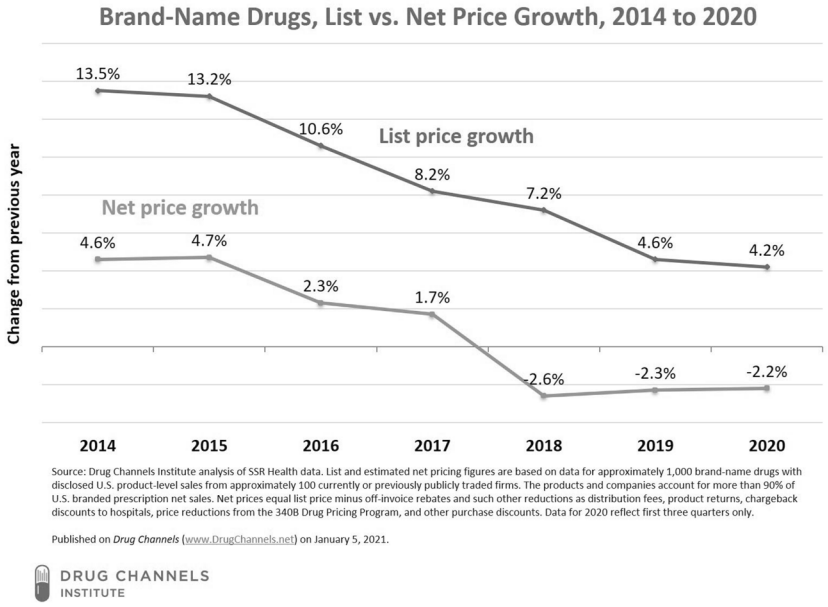
Figure 3

Figure 4



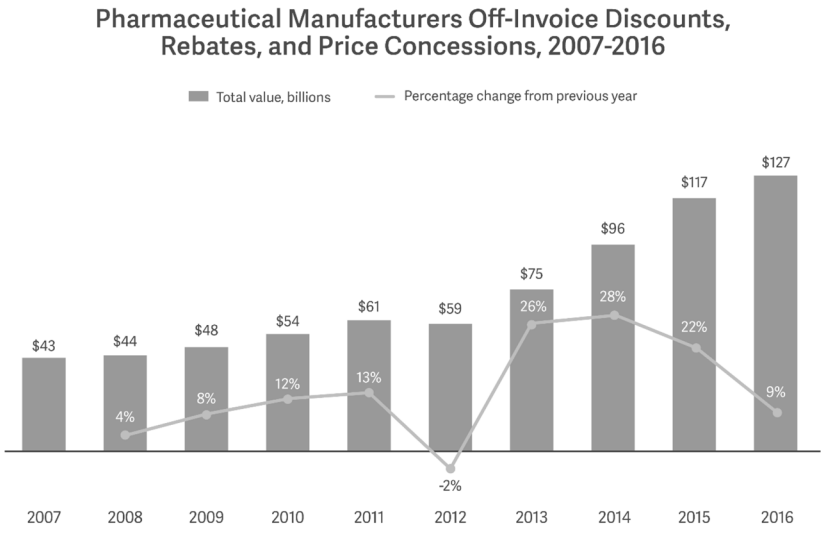
Source: *https://www.drugchannels.net/2021/01/the-big-three-pbms-ramp-up-specialty.html*

Figure 5



Source: *https://www.drugchannels.net/2021/01/surprise-brand-name-drug-prices-fell.html*

Figure 6

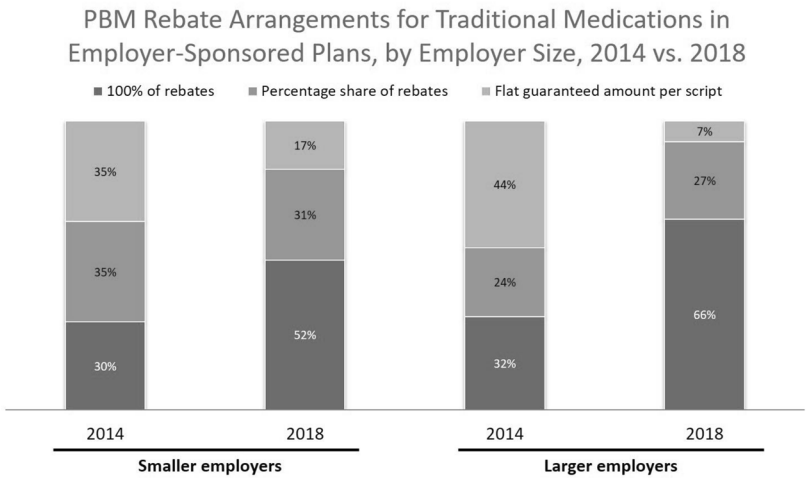


Source: Pembroke Consulting analysis of *Medicines Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021*, QuintilesIMS, May 2017. Published on Drug Channels (www.DrugChannels.net) on June 14, 2017.

DRUG CHANNELS INSTITUTE

Source: Drugchannels.net, available at: *http://www.drugchannels.net/2017/06/new-data-show-gross-to-net-rebate.html*

Figure 7



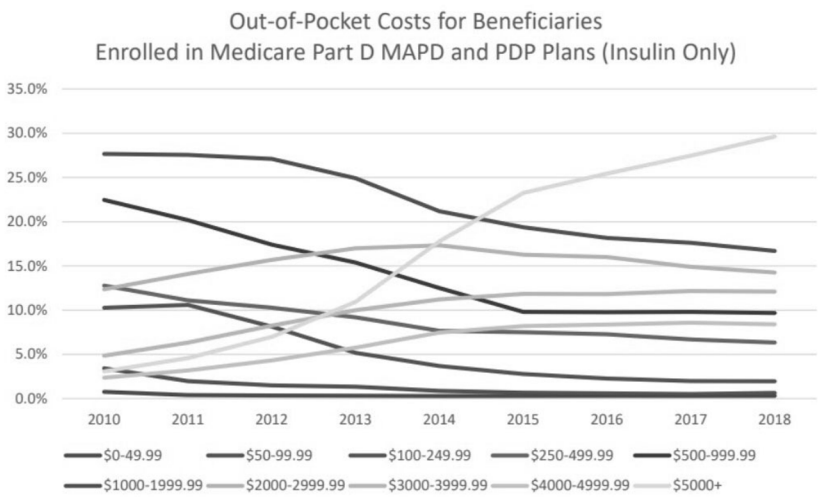
Smaller employers = 5,000 or fewer covered lives; Larger employers = more than 5,000 covered lives. Number of covered lives includes employees and dependents. Source: Drug Channels Institute analysis of *Trends in Drug Benefit Design*, PBMI, various years. Data include only responding firms that receive rebates. 2014 figures recomputed to exclude those who were not sure about their company's rebate arrangements.

This chart appears as Exhibit 132 in *The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Drug Channels Institute*. Available at http://drugch.nl/pharmacy

DRUG CHANNELS INSTITUTE

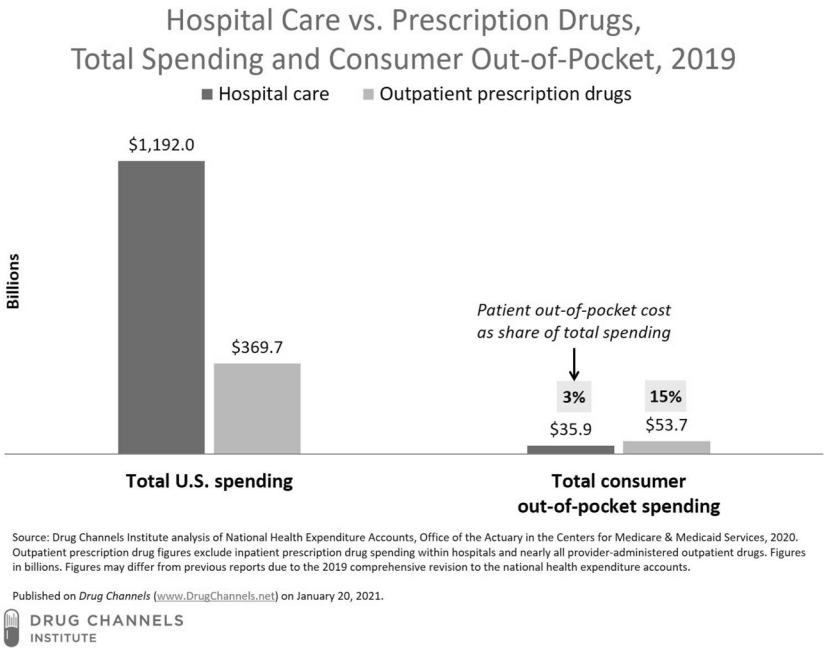
Source: *https://www.drugchannels.net/2019/03/employers-are-absorbing-even-more.html*

Figure 8



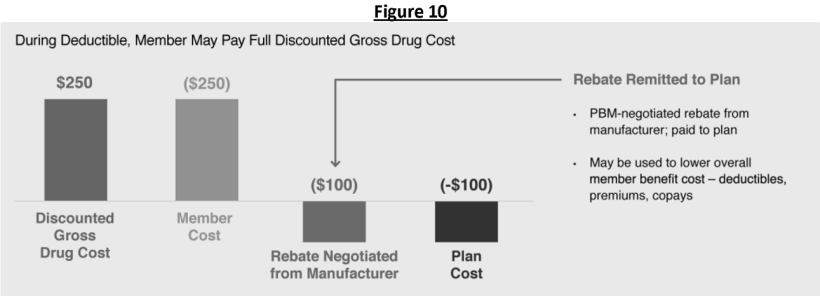
Source: *https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf*

Figure 9



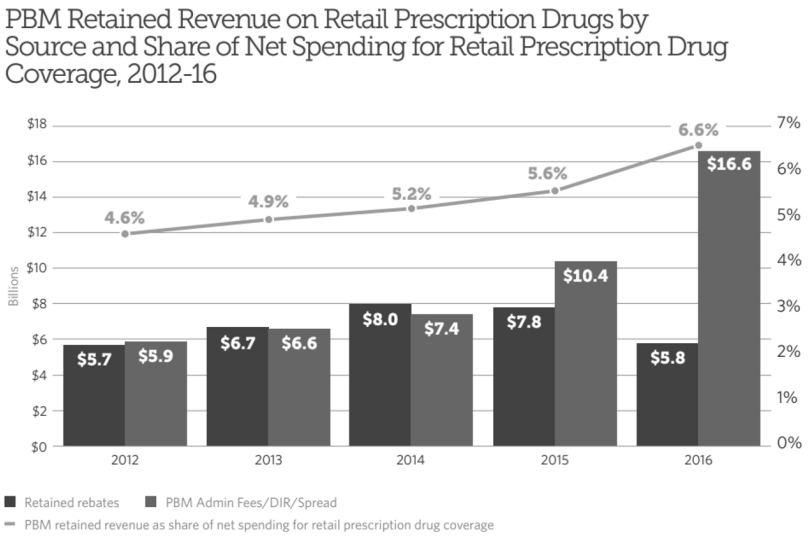
Source: *https://www.drugchannels.net/2021/01/latest-cms-data-reveal-truth-about-us.html*

Figure 10



Source: *https://payorsolutions.cvshealth.com/insights/consumer-transparency*

Figure 11



Source: *https://www.pewtrusts.org/-/media/assets/2019/03/the_prescription_drug_landscape-explored.pdf*

Figure 12

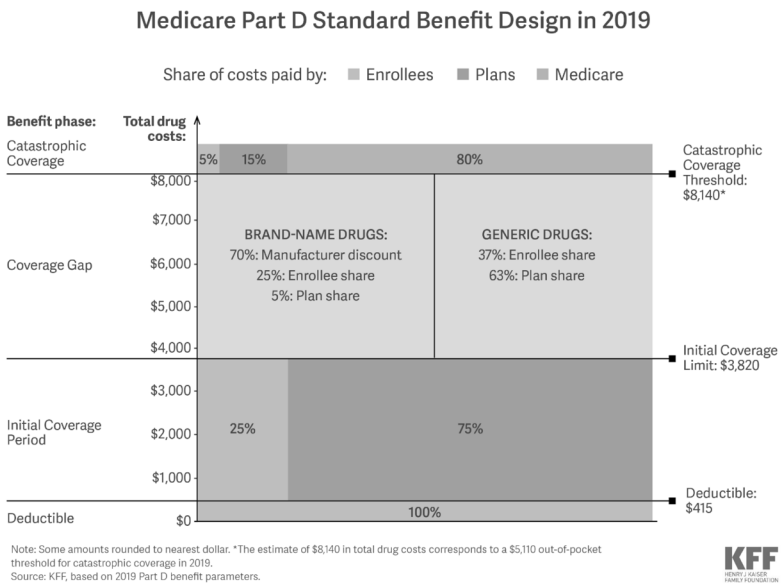
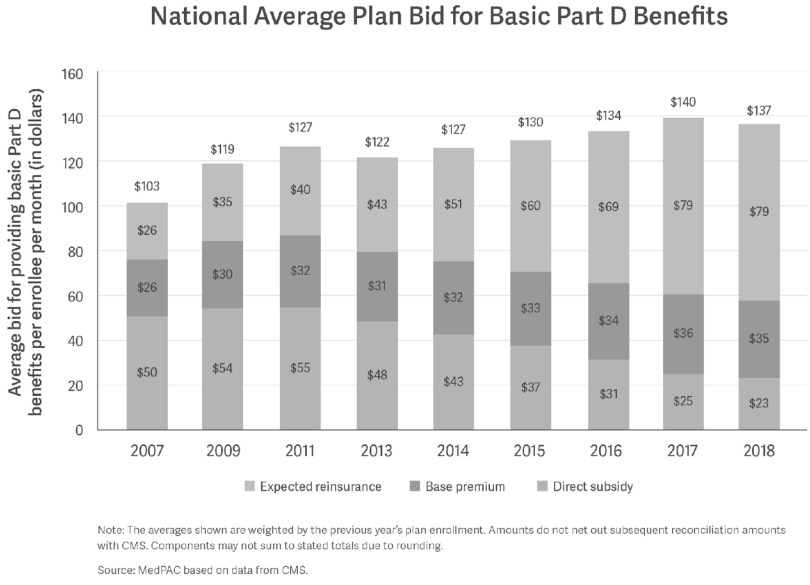


Figure 13



Senator BLUMENTHAL. Thank you very much, Professor. We will now go to Professor Feldman.

STATEMENT OF PROFESSOR ROBIN FELDMAN, ARTHUR J. GOLDBERG DISTINGUISHED PROFESSOR OF LAW, ALBERT ABRAMSON '54 DISTINGUISHED PROFESSOR OF LAW CHAIR, DIRECTOR OF THE CENTER FOR INNOVATION, UNIVERSITY OF CALIFORNIA HASTINGS LAW

Ms. FELDMAN. Thank you, Mr. Chairman, and esteemed members of the Subcommittee. Open and vigorous competition is the backbone of U.S. markets. But we are not seeing that with pharmaceuticals. Instead, we are seeing troubling and persistently rising prices on everyday medications.

Now, there are many contributors to rising prices, but a critical place to start is with the industry that sits at the center of everything. Specifically at the heart of the drug pricing system lies the industry known as pharmacy benefit managers or PBMs. And historically, PBMs operated mostly as claims processors, just handling the paperwork flow.

However, 15 years ago, when Medicare expanded to include prescription drugs, PBMs took on an expanded role as well. They began serving as a health plans representative for negotiating better prices from drug companies. There are many contributing factors, but the price increases that followed have been dramatic. For example, the prices of 65 common medicines have almost tripled just during those 15 years.

So how did this happen? How did PBMs, which were supposed to help control prices, end up helping inflate prices instead? Well, the problem has emerged because rather than act fully as honest brokers for the health plans, PBMs, perhaps unsurprisingly, act in their own interests. And it turns out that their interests are not aligned with keeping prices low. So to set the stage for how this works, consider a store that raises the price of a jacket before putting the jacket on sale at the old price.

When you walk in the store, the markdown looks like a great bargain, but it is not. For PBMs, their best interests are served when drug companies increase the starting price of the drug. That price is known as the list price. If the list price goes up and the PBM negotiates a rebate back down, the PBM looks more successful. It gets paid more by the health plan because the PBMs pay depends on the size of the rebate.

In addition, because PBMs generally get to keep a portion of the rebate, they get to pocket even more. All this might not be so bad if no one actually paid that high list price, but many plans are set up so that people do pay that list price out of pocket in various ways, and many Americans don't have coverage for prescription drugs. I talked before about raising the price of a jacket so you can put it on sale at the old price, but it gets worse.

Imagine if the price jump is higher than the sale discount. That is what is happening with medicine. Prices are rising faster than the rebates. Between 2010 and 2017 in Medicare, prices for drugs after rebates still rose 313 percent on average. We are buying the same jacket, but it is costing us more and more. And a significant portion of that increase is going to the PBMs.

And despite the fact that PBMs should be serving as honest brokers for health plans, PBMs also take side payments from drug companies for providing services to the drug companies themselves.

And what can PBMs offer drug companies to continue this payment stream of rebates and side income? Well, PBMs stand at the center of the system. As well as negotiating prices, they help decide if patients will be reimbursed for a particular medicine, how much they will be reimbursed.

So PBMs can agree with the drug company that they will exclude the competitor's product and they can also make it harder for patients to get the competitor's medicine. That is of great value to a drug company. Finally, PBMs and drug companies claim that those rebate details are trade secrets and can't be disclosed even to the health plan. Now, markets thrive on information.

And when heavily concentrated industries tightly control the flow of information, the end result is rarely in the interests of consumers. Most important, from an intellectual property perspective, simple price and price terms shouldn't be considered trade secrets at all. Thank you, and I look forward to your questions.

[The prepared statement of Ms. Feldman follows:]

PREPARED STATEMENT OF PROFESSOR ROBIN FELDMAN, ARTHUR J. GOLDBERG DISTINGUISHED PROFESSOR OF LAW, ALBERT ABRAMSON '54 DISTINGUISHED PROFESSOR OF LAW CHAIR, DIRECTOR OF THE CENTER FOR INNOVATION, UNIVERSITY OF CALIFORNIA HASTINGS LAW

Mr. Chairman and esteemed members of the Subcommittee, I am honored to be here today to address an issue that is causing real pain for consumers and for those trying to help them.

Open and vigorous competition is the backbone of U.S. markets, but we are not seeing that in the pharmaceutical industry. Instead, we see persistently rising prices on the medications people depend on, day after day, to treat widespread problems such as diabetes, high blood pressure, high cholesterol, and opioid addiction.[1] There are many contributors to the rising prices, but a critical place to start is with the industry that sits at the center of everything.

Specifically, at the heart of the drug pricing system lies the industry known as pharmacy benefit managers or PBMs.[2] Historically, PBMs operated mostly as claims processors, just handling the paperwork flow.[3] However, when Medicare expanded in 2006 to include prescription drugs, PBMs took on an expanded role, as well. They began serving as the health plan's representative for negotiating better prices from drug companies.

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[1] See CTR. FOR MEDICARE & MEDICAID SERV., FACT SHEET, DRUG SPENDING INFORMATION PRODUCTS (2018), *https://www.cms.gov/newsroom/fact-sheets/drug-spending-information-products-fact-sheet* (listing the ten drugs with highest annual price increases from 2012 to 2016 covered by Medicare); CAL. OFFICE OF STATEWIDE HEALTH PLANNING AND DEVELOPMENT, PRESCRIPTION DRUG WHOLESALE ACQUISITION COST (WAC) INCREASES (2019) (detailing wholesale price increases of more than 16 percent for hundreds of drugs between 2017 and Q2 of 2019); Feldman, Devil, supra note 1, at 2.

[2] For additional information on pharmacy benefit managers, see ROBIN FELDMAN, DRUGS, MONEY, AND SECRET HANDSHAKES: THE UNSTOPPABLE GROWTH OF PRESCRIPTION DRUG PRICES (2019) (discussing the role of PBMs in the pharmaceutical market); Robin Feldman, *Perverse Incentives: Why Everyone Prefers High Drug Prices—Except for Those Who Pay the Bills,* 57 HARV. J. ON LEG. 303 (2020) (describing the incentive structures that lead PBMs to contribute to rising drug prices); Robin Feldman, *The Devil in the Tiers,* 8 J.L. & BIOSCI. 1 (2021) (analyzing the role PBMs play in distorting the organization of drug formularies); Robin Feldman, Why Prescription Drug Prices Have Skyrocketed, WASH. POST (Nov. 26, 2018), *https://www.washingtonpost.com/outlook/2018/11/26/why-prescription-drug-prices-have-skyrocketed/* (discussing the role PBMs play in the pharmaceutical market). For a discussion of potential solutions, see Feldman, Devil, at 31–41 (suggesting that drugs should be located on formulary tiers based on list, rather than net, price to remove the incentive for anticompetitive formulary manipulation); FELDMAN, SECRET HANDSHAKES, at 95–102 (describing the significance of transparency and potential state and Federal level responses). For an explanation of why prices and price terms negotiated between PBMs and drug companies do not constitute trade secrets, see Robin Feldman & Charles Tait Graves, *Naked Price & Pharmaceutical Trade Secret Overreach,* 22 YALE J.L. & TECH 61 (2020) (defining trade secrets and discussing PBM efforts to assert that pricing arrangements should be considered trade secrets).

[3] Feldman, WASH. POST, supra note 1.

Although there are many contributing factors, the rise in prices that followed that shift fifteen years ago has been dramatic. Looking, for example, at sixty-five common medicines that need to be taken over a long period of time, prices have almost tripled during those fifteen years.[4]

So how did this happen? How did PBMs—which were supposed to make healthcare *more* efficient—end up helping to inflate drug prices instead? The problem has emerged because rather than act as honest brokers for health plans, PBMs, unsurprisingly, act in their own interests. And it turns out that their own interests are not aligned with keeping prices low. To set the stage for how this works, consider a store that raises the price of a dress before putting the dress on sale at the old price. When you walk in the store, the sale price looks like a great bargain; but it's not.

PBMs, similarly, have discovered that their best interests are served when drug companies increase the starting price of the drug. That price is known as the list price. If the list price goes up, and the PBM negotiates a rebate back down, the PBM looks more successful. It gets paid more by the health plan, and—because PBMs generally keep part of the rebate—it gets to pocket more.

All of this might not be so bad if no one actually paid that high list price. But people do. Many consumers have what are called high-deductible plans, in which they pay that high list price out of their pocket until they reach a certain threshold[5]; other plans require that patients pay a percentage of the high list price as what is known as co-insurance.[6] And many Americans still do not have coverage for prescription drugs, even if they have health insurance. Thus, people are often forced to pay the high list price.

I talked before about raising the price of a dress so you can put it on sale at the old price. It gets worse. Imagine if the price jump is higher than the sale discount. That's what is happening in the case of medicine. Prices are rising faster than the rebates are rising. For example, between 2010 and 2017 in Medicare, prices for drugs *after* rebate still rose 313 percent on average.[7] We are buying the same dress, but it is costing us more and more. And a significant portion of that increase is going to PBMs.

In addition, despite the fact that PBMs should be serving as honest brokers for health plans, PBMs also take side payments from drug companies for providing services to the drug companies.

And what do the PBMs have in their pocket to offer drug companies to continue this payment stream of rebates and side income? PBMs stand at the center of the system. As well as negotiating prices, they help decide whether a patient will be reimbursed for a particular medicine and how much they will be reimbursed. Therefore, PBMs can agree with a drug company that they will exclude the company's cheaper competitors or make it harder for patients to get the competitor's medicine.[8] That is of great value to a drug company.

PBMs and drug companies refuse to disclose the precise size of rebates or the details of the terms given, asserting that the information is a trade secret. Even auditors and regulators are not given full access. Trying to reform the system—or even talk about it—is like shadow boxing.

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[4] STEPHEN W. SCHONDELMEYER & LEIGH PURVIS, AARP PUBLIC POLICY INSTITUTE, TRENDS IN RETAIL PRICES OF BRAND NAME PRESCRIPTION DRUGS WIDELY USED BY OLDER AMERICANS, 2006 TO 2020 1–2 (2021).

[5] For an example of a plan requiring that the patient pay 100 percent of the costs of drugs up to a certain limit, see the Anthem insurance plan described at First Am. Consolidated Class Action Compl., at para. 13, In re Express Scripts/Anthem ERISA Litigation, 2018 U.S. Dist. LEXIS 3081 (S.D.N.Y. 2016) (No. 16–3399).

[6] See Medicare Payment Advisory Comm'n, Report to the Congress: Medicare Payment Policy 408–09 (2017).

[7] Feldman, Devil, supra note 1, at 19, 21–22.

[8] *See, e.g., Charles Ornstein & Katie Thomas, Take the Generic, Patients Are Told. Until They Are Not.,*)N.Y. TIMES (Aug. 6, 2017) (describing health plans forcing patients to pay more for the generic version of a drug or declining to reimburse for the generic at all;, *https://www.nytimes.com/2017/08/06/health/prescription-drugs-brand-name-generic.html?mtrref=undefined* [*https://perma.cc/U4JU–4P3X*]; *see also* Complaint, Shire U.S., Inc. v. Allergan, Inc., No. 17–7716 (D.N.J. 2017) (alleging bundled rebates for the eye medication Restasis deterred health plan formularies from including competitors); Complaint, Pfizer, Inc., v. Johnson & Johnson and Janssen Biotech, Inc., 2018 U.S. Dist. LEXIS 31690 (E.D. Pa. 2018) (No. 17–4180) (bundled rebates for the rheumatoid arthritis drug Remicade resulted in hospitals and health plan formularies essentially excluding the lower-priced biosimilar).

Finally, the PBM industry is highly concentrated. Just three PBMs control 80 percent–85 percent of the market.[9] They tend to offer the same terms to health plans. Thus, if health plans want something different, they are out of luck.

Markets thrive on information, and when heavily concentrated industries control the flow of information, the end result is rarely in the interests of consumers. Most important, from an intellectual property perspective, simple price and price terms shouldn't be considered trade secrets at all.[10]

One cannot overemphasize the major life improvements over the past century that flow from innovation in prescription medications, including new lifesaving antibiotics, treatments for pain, psychopharmacological treatments and cancer drugs. However, if we don't get a handle on the perverse incentives operating in various parts of the drug supply chain, the burden on consumers and taxpayers will continue to be crushing.

Thank you, and I look forward to your questions.

Senator BLUMENTHAL. Thanks so much, Professor Feldman. And now, Mr. Scott.

STATEMENT OF JUAN CARLOS "JC" SCOTT, PRESIDENT AND CEO, PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

Mr. SCOTT. Good morning, Chairman Blumenthal, Ranking Member Blackburn, and members of the Subcommittee. My name is J.C. Scott. I am the President and CEO of the Pharmaceutical Care Management Association, the national trade association representing pharmacy benefit managers. On behalf of PCMA's member companies, I appreciate the invitation to testify today.

Mr. Chairman, we agree drug pricing and affordability is a challenge for too many patients in America. We can and should talk about what is driving that affordability challenge and how we solve for it, which begins with an understanding of the entirety of the prescription drug supply chain, from manufacturer to wholesaler to pharmacy to those paying the bills.

Today, the Subcommittee is focused on just one piece of that ecosystem, understanding the work done by our companies pharmacy benefit managers. I appreciate the opportunity to share our perspective that our companies are delivering value for those who pay for health care coverage for patients and for patients themselves by making sure they have seamless, safe, and affordable access to the medications they need.

I know that during your time in the Senate, you have met with many people representing the health care industry. With respect to prescription drugs, you have heard from retail pharmacies who are essential to serving patients and providing access to medications, and generally speaking, argue for higher payments.

Representatives of drug manufacturers, those responsible both for the amazing innovations that benefit patients and for setting the prices, generally seek to justify their price setting decisions and

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[9] Neeraj Sood, Dana P. Goldman, & Karen Van Nuys, Follow the Money to Understand How Drug Profits Flow, STAT (Dec. 15, 2017), *https://www.statnews.com/2017/12/15/prescription-drug-profits-pbm/* ("The top three pharmacy benefit managers, which negotiate drug prices on behalf of insurers and self-insured employers, dominate 85 percent of their market."). See also Neeraj Sood, Transcript of Understanding Competition in Prescription Drug Markets: Entry & Supply Chain Dynamics Workshop (Nov. 8, 2017), *https://www.ftc.gov/system/files/documents/videos/understanding-competition-prescription-drug-markets-panel-2/ftc_understanding_competition_in_prescription_drug_markets_-_transcript_segment_3.pdf.*

[10] Robin Feldman & Charles Tait Graves, *Naked Price & Pharmaceutical Trade Secret Overreach,* 22 Yale J.L. & Tech 61 (2020) (discussing PBM efforts to assert that price and price terms should be considered trade secrets).

argue for higher, not lower prices. I am not trying to judge either of those arguments.

I simply want to make the point that the PBM industry is the only stakeholder in the chain dedicated to seeking lower costs, and we are proud to play that role. PBMs do that work for the employer, union, health plan, and Government clients who hire them, and most importantly, the patients for whom those plans provide coverage. PBMs return $10 in savings for every $1 spent on their services.

PBMs will lower the cost of health care by $1 trillion this year alone. And for many of us, that can be a hard number to get our head around. But it comes down to savings of about $962 per person per year.

PBMs lower prescription drug costs by encouraging competition in the market, promoting the use of generic medications, negotiating discounts and rebates, encouraging better pharmacy quality, and offering things like home delivery for those on chronic medications. Understandably, stakeholders in the supply chain want to be paid more for their services and products.

For the plan sponsors who are paying the bills, they need a balancing force to push for lower costs and better access, and that is where PBMs come in. The Medicare Part D program is a great example where seniors are able to choose among private plans to get their drug benefits. PBMs support Part D plans by negotiating rebates and discounts and promoting better pharmacy quality, passing the savings from those negotiations to the plans, who in turn use that to keep premium costs reliably low for seniors.

It is worth emphasizing, no employer, union, pension fund, or health plan has to hire or use a PBM, but virtually all do choose to use a PBM to lower the cost of providing health care and to better serve the patients they represent. PBM clients choose their PBMs through a transparent and highly competitive bidding process.

And Mr. Balto was right. I am going to tell you that with over 70 full service PBMs in the marketplace, including new entrants coming into the market regularly, plan sponsors have a tremendous diversity of opportunity to contract with the PBM that best meets their unique needs. Some may choose a PBM based on their scale and ability to negotiate deep discounts and manage the risk of price changes. Others choose to hire PBMs based on their innovative care management programs or different levels of service.

It is important that there is choice and the ability for plan sponsors to decide how to set up their drug benefits to best serve their unique populations. PCMA and the companies we represent are committed to working with the Subcommittee and all stakeholders to continue improving the affordability of prescription drugs for patients.

While I have talked a lot about the work we do for those who provide health coverage for consumers, the most important lens through which to judge these issues are not what will best benefit the plan sponsor or the PBM or the retail pharmacy or the manufacturer. It comes down to what best serves the consumer.

Through their work, PBMs are contributing to lower costs for health coverage for consumers, lower cost for medications, and bet-

ter access, which means more people getting the medicines they need to lead healthier lives.

I hope that this hearing is an opportunity for a continued conversation not only about the work done by PBMs, but to look at the entire supply chain so that we can identify solutions for patients and consumers. Thank you again for the opportunity to speak with you. I look forward to your questions.

[The prepared statement of Mr. Scott follows:]

PREPARED STATEMENT OF JUAN CARLOS "JC" SCOTT, PRESIDENT AND CEO, PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

Introduction

Good morning, Chairman Blumenthal, Ranking Member Blackburn, and members of the Subcommittee on Consumer Protection, Product Safety, and Data Security.

My name is JC Scott. I am the President and CEO of the Pharmaceutical Care Management Association (PCMA).

PCMA is the national association that represents America's Pharmacy Benefit Managers (PBMs), which administer prescription drug plans and operate specialty and mail-order pharmacies for more than 266 million Americans who have health coverage from a variety of sponsors, including through employers, labor unions, health insurers, Medicare Part D plans, state government employee plans, Medicaid plans, the Federal Employees Health Benefits Program, TRICARE and others.

PBMs are proud of the work they do to reduce prescription drug costs, expand affordable access to medications, and improve patient outcomes. PBMs negotiate with drug companies to lower prescription drug costs. PBMs work with pharmacies to create networks of pharmacies that provide the best value. PBMs facilitate home delivery of prescription drugs to patients safely and seamlessly, and PBMs help patients stay on their prescription drugs to live healthier lives. PBMs advocate for patients in the fight to keep prescription drugs accessible and affordable.

On behalf of PCMA's member companies, I appreciate the invitation to testify before the subcommittee today as it seeks to understand better the role PBMs play in the drug supply chain and our impact on consumers, small businesses, and drug costs.

Drug pricing and affordability are a challenge for too many patients in America. We can and should talk about what is driving that affordability challenge and how we solve it, which begins with an understanding of the entirety of the prescription drug supply and payment chain, from manufacturer to wholesaler to pharmacy to those providing health coverage.

Today, the subcommittee is focused on just one piece of that ecosystem—understanding the work done by our companies, PBMs.

During your time in the Senate, you have met with many people representing the health care industry.

With respect to prescription drugs, you have heard from retail pharmacies, which are essential to serving patients and providing access to medications, and which, generally speaking, argue for higher payments, which lead to higher drug costs.

Representatives of drug manufacturers, those responsible for both the amazing innovations that benefit patients and for setting prices, generally seek to justify their price-setting decisions and argue for higher, not lower, prices.

Understandably, stakeholders in the supply chain want to be paid more for their services and products. That is the way the market functions. But those paying the bills need a balancing force to push for lower costs and better access, and that is where PBMs come in.

The PBM industry is the only stakeholder in the chain dedicated to seeking lower costs. PBMs do that work for the employer, union, health plan, and government clients who hire them, and, most importantly, the patients for whom those health plans provide coverage.

PBMs return $10 in savings for every dollar spent on their services. As a result, PBMs will lower the cost of health care by $1 trillion this year alone.[i] For many of us, that can be a hard number to get our heads around, but it comes down to saving about $962 per person per year.

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[i] Visante. The Return on Investment (ROI) on PBM Services. An analysis prepared by Visante on behalf of PCMA. February 2020. Available at *https://www.pcmanet.org/wp-content/uploads/2020/02/ROI-on-PBM-Services-FINAL_.pdf*.

PBMs are able to negotiate for lower drug costs when they can bring competition between pharmaceutical manufacturers and between pharmacies to bear. PBMs lower prescription drug costs by using these negotiations to deliver discounts and rebates, promoting the use of generic medications, encouraging better pharmacy quality, and offering things like home delivery for those on chronic medications.

Simplifying the Consumer Experience

People with insurance filled more than 6.4 billion prescriptions in retail pharmacies in 2021.[ii] Every day, that amounts to nearly 15 million prescriptions, so it is critical that patients can pick up their prescriptions as quickly as possible at the pharmacy counter to establish and maintain medication adherence. PBMs perform many essential functions that combine disparate information and expertise, as well as advanced technology to facilitate and streamline getting a prescription filled as seamlessly as possible.[iii]

To achieve optimal PBM-patient coordination, once a pharmacy enters a prescription into the system, it is sent electronically to the patient's PBM, which checks the pharmacy benefit information to confirm the patient's insurance status and cost-sharing amount, as well as the patient's medication history for any errors and possible harmful dangerous drug interactions. While pharmacies have records of prescriptions filled by them or a fellow chain pharmacy, they do not have records of prescriptions filled in other pharmacies. However, PBMs do, as long as the patient has used insurance. Given that information and the technology, in real-time and almost instantaneously, the PBM can determine if the prescribed drug should not be taken by that patient and can alert the pharmacist to any dangerous interactions before the patient pays any cost sharing and receives any medication. All of this happens rapidly, seamlessly, and behind the scenes to improve patient safety and care.

Reducing Health Benefit Costs for Businesses

PBMs have an established record of negotiating with drug manufacturers and pharmacies to reduce drug costs. PBMs work to bring drug prices down to the lowest net cost for employers, both large and small, and others who provide health insurance.

No employer, union, pension fund, or health plan has to hire or use a PBM. But virtually all do choose to hire a PBM to lower the cost of providing health care coverage and to better serve the patients they represent.

PBM clients choose their PBMs through a transparent and highly competitive bidding process. With more than 70 full-service PBMs in the market, including regular new entrants, unions, and employers, health plans have a tremendous diversity of opportunities to contract with the PBM that best meets their unique needs.[iv]

Some may choose a PBM based on its scale, ability to negotiate deep discounts or manage the risk of price changes. Others choose to hire PBMs based on their innovative care management programs or different levels of service. For small employers, many of whom may struggle to provide health insurance to employees, PBMs lower drug costs and provide cost predictability, enabling them to stretch their benefit dollars even further.

For all those sponsoring health insurance, it is important that there is choice among PBMs and the ability to decide how to set up their drug benefits to best serve their unique populations.

PBMs typically develop a basic preferred drug list, or formulary, under the guidance of their pharmacy and therapeutics (P&T) committee. P&T committees are comprised of independent physicians, pharmacists, and other clinical experts who consider the most recent data on prescription drugs and tell the PBM what drugs it must include, must not include (for safety reasons), and may include on its formulary. The drugs it "may" include are typically for conditions or diseases for which there are competing therapeutically equivalent treatments, and for which the PBM may leverage competition between drug manufacturers to negotiate lower costs. Once the PBM has concluded its negotiations and devised its formulary, it then recommends it to those sponsoring health insurance, who may choose to utilize it, cus-

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[ii] IQVIA. The Use of Medicines in the U.S. 2022. April 2022. Available at *https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2022.*

[iii] Pharmaceutical Care Management Association (PCMA). PBM Technology and Expertise Improves Patient Health Outcomes. June 2016. March 8, 2022. Available at *https://www.pcmanet.org/pbm-technology-and-expertise-improves-patient-health-outcomes/*.

[iv] Pharmaceutical Care Management Association (PCMA). The PBM Marketplace Is Highly Competitive. April 2021. Available at *https://www.pcmanet.org/wp-content/uploads/2021/04/PBM-Landscape-2021.pdf.*

tomize it, or go with another approach.[v] PBMs create formularies of clinically appropriate drugs, preferring ones that are the most cost effective, including generic drugs, biosimilars, and lower-cost alternative brand drugs.

One method that PBMs use to lower drug costs is incentivizing the use of lower-cost generic alternatives to name-brand drugs. Indeed, generic dispensing has grown over the past decade as more generics have entered the market and patients have responded to health plan designs encouraging their use, so that now roughly 90 percent of prescriptions filled in the United States are for generic drugs, at a fraction of the cost of their brand-name equivalents.[vi] PBMs also sometimes, for some conditions, require patients to try generic drugs before trying more expensive brand drugs, and employ other tools designed to deliver high-quality drug benefits while bringing down costs.[vii]

As a result, PBMs have a pro-competitive influence on the prescription drug marketplace, and PBM services provide a significant and measurable benefit for businesses and others providing health insurance. Without PBMs in the marketplace, those organizations would be left to negotiate drug costs on their own or pay the full costs of these drugs.

Lowering Drug Costs for Consumers

As mentioned earlier, PBMs, working with those providing insurance, encourage patients through formulary design and cost-sharing incentives to use the most affordable drugs, which are usually generics. For many brand drugs, PBMs negotiate directly with drug manufacturers who compete for formulary placement by offering a type of discount called rebates.[viii] For drugs on the preferred tier of a plan's formulary, consumers typically have lower cost sharing.[ix] As competing products enter the market, PBMs gain the flexibility to leverage competitor products to negotiate deeper drug discounts for patients and payers.[x]

PBMs have also led the industry in creating contracts that account for the value of specialty and high-cost medications.[xi] Value-based arrangements are at the forefront of new drug payment designs and will be critical to managing the costs of next-generation therapies like cell and gene therapies, orphan drugs, and ultra-expensive specialty drugs. Value-based contracts will better allow plans to manage these high costs, and health plans will need broad flexibility to craft and employ value-based contracts.

The Medicare Part D program, where older Americans and those living with disabilities can choose among private plans to get their drug benefits, is a great example of PBM value. PBMs support Part D plans by negotiating rebates and discounts and promoting better pharmacy quality, passing 99.6 percent of those savings from those negotiations to the Part D plans, which in turn use them to enhance drug benefits and keep premium costs reliably low for beneficiaries.[xii]

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[v] Pharmaceutical Care Management Association (PCMA). The Management of Specialty Drugs. June 2016. Available at *www.spcma.org/wp-content/uploads/2016/06/sPCMA_The_Management_of_Specialty_Drugs.pdf.*

[vi] U.S. Food and Drug Administration (FDA). Generic Drugs. February 5, 2021. Available at *https://www.fda.gov/drugs/buying-using-medicine-safely/generic-drugs.*

[vii] Pharmacy Benefit Management Institute (PBMI). Solving America's High Drug Cost Problem: Prevent Drug Company Tactics that Increase Costs and Undermine Clinical Quality. 2020. Available at *https://www.pcmanet.org/wp-content/uploads/2021/01/Solving-America%E2%80%99s-High-Drug-Cost-Problem_whitepaper_FINAL2.pdf.* Pharmacy Benefit Management Institute (PBMI). 2017 Trends in Specialty Drug Benefits. 2017. Available at *www.pbmi.com/research.* Pharmacy Benefit Management Institute (PBMI). 2016 Trends in Drug Benefit Design. 2016. Available at *www.pbmi.com/research.*

[viii] Foley Hoag. The History of Rebates in the Drug Supply Chain and HHS' Proposed Rule to Change Safe Harbor Protection for Manufacturer Rebates. April 2, 2019. Available at *https://foleyhoag.com/publications/ebooks-and-white-papers/2019/march/the-history-of-rebates-in-the-drug-supply-chain.*

[ix] Congressional Budget Office (CBO). Prescription Drugs: Spending, Use, and Prices. January 17, 2020. Available at *https://www.cbo.gov/system/files/2022-01/57050-Rx-Spending.pdf.*

[x] Congressional Budget Office (CBO). Prescription Drugs: Spending, Use, and Prices. January 17, 2020. Available at *https://www.cbo.gov/system/files/2022-01/57050-Rx-Spending.pdf.*

[xi] Pharmacy Benefit Management Institute. Solving America's High Drug Cost Problem: Prevent Drug Company Tactics that Increase Costs and Undermine Clinical Quality. January 2021. Available *https://www.pcmanet.org/wp-content/uploads/2021/01/Solving-America%E2%80%99s-High-Drug-Cost-Problem_whitepaper_FINAL2.pdf.*

[xii] Government Accountability Office (GAO). Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization. August 13, 2019. Available at *https://www.gao.gov/products/gao-19-498.*

As another cost-saving measure, PBMs offer prescription home delivery through highly efficient, virtually error-free mail-service pharmacies. As with many other products, patients can safely access prescription drugs through home delivery. Mail-service pharmacies are convenient, dependable, and affordable. Patients will often fill the first few prescriptions at a retail pharmacy if the prescription is for a chronic condition. Patients may then choose to use a mail-service pharmacy for home delivery once they are stabilized on the medication(s). On 90-day supplies of medicines, mail-service pharmacies result in lower copayments for consumers and improved medication adherence overall.[xiii]

Savings from PBMs benefit health plans, employers, and consumers directly. Prescriptions cost health plans and employers an average of $1,315 per person per year, with consumers paying an average of $180 for their prescriptions, or 14 percent.[xiv] Without PBMs and the savings they generate, drug costs could be $2,000 per person per year.[xv]

The Value of Pharmacy Networks

PBMs lower pharmacy costs by negotiating with pharmacies to establish competitive rates at which the PBM will reimburse for each prescription that a pharmacy fills, which enables the PBM to form preferred pharmacy networks. Through these pharmacy negotiations, pharmacy networks enable PBMs to maximize accessibility, choice, and quality of service, as well as hold down costs for patients enrolled in health plans, including, among others, Medicaid, Medicare Part D, state employee plans, and employer-sponsored plans.

Pharmacies have been willing to negotiate price concessions, some based on proven volume, to ensure they have access to the plans and PBMs with the largest and fastest-growing membership bases. Often, but not always, independent pharmacies participate in preferred networks through contracts negotiated and administered by their Pharmacy Service Administration Organizations or PSAOs. As of 2019, all but one major PSAO chose to negotiate for the pharmacies they represent to participate in PBMs' preferred networks and fill prescriptions for patients served by plans utilizing those networks.[xvi] Some 83 percent of independent pharmacies contract with a PSAO.[xvii] Between 2011 and 2021, the number of independent pharmacies nationwide increased by approximately 13 percent (or by 2,645), whereas chains lost around 80 stores (0.2 percent) on average.[xviii] Today, there are more retail pharmacies in the U.S. than Starbucks, McDonald's, Burger Kings, and Subways combined.

By creating preferred networks, PBMs are able to negotiate savings that reduce Medicare Part D premiums by $63 per member per year. One study estimated that preferred networks created by PBMs for Part D health plans save Federal taxpayers at least $870 million annually.[xix]

When patients present a prescription to be filled, the pharmacies in a PBM's network dispense prescriptions for them using prescription drugs that they have purchased directly from wholesalers or manufacturers. Before dispensing a drug, the

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[xiii] O. Kenrik Duru, Julie A. Schmittdiel, Wendy T. Dyer, Melissa M. Parker, Connie S. Uratsu, James Chan, and Andrew J. Karter. January 2010. Mail-Order Pharmacy Use and Adherence to Diabetes-Related Medications. American Journal of Managed Care. Vol. 16, No. 1: 33–40. Available at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3015238/*.

[xiv] Visante. The Return on Investment (ROI) on PBM Services. February 2020. An analysis prepared by Visante on behalf of PCMA Available at *https://www.pcmanet.org/wp-content/uploads/2020/02/ROI-on-PBM-Services-FINAL_.pdf*.

[xv] Visante. The Return on Investment (ROI) on PBM Services. February 2020. An analysis prepared by Visante on behalf of PCMA Available at *https://www.pcmanet.org/wp-content/uploads/2020/02/ROI-on-PBM-Services-FINAL_.pdf*.

[xvi] Pharmaceutical Care Management Association (PCMA). Putting the Growth of Pharmacy DIR in Context. August 2021. Available at *https://www.pcmanet.org/wp-content/uploads/2021/11/Putting-the-Growth-of-Pharmacy-DIR-in-Context-2021.pdf;* Fein, Adam. The Law of Holes: Some Independents Skip 2019 Part D Preferred Pharmacy Networks. Drug Channels. October 23, 2018. (Oct. 23, 2018), Available at *https://www.drugchannels.net/2018/10/the-law-of-holes-some-independents-skip.html/*.

[xvii] Pharmaceutical Care Management Association (PCMA). Pharmacy Services Administrative Organizations (PSAOs) and their Little-Known Connections to Independent Pharmacies. January 25, 2021. Available at *https://www.pcmanet.org/research-pharmacy-services-administrative-organizations-psaos-and-their-little-known-connections-to-independent-pharmacies/*.

[xviii] Pharmaceutical Care Management Association (PCMA). Putting the Growth of Pharmacy DIR in Context. August 2021. Available at *https://www.pcmanet.org/wp-content/uploads/2021/11/Putting-the-Growth-of-Pharmacy-DIR-in-Context-2021.pdf*.

[xix] Pharmaceutical Care Management Association (PCMA). Putting the Growth of Pharmacy DIR in Context. August 2021. Available at *https://www.pcmanet.org/wp-content/uploads/2021/11/Putting-the-Growth-of-Pharmacy-DIR-in-Context-2021.pdf*.

pharmacy checks with the PBM to confirm the applicable plan design for the patient to determine eligibility, coverage, and cost-sharing information.

After the prescription is filled, the PBM reimburses the pharmacy at a contractually agreed-upon rate minus any applicable cost-sharing collected by the pharmacy from the patient. The PBM then separately bills the health plan at the rate negotiated between the PBM and the health plan.

Patients recognize potential savings and, as a result, most prefer plans with preferred networks. For plan year 2021, 99 percent of Part D beneficiaries chose Part D plans with preferred pharmacy networks—an increase from 92 percent in 2020. In a survey, 85 percent of Medicare Part D beneficiaries reported satisfaction with their preferred network plan, and nearly 80 percent said they would be disappointed if their plan were eliminated.[xx] These examples demonstrate that PBMs are delivering value to patients through intense competition amongst pharmacies for access to preferred networks.

PBMs are instrumental in ensuring that patients have good options for where to fill their prescriptions at reasonable prices, including at independent pharmacies. In Medicare Part D, PBMs and Part D plan sponsors use a form of value-based contracting referred to as "pharmacy DIR" to reward high-performing pharmacies, create high-quality pharmacy networks, promote quality access for beneficiaries, improve health outcomes, and reduce premiums. Pharmacies that help Medicare beneficiaries stay on their medications, increase generic dispensing, and improve overall patient access to care are rewarded through pharmacy DIR.

Meaningful, Actionable Transparency

Transparency that helps patients and payers is necessary across the entire prescription drug chain. PBMs support and practice actionable transparency that empowers patients, their physicians, those sponsoring health coverage, and policymakers, so that they can make informed decisions that can lead to lower prescription drug costs. Actionable transparency encourages consumers to shop for coverage that best fits their health needs and budgets, and once covered, use the most cost-effective, highest-value healthcare goods and services. It enables prescribers and patients to avoid pharmacy-counter surprises and helps ensure that physicians can prescribe drugs that are affordable for patients. To that end, PBMs provide consumers and prescribers with real-time benefit tools (RTBTs), which provide real-time information on exactly where the patient is with respect to progressing through a deductible or another benefit phase, what drugs are on the patient's formulary, and exactly what cost-sharing to expect for a given drug at the pharmacy. PBMs also provide consumers with information on in-network pharmacies, premiums, general cost-sharing, and benefits for their prescription drug coverage.

PBMs provide health plans, employer plan sponsors, and consumers with a broad array of accurate, actionable information on price and quality to make efficient purchasing decisions. PBMs' customers are able to set the terms of the transparency and information they want to receive, as well as their audit rights, as part of their contracts.

In recent years, Congress has added more requirements for PBMs to report to Federal agencies, as well as public reporting in more aggregated form, in both cases with appropriate protections for confidential data to avoid encouraging tacit collusion, efforts that we support. As the Federal Trade Commission has noted, there are limits to the benefits of transparency and unintended consequences that can result.[xxi] PBMs encourage Congress to focus its efforts on actionable transparency that reduces drug costs versus transparency that raises them.

Promising Policy Solutions

PCMA supports efforts to increase competition in the pharmaceutical market and increase patient access to needed medications. Generally, we support bills by several of the committee's members and others that would:

- Increase competition in the pharmaceutical market and eliminate patent system abuses that stifle competition.

[xx] Pharmaceutical Care Management Association (PCMA). Putting the Growth of Pharmacy DIR in Context. August 2021. Available at *https://www.pcmanet.org/wp-content/uploads/2021/11/Putting-the-Growth-of-Pharmacy-DIR-in-Context-2021.pdf.*

[xxi] See FTC Staff Comment to the Honorable James L. Seward Concerning New York Senate Bill 58 on Pharmacy Benefit Managers (PBMs), FED. TRADE COMM'N. March 2009. Available at *https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf*

- Prevent pay-for-delay patent settlements for patent infringement claims between brand and generic manufacturers.
- Put an end to abuses of the citizen petition process that may slow new competition by slowing applications seeking market approval.
- Improve Medicare's online pricing tools, allowing beneficiaries to compare costs across healthcare settings.
- Prohibit product hopping that would allow drug manufacturers to switch from an expiring patent on a reference drug to a later-expiring patent on a follow-on product.
- Reimagine and modernize Medicare Part D to allow for comprehensive benefit redesign and increased transparency while protecting sensitive proprietary pricing information and avoiding inadvertent price increases for patients and the Federal government.

I want to thank Chairman Blumenthal and Ranking Member Blackburn and Senators Klobuchar, Cruz, Peters, and others for their work on these efforts. The PBM industry looks forward to working with the committee's members on these policy concepts.

Conclusion

PCMA and the companies we represent are committed to working with the subcommittee and all stakeholders to continue improving the affordability of prescription drugs for patients. While I have spoken a lot about the work we do for those who provide health coverage for consumers, the most important lens through which to judge these issues is not what will best benefit the plan sponsor, the PBM, the retail pharmacy, or the manufacturer; it should come down to what best serves the consumer—the affordability of their health care, the ease of their access, and ultimately their health care outcomes.

Through their work, PBMs are contributing to lower costs for health coverage, lower costs for medications, and better and more affordable access for patients, which means more people getting the medications they need to lead healthier lives.

I hope that this hearing is an opportunity for a continued conversation not only about the work done by PBMs but a look at the entire supply chain so that we can identify solutions for patients and consumers.

Thank you again for the opportunity to speak with you. I look forward to answering your questions.

Senator BLUMENTHAL. Thanks, Mr. Scott. And this hearing will be indeed an opportunity to continue the conversation about all the segments of this industry. PBMs, as I indicated, right at the start, are far from the only source of increased costs. But they are, in fact, bedeviling many of the consumers we represent. Whatever the abstractions and the generalities we here in this committee room, are real life experience in Connecticut or Tennessee or elsewhere in the country show that PBMs can have a detrimental impact. And I will give you just one example.

The 47-year-old woman in Norwich, Connecticut who told my office about PBMs getting in the way of her treatment and her access to cancer drugs that she was prescribed, an oral cancer drug that was denied twice by the PBM before there was approval for the generic. The problem with the generic is that it added larger out-of-pocket costs for the patient than the brand name drugs she was denied.

I want to reiterate, she was prohibited from using the brand name drug that was prescribed, even though it would have been more affordable to her, and that is because of how the PBM set up her drug plan. Instead, she had to find assistance, literally from a charity. This 47 year old woman in Norwich had to go to a charity for help.

The PBMs who are responsible for creating these formularies, the formularies are for the health care plan. It is a core part of how

the PBMs operate, but the net effect is to deny certain drugs for patients. So if the purpose of PBMs is to lower costs for patients, how is it possible that she was denied access to a drug that would have cost her less out-of-pocket?

Mr. SCOTT. Thank you, Mr. Chairman. I think that question is for me, so I will jump in. And I think you are right to focus on the real life experience. I will share briefly, if I could, my PBM story when my dad suffered from cancer as well and Alzheimer's disease, and at the end of his life as many people who have family members who suffered through dementia and Alzheimer's know, there was a constant switching of medications that was necessary that the doctor was recommending in order to control that process.

And the plan, the Medicare plan that he was on was affordable. The drugs were covered. He was able to get the access he needed, which meant thanks to that work done by the PBM to make the system work, my mom and I were able to focus on spending time with my dad rather than focusing on those issues of medication access. So I am grateful for the work that was done.

In regards to the example you raised, Mr. Chairman, about a patient with cancer drugs and having troubles navigating the formulary system, I will just level—say if I could, that first of all, PBMs develop and recommend formularies, those lists of what drugs are covered at what cost sharing amount for the patient for the plan sponsors that hire them.

Ultimately the plan sponsors making the decision to go with the PBM recommended formulary, make alterations to it, do something else altogether. Those formulary recommendations are developed with two important lenses. The very first one is always the clinical consideration, what drugs are necessary to cover in order to meet patients' therapeutic needs.

We employ teams of physician—of outside physicians and clinicians to help make those determinations. And then in those areas where there are competing therapies available that are going to work equally well for the patient, then the lens is the economic one where the PBM is recommending the preferred formulary status to the lowest net cost drug.

So that, the intention is to address the clinical, address the lowest net cost drug, which in theory should keep the health coverage more affordable for the plan offering it and for the patient who is getting access through that plan.

Senator BLUMENTHAL. In theory, but in practice, what we see in the real world is that patients don't have access to drugs at affordable prices. And the kinds of legislation that have been introduced, and I want to give credit to our chairman, Senator Cantwell, for her work in this area and her interest in this hearing, shows that all of us on both sides of the aisle are responding to a felt need that we see in the real world.

And I might just tell you, the woman I mentioned eventually got the drugs she needed, but it took 4 months. It is a woman with advanced breast cancer waiting 4 months to get the treatment she needed. Time is not on the side of a patient. It is not a neutral factor. It is not like waiting in line for your ticket at the movies. I have heard multiple stories of patients being denied coverage of cancer drugs, and the problem is only seemingly getting worse.

While there were two cancer drugs excluded from formularies in 2017, the number now or as of 2021 is 60 cancer drugs. Professor Garthwaite provided a graph that shows the number of rapidly—that that number is rapidly increasing, especially in the last 4 years. So what assurance can you give us that this increase in exclusions isn't leading to more disturbing stories like the one that I just gave you from Connecticut?

Mr. SCOTT. Mr. Chairman, first, I completely understand the urgency of the scenario that you presented, and for any patient. As I have heard others say, every family has a lot of problems until someone gets sick and then you just have one problem.

And we probably all been through that experience of feeling that urgency. When you have a sick loved one, when you are sick yourself, you simply want to get access to the medications that you need. There are steps in the process that the PBM provides to make that in theory, again, work seamlessly so that if a doctor is recommending a different drug, if they need to go through that step therapy process, that should work in real time. There are times, as you pointed out, where there is that abrasion for the patient.

I think the entire health care system could do better making use of electronic tools and certainly in the PBM industry's case, continuing to dive into that technology, which we have started down that path, to make sure that that can happen in a more real time ways, so these questions are resolved quickly when patients need to switch their medications.

Senator BLUMENTHAL. Well, I am going to yield to the Ranking Member and then come back for some additional questions. But I just want to show you this graph. It is figure 4 in Professor Garthwaite's testimony. It is pretty—pretty graphic, pretty dramatic. And I am going to be asking some additional questions about the FTC and why it hasn't taken some action to investigate. Let me yield to the ranking member.

Senator BLACKBURN. And thank you, Mr. Chairman. Mr. Garthwaite, we hear from seniors all the time that are looking for lower cost alternatives. And so talk to me about list price erosion, what you see there, and Medicare patient out of pocket cost, and how are they going to be—when you look at these things, how are you going to be able to get to lower cost, especially as you look at biosimilars that are coming into the marketplace in 2023, and maybe they are not on the formulary, maybe there is another rebate. So, just in the nugget, let's touch that impact on the market.

Mr. GARTHWAITE. I will do my best as an academic. To speak in a nugget, it is not really what we are good at——

[Laughter.]

Mr. GARTHWAITE.—but I think one thing is you want to think about what—we say cost, what we mean, right, and there is sort of clearly, there is out-of-pocket cost and then sort of the cost of the plan. I think what we have seen, particularly in Medicare Part D, is surging out-of-pocket costs for seniors. And I encourage Congress, in my testimony, to do something to address that.

There is no reason why we should see patients spending thousands of dollars out of costs to get access to medication other than using that to try and return money back to the insurer to decrease

the price of the insurance plan overall. It is not serving anything good——

Senator BLACKBURN. OK, then let me ask you this. When you look at the PBMs, is the costs the PBM inserts in the marketplace worth the benefit to the patient?

Mr. GARTHWAITE. I don't think I can answer that. I am not trying to evade your question. I think it gets back to your point and why I think your bill is very important. We just don't know enough about where the money is going as it flows through the system to figure out exactly, you know, whether the PBM is, "worth it or not."

What I will say, and I think the Senate Finance committee report on insulin pricing you talked about is very instructive on this, that so much of the demand for high list prices appears to be coming from the plan sponsor. As I quote in my testimony, the head of diabetes for Lily, right, saying like, listen, we can't lower our list price because our plan sponsor wants the rebate so that they can maintain competition in the market.

And I think that is not the goal of insurance and certainly not of insurance that doesn't include medical underwriting and is supposed to be community rated. That we are taking money from healthy—or from sick patients and transferring it to healthy patients in the form of lower premiums. But the politics, as I understand it, when we look sort of at the debate to get rid of rebates are such that anything that increases the premiums for seniors is a nonstarter. The part of the conversation we are going to have to have here is there is going to be a tradeoff.

If you would like to get list prices lower, if you would like to remove rebates from the system, if you like to get drug prices lower, access is going to be impinged somewhere, right. It is either going to be because the PBM puts an exclusion list, or it is going to be because prices get pushed down and we get fewer drugs in the future.

We have to make a choice somewhere about where we want to have reduced access if we want lower prices.

Senator BLACKBURN. That is true. You have got to make choices within the system. But what Medicare enrollees tell us is there are fewer choices for them, and the prices are higher, and restrictions seem to increase every single enrollment period. And we know there will be an additional impact on the marketplace in 2023. Ms. Feldman, let me come to you.

Ms. FELDMAN. Yes, ma'am.

Senator BLACKBURN. Mr. Scott wrote an op-ed recently, and he is with PCMA. He is here as one of our witnesses. He argues in this that drug makers alone are responsible for setting and raising the prices. So do you agree with this, yes or no?

Ms. FELDMAN. No. I think there is plenty of blame to go around in this system. The prices are negotiated terms. That is what the PBMs are supposed to be doing, negotiating price with the drug companies. If there is no negotiation going on, why are they there?

Senator BLACKBURN. OK. So this current rebate system that we have, is it working to effectively lower the prices? Kind of the same question to you that I had to, Mr. Garthwaite, is the cost delivering the expected benefit?

Ms. FELDMAN. Let me just try to put it in very simple terms. If my job is to bring prices down, however you define price, and if we look across 15 years and we see that prices after rebates are rising dramatically, I am not doing my job somehow. I do want to be clear that rebates aren't the only problem.

There are all kinds of other flows of payments from drug companies to the PBMs. So we can call things a rebate or a flat fee or an elephant, it is still a flow of lucrative dollars and the influence that brings.

Senator BLACKBURN. OK, thank you. I would like to hear a little bit more, but I am going to ask for it in writing. Mr. Garthwaite to you, and Professor Feldman to you, I would like to know what you would see a competitive marketplace be. We know there has been consolidation.

Mr. Scott says there are 70 PBMs, but we know we have very few players in this area. So in a perfect world, how would you structure a competitive PBM marketplace that would indeed yield our Medicare enrollees a lower cost? Thank you. Thanks, Mr. Chairman.

Senator BLUMENTHAL. Thank you. Thanks for that assignment to the professors and other witnesses here.

[Laughter.]

Senator BLUMENTHAL. And by the way, I would invite all of the panelists to respond to that question in writing. It is a big question and at the heart of what we are doing here. We have been joined by the Chairwoman of the Committee. I mentioned earlier her leadership in this area, and we are grateful to her for coming today. And I recognize Senator Cantwell for her remarks and questions.

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

The CHAIR. Thank you, Chair Blumenthal and Ranking Member Blackburn, for holding this important hearing. We know that the lack of transparency in the marketplace is a concern to all of us, and let's understand where we are today. Since 2014, prescription drug prices have increased much faster than the rate of inflation. Drug prices have gone up 35 percent, while the cost of all goods and services have jumped just 19 percent. So price increases for prescription drugs have outpaced wages, gas, telephone, Internet services, food, tuition, transportation, and personal care.

So there is a consistent issue here. We have found the prescription drug prices have increased for 30 percent of Americans who take prescription drugs medications, many of whom have experienced increased annual cost of more than $100. The worst news, however, is that many who saw such spikes in their out-of-pocket costs were almost twice as likely not to fill a prescription or skip their medication.

So this is of concern. We know that the average list price for insulin has doubled over the past 10 years, even though insulin has been available for patients for over 100 years, and significant hike prices have become a matter of life or death for many Americans with diabetes. In my state, Molly Stenson, a Washington resident, used to travel from Mason County to Canada just to purchase insulin.

That is because at the time the average price of insulin was $450 a month. It wasn't until Washington State passed a law and put a cap on insulin at $100 a month that she was able to finally stop making these trips. Unfortunately, only 18 states have this cap on insulin co-payments. So there are drug insulin prices increasing faster than most goods and services.

According to Senate Finance Committee staff report released by Senators Grassley and Wyden, the price increases are due in part to the business practices of pharmacy benefit managers. That is the subject of today's hearing. They are—PBMs are contracted by Government programs, insurance companies, self-insured employers to negotiate on behalf of the pharmaceutical firms.

And the way the system works, they also make a lot of money driving up the price on consumers. Today, fewer than five PBMs control more than 80 percent of the drug benefit for over 260 million Americans. These companies, who most Americans know nothing about, set drug costs, decide what drugs will be included in your plan, and determine how drugs are dispensed. And these companies have abused their responsibility to protect Americans from these drug pricing crises—continued an opacity on the drug supply chain.

So we want to shine a bright light here. We want PBMs, the effective drug price for consumer—we want to understand how PBMs affect drug prices for consumers. First, PBMs develop what is known as formularies, which are a list of covered drugs on behalf of insurers or payers. To get their drugs placed on the formulary, manufacturers provide rebates to PBMs, some of which are passed on to consumers, but they keep some for themselves.

And because PBMs retain a share of that rebate, they have an incentive to keep those list price high. And who bears the brunt of that? Consumers, particularly if their cost sharing is based on a percentage of the list price or if they are among the 25 percent of Americans who have a high deductible health plan. The second way PBMs are affecting drug prices is something called spread pricing.

Spread pricing occurs when a PBM charges an insurer a higher price for the drug than the amount it is reimbursed by the pharmacy, with the PBMs keeping the difference. According to an investigative report, PBMs skimmed off $1.3 billion of the $4.25 billion that Medicaid insurers spent on drugs in 2017.

There are examples of that. In 2015, PBMs charged Indiana's Medicaid program $204 for a drug and reimbursed the pharmacies only $197, with the PBMs pocketing the $7. Three years later, in 2017, PBMs charged the Medicaid program $147, but reimbursed the pharmacy $17, with PBMs pocketing $130.

That is right, PBMs profits increased by $123 for a single 30 day supply of a heartburn medication, all at the expense of the American consumer. And what makes spread pricing possible? The lack of transparency in the PBM market. PBMs affect drug pricing for consumers by enforcing a number of post-sale fees on pharmacies, effectively limiting the pharmacy's profits.

PBMs keep these fees—and just let me be clear, I am a big fan of the pharmacies. There is a guy across or a woman across the counter, when you go in to get your prescription, who tells you some things about that medication. Oh, be careful of this, what

about this, are you taking this? So they are part of our health care delivery system. So the notion that some people want to have mega conglomerates control pharmacy drugs by mail and control the market and have a continued concentration, mark me down as not a fan.

PBMs keep these fees and really pass them on to consumers, thereby raising the costs for pharmacy—pharmaceutical market as a whole. Now, believe me, I am from an innovation State, and I also worked in software for 5 years. It is easy to raise capital if you are going to produce a product in 6 months and ship it. It is a lot harder to raise money for a product you have to have for 18 years.

So no one is saying that it isn't hard to get capital to invest in new groundbreaking drugs. But the issue is, do we have enough transparency in this market? In 2019, the Washington legislature passed a law prohibiting PBMs from charging phantom fees that raised the costs of dispensing medications.

Several states have enacted laws requiring PBMs to obtain a license to operate in their state, and some have gone further prohibiting or regulating spread pricing and requiring PBMs to report pricing and rebate information to promote transparency. And they have brought enforcement actions. For example, April 13, 2022, the Louisiana Attorney General sued Optum Rx—Optum Rx, I believe that is the pronunciation, for inflating the price of prescription drug charges in their State's Medicaid program, included by spread pricing and claw back money from pharmacies without passing it back—without passing it back to the state.

But we in Congress must do more to ensure that all Americans and all American consumers are protected. That is why I am so appreciative of Chairman Blumenthal holding this hearing this morning and using your experience as a former AG to help us work through these issues at today's hearing.

We know that we have a system where patients get—if our system is where patients get inferior treatment and still pay more, this is setting us back. So it is time for us to take action on this. Mr. Chairman, I will put the rest of my statement in the record, but I would like to turn to our witness, Mr. Balto.

I understand that you are an attorney at the FTC for several years and were involved in many FTC's earliest enforcement actions involving pharmaceutical and health care companies. Could you explain why the FTC action against PBMs under a current authority of unfair and deceptive practices, and what more authority could help us in moving the market to a more transparent market?

Mr. BALTO. Thank you, Senator. I think the FTC has made some major errors in terms of enforcement in this area, and part of it is relying a lot on economic theory and not looking at the reality of what is going on, and also not properly defining who the consumer is. You and I and everybody else in the room know that the ultimate consumer is, you know, real people. The FTC focuses almost exclusively on the question of the first buyer, the plan sponsor, and whether the plan sponsor is harmed, and in that way misses a lot of the anti-competitive effects.

Just to give you one example that sort of hits the point you are making about the service in the community pharmacist. Assume that you are a person who needs a complex specialty drug in which

you really need the services of your community pharmacist. The PBM engages in various tactics to drive that community specialty pharmacist out of business or make it very hard for them to compete.

You are forced, perhaps into an exclusive PBM owned specialty pharmacy. And by the way, the FTC has permitted the PBMs to acquire all these specialty pharmacies. You move then from having—being able to see your community pharmacist, having them monitor your health care, having them give you advice, to all of a sudden having a pharmacist at a 1–800 number. And there is terrific testimony about HIV patients that I testify—that I cite in my testimony, that suggest how this is a problem.

The FTC Act is broad. And one thing that could be very helpful besides the efforts by Senator Blackburn and other members to compel the FTC to do well, to have the GAO do a comprehensive study of this market, and I know Senator Grassley and others have suggested the FTC to do a study, would be for Congress to specify what are unfair methods of competition that the FTC should scrutinize.

And the FTC Act is broad. It prohibits unfair methods of competition and unfair trade practices. And Congress can specify what some of those practices are. And when you look at things like the gag clauses, you know, preventing pharmacies from telling consumers where the lowest priced drug is, I mean, that is blatantly an unfair method of competition. It blatantly is something that harms consumers.

Consumers are in no fashion better off when a pharmacist can't tell them where the—you know, what is the lowest price without means of getting the drug at the lowest price. And there is no reason for that other than for PBMs to protect their PBM rebates. And so, you know, that is the kind of practice that could be specified.

Also, some of the practices that prevent generics or biosimilars from getting on the formularies because, again, PBMs are preferring drugs with a high rebate to these lower cost biosimilars or generics, which offer a lot of promise for ultimately lowering drug costs.

In my testimony, I specify about five or six practices that could be outlined in legislation to attack these unfair methods of competition that ultimately harm consumers.

The CHAIR. Could you remind me, Mr. Balto, because I feel like we had this hearing a decade ago or maybe longer, and I thought we took action as a Congress to outlaw PBMs being owned by drug companies, and so that some of these same practices wouldn't be continued. What did we do before and why are we here again?

Mr. BALTO. In the Clinton Administration, we recognized that pharmaceutical manufacturers owning PBMs was like the fox guarding the henhouse. Unfortunately, in the past several Administrations, we forgot that basic principle of economic policy, you don't want foxes looking after chickens.

And so they have permitted the PBMs to acquire all of, you know, all these major pharmacies. They all have their own mail order pharmacies, which they prefer. They go and aggressively audit independent pharmacies. They reduce their reimbursement to ultimately force them to dispense below cost. They capture these

retroactive DIR fees. Do you think they do those things with their own pharmacies? I don't think so.

And so that kind of fox owning the henhouse operation is just a poor recipe for competition. And by the way, Senators, you know, there is a lot of legislation going on right now to address this problem in high tech industries where we are very concerned about the major tech firms having their own—preferring their own businesses.

I don't know why we should let this happen with PBMs. As important, PBMs being able to secure part of the rebates distorts their incentives and turns competition on its head so that PBMs prefer higher, not lower drug prices.

And by the way, you have identified, many of you have identified the key issue here, which is ultimately non-uninsured consumers lose. And that is, even Professor Garthwaite identifies that problem. And that is why consumer groups, if you will note in footnote five of my testimony, consumer groups supported the past Administration's proposal to eliminate the anti-kickback safe harbor for PBM rebates.

Aggressive—and PBM rebates are just screwing up health care decisions right now and leading to a rapid escalation in drug prices, as demonstrated by the Grassley, Wyden report.

The CHAIR. Thank you. I wanted to ask you about the FTC brought a case against ABV, I think it is. If you recall, this was a court awarded the FTC $448 million in consumer redress, which had been—had to be invalidated as a result of the AMG decision. So how does the absence of 13(b) redress affect the FTC's ability in this space?

Mr. BALTO. It should be a significant priority of everybody in Congress to pass legislation to return the FTC's power to secure our financial redress. I know as being the former policy director, how crucial that is to being able to effectively enforce the antitrust laws. If bad actors, including major corporations, know that they can engage in conduct and basically get a slap on the hand, just stop now.

That is not going to deter them much from engaging in bad conduct. It is only when you can stick a significant monetary penalty on them that they know that they are going to have to pay the piper. So I think that you absolutely have to—that this is a major priority to strengthen the FTC's enforcement powers here.

And certainly if the FTC had that restored, it could look at these egregious practices that PBMs engage in and possibly bring actions under Section 13(b) to provide redress to payers and consumers for these egregious actions.

The CHAIR. So what exactly does the Committee need to do to give the FTC the authority to properly police this market?

Mr. BALTO. I think the FTC need—the Committee needs to strengthen the FTC's powers under—well, let me start off. First, I think the importance of a study is crucial, and I agree with the professor that study and more information is really vital. However, the Committee needs to instruct the FTC. It needs to identify the right consumer.

The FTC's past studies like their mail order study two decades ago just looked at the impact of the plan sponsor. You know, and

a plan sponsor may or may not care, you know, if the consumers are harmed in the fashion that Senator Blumenthal and Senator—and Ranking Member Blackburn describe. They are not necessarily going to care. They need to do a study and actually focus on the real consumer.

Then, I think it is vital for the Committee to consider identifying specific practices by PBMs that are unfair methods of competition that harm consumers. For example, the DIR—you know, and to me the patient—the gag clauses is a very straightforward example.

But also the DIR fees, especially DIR fees imposed by a rival, seem relatively—seem like the kinds of things that you could consider to be an unfair method of competition, and that the Committee—the Commission needs its powers strengthened by identifying some of those practices that they should look at as unfair methods of competition or unfair trade practices.

The CHAIR. And you—but you think that those—in your testimony you outline, I think it is on page 13 here, legislative action to prevent PBM abuses. So you think there are known practices now? Is that correct?

Mr. BALTO. Absolutely, absolutely. And the fact, I mean, the FTC has brought no actions—I mean, they have received hundreds upon hundreds of complaints by pharmacies about some of these actions, about PBMs going and taking information from its PBM affiliate and sending it to its pharmacy affiliate so that pharmacy could target and try to steal those customers, or PBMs imposing, you know, egregious audit practices to try to drive those independent pharmacies out of market.

Again, you know, you are going to—you know, in other industries when you see those kind of practices occur, five alarms go off, and they should certainly go off in these industries because consumers really care tremendously about their ability to access community pharmacies.

The CHAIR. Thank you. Thank you, Mr. Chairman.

Senator BLUMENTHAL. Thanks very much, Chairman Cantwell, for the excellent remarks and questions. And I want to follow up on some of them. I think there is no question that there ought to be a study by the FTC under 6(b) into the PBM market.

As a number of our witnesses have said, there is a lack of transparency, there is a lack of current data. The 2005 study is woefully out of date. That is the reason that I and others, including Senator Grassley, six Republicans, two Democrats, have sponsored the Prescription Pricing for the People Act of 2021, S. 1388.

There are a number of other legislative proposals in this area that would produce more data and more authority for the FTC to take action. You know, one of the areas that has been mentioned is rebates. The fact of the matter is patients should know that they have to pay co-pays and deductibles based on the list price, not the actual price after rebates. That is a glaring injustice here.

This arrangement is actually costing them money. So two questions for you, Mr. Scott. How does a consumer know what this list price is, what the basis is for that payment of deductibles, what the rebates are to the PBMs, which is benefiting from the higher list price, how do they know? And did they see any direct benefit from the rebates?

Mr. SCOTT. Thank you for the question, Mr. Chairman. The short answer is, yes. The individual patient, the individual consumer does see benefit from the rebates. Again, the rebate is simply a discount that is negotiated by the PBM from the manufacturer to try and get to the lowest net cost for the drug. What typically happens in the Medicare program——

Senator BLUMENTHAL. The co-pays and deductibles are based on the list price, correct?

Mr. SCOTT. Yes, sir. And I will get there very quickly. So the Medicare example, that net—those rebates are negotiated, fully pass through to the plan sponsor, and then the plan sponsor makes the determination, even in the commercial market, how to use those savings. Are they going to go to defray premiums—?

Senator BLUMENTHAL. So you are saying that the plan sponsor has a kind of throttle or hand on whether or not consumers benefit, and if out of the goodness of their heart they decide consumers should share in the benefit, which is key to their profits, then they will do it, but there is no automatic benefit.

Mr. SCOTT. So the consumer is benefiting. The cost of the drug itself is too expensive. That is sort of a fundamental starting point that I think we can all agree on. What the plan is trying to determine is where they are going to squeeze the balloon. Is it going to be to try and bring the consumers premium cost down? Is it going to try and bring their out-of-pocket costs down?

We have to address the underlying cost of the drug that is set by the manufacturer, because otherwise it is a series of tradeoffs, and one way or the other, the consumer pays whether—depending on the plan sponsor's design.

Senator BLUMENTHAL. I think you have just summarized the problem here, one way or the other, the consumer pays.

Mr. SCOTT. Until we address the cost of the drug——

Senator BLUMENTHAL. Let's talk about——

Mr. SCOTT.—underlying drug, that is correct. Yes, sir.

Senator BLUMENTHAL. And the incentives for higher costs of the underlying drug, those incentives are increased by PBMs that profit from discounts on that higher list price. Is that true, Professor Feldman? I think that is the point you were making.

Ms. FELDMAN. Yes. The interests of PBMs are aligned with the drug companies in those moments for higher prices because their pay is based on the difference and because they get, in some cases, to keep some of those rebates.

Senator BLUMENTHAL. You agree, Professor Garthwaite?

Mr. GARTHWAITE. There are certainly contracts where that is true, but over half of employers now are in contracts where 100 percent rebates are going back to the plan sponsor. And so, again, at times—we can point to negative parts of the system we don't like and say PBMs are at fault. But I also think we need to look at insurance companies and those plan sponsors and we start talking about the consumer that is harmed.

There is the person buying the drug and then there is actually the vast majority of the insurance pool that is paying the premium but not paying for expensive medications. And they are benefiting because they are taking money from those sick patients and getting lower premiums.

Senator BLUMENTHAL. So it is a lose, lose for consumers. In fact——

Mr. GARTHWAITE. Well, it is a win for the consumer with a lower premium.

Senator BLUMENTHAL. Well, let me—let me recite to you from Professor Feldman's journal article. "In short, it is the perfect lose, lose for patients. Manufacturers raise the price, the consumer pays the higher price, the extra goes to the PBM, and in exchange, the PBM creates competition free zones for the drug company's drug.

In the short term, the patient pays more in the form of higher prices. In the long term, the patient pays more in the form of fewer competitors to offer lower priced drugs." Professor Feldman, that is roughly the current situation, correct?

Ms. FELDMAN. I believe that is a clear summary of what is happening for the consumer and the patient on all ends. Everyone is benefiting other than the consumer, the drug companies, the PBMs, and the plans themselves that may decide to pass through some of those rebates to some of the consumers that sometimes or may not. That could go into many other places, including their own pay. So everybody makes off well, except for the patient, the consumer.

Senator BLUMENTHAL. Mr. Scott, in your prepared remarks, you say that employers and unions, "have a tremendous diversity of opportunities" to select a PBM power. As evidence you offer that there are 70 full service PBMs in the market, but the Council of Economic Advisers pretty recently under the Trump Administration found, "three PBMs account for 85 percent of the market, which allows them to exercise undue market power against manufacturers and against health plans and beneficiaries they are supposed to be representing."

All the witnesses so far have raised the issue of consolidation, lack of competition. Among PBMs, three companies clearly controlled the market for PBMs. How can you claim there is tremendous diversity of opportunity?

Mr. SCOTT. Thank you for the question, Mr. Chairman. I think the first point to understand is that no entity, no plan sponsor, no employer, pension fund union is required to hire a PBM. This is all a voluntary decision to hire companies that they believe are going to add value in helping them to manage the cost of their drug benefit for the patients that they represent.

Senator BLUMENTHAL. But let me just interrupt to say——

Mr. SCOTT. Yes, sir.

Senator BLUMENTHAL. There is no principle of competition policy that says antitrust law and requirements for competitive conduct apply only when a consumer or some other entity is required or mandated to buy a product, right.

Mr. SCOTT. So if I could address your question about the consolidation in the market, you are correct. My testimony cites 70 PBMs actively in the marketplace today. That is actually about a 10 percent increase in new entrants into the market over just the last 3 years. So we are seeing new iterations of PBMs, new players see an opportunity to come into the market because they believe it is competitive.

You have probably read in the headlines, Amazon is looking to get into the space. Mark Cuban is looking to get into space. These are sophisticated players who see opportunity in a competitive marketplace to pick up business from employers, pension funds, and others. Some, you know, employers who choose to hire a PBM are doing it because they just simply want to get the deepest discounts possible to really focus in on that ability to negotiate.

That requires scale in the marketplace in order to be the most effective at those negotiations. Others may be looking for different services from their PBMs that are better offered by a smaller, standalone company.

Senator BLUMENTHAL. Well, let me just, again, Professor Garthwaite, this is your graph, another graph.

Mr. GARTHWAITE. It is not my graph, but yes.

Senator BLUMENTHAL. Well, I apologize. It is from Drug Channels Institute based on 2021 data. This shows CVS Health, Caremark 33 percent, Cigna, Evernorth Express Scripts 26 percent, United Health, Optum Rx 21 percent, and then way down there, there is Humana Pharmacy Solutions 8 percent, and all the others, there are only two others at 4 percent. All other PBMs, cash pay, all of them, all those 70, or let's say 64 at 4 percent. That is not what I would call a competitive market with a diversity of opportunities.

Mr. SCOTT. What we experienced in the marketplace, Mr. Chairman, is that employers have choice. They exercise that choice. So within those competitors that you see out there, whether it is those with the larger market share or the smaller ones, there is—active changes are made to over time as they look for different types of service. And they have the ability to do that because there is enough competition in that market.

Senator BLUMENTHAL. Mr. Balto, I suspect you may have something to remark.

Mr. BALTO. Yes, I just wanted to point out, the question isn't the number of competitors, the question is, can they constrain anti-competitive conduct? And obviously they haven't been—if you see—especially if you see their profits increasing so dramatically. By the way, I represent union plan sponsors and those union plan sponsors do not believe they have many alternatives. They think it is basically these three.

I wanted to also go back to a point, just so we really get this down about, you know, this question about rebates benefiting all of the subscribers, and maybe there is a small subset that are hurt. As the chairman noted, there are lots of uninsured people. There are lots of people on high deductible plans. Those people are all harmed.

And as a matter of just general competition policy, we don't say that firms can engage in anti-competitive conduct because it benefits one segment of consumers, but other segments of consumers are harmed. If there is anti-competitive conduct harming any consumers, that is a violation of the antitrust laws.

Senator BLUMENTHAL. And let me just point out a stunning fact about this health care market and the relationships involved here. Each of these three dominant PBMs are owned by or own their health insurers and have financial relationships with pharmacies

and medical providers. This is a vertical integration in a consolidated industry. It is concentrated power through the industry, and it creates a high risk of conflict of interest, and in effect, a take it or leave it approach toward competitive pharmacies.

And as the Chairman rightly remarked, the pharmacies often try to offer choices and advice and pro-consumer conduct. Mr. Balto, in his testimony said, "because of their market power and vertical integration, these middlemen increasingly stifle competition from this country's most accessible and trusted health care professionals, community pharmacies."

The AIDS Health Care Foundation wrote in February that PBMs, "steadily squeeze specialty pharmacies, preventing patients insured by their parent companies from using specialized pharmacies like AHF's." I am going to stop there. I have a couple more questions, but I want to yield to Senator Cantwell if she has any additional questions.

The CHAIR. Well, thank you, Mr. Chairman. I think I just wanted to drill down on this a little bit more, given some of the—your questions and the response, and certainly our witnesses which we appreciate them being here. But, Ms. Feldman, I saw in her testimony where she said, you know, trying to get to the bottom of this is like shadow boxing. And that is the point.

The point is PBMs negotiate on behalf of some consumers, but they pocket a lot of the discount. And that is what we are trying to get at. Like what is—we believe in buying in bulk that, yes, you get a discount. But who is getting the discount? And the question is they are pocketing that. And when we want to understand what this is about, this issue of spread pricing, there is no transparency.

So the consumer doesn't have the information to make the choice or the plan that someone is representing who wants to say, why should I let somebody go negotiate a deal for me and say that they are going to give me a 30 percent discount and then basically only give me a third of that discount and then pocket the rest, and then when I go to the pharmacy, I end up having to pay more because the out-of-pocket expense is different.

So this lack of transparency is not giving us choice. So do I have that right, Mr. Balto and Ms. Feldman on the spread pricing, is this—do I have this correct?

Ms. FELDMAN. The spread pricing and the all the price in the price terms are held as deep secrets. Both the pharmaceutical companies and the PBMs assert that they are trade secrets, and they are deeply hidden, even from the plans themselves. Auditors aren't given full access to the terms.

Regulators aren't given full access to the terms. Certainly consumers and those who might disrupt the industry don't have access to any of these things. Markets in general thrive on information, and you have got a throttle on information here.

Mr. BALTO. I totally agree. Information is essential for consumer sovereignty. And look, the PBMs won't even allow your pharmacists to tell you, don't use that card, just pay cash, you will pay less. Obviously, they are doing a lot to throttle information so that they can protect their stream of rebates.

The CHAIR. I think we had a similar situation with what was it Ticketmaster where people were going and buying all these tickets

up in bulk and then charging extra pricing and then saying to people, here is what—you know, I am doing you a favor because I got these tickets. But in reality, they were just—had supply and gamed the market and then charged up, increasing pricing.

And so I think that the issue here is where is the transparency so that consumers can understand, or a plan who is making a purchase, can understand because there may be other avenues. Not saying that every PBM isn't doing something, but at what cost, at what price should be PBMs just because they got to go to negotiate a deal, how much should they be pocketing instead of passing that on to the consumer?

So, Mr. Chairman, I think that is my question and it has always been my concern, because I do think buying in bulk should get you a discount. I just believe that most of the money should go to the consumer. And the fact that we can't get answers, or the consumer can't get an answer about this is very frustrating because then they can't make decisions about these plans, or they certainly can't make judgments as it relates to what kind of savings that their plan is entitled to.

I do really, though, have a concern about this—where this keeps going. And so not surprising that more people want to jump in. Well, why not, if you can make this much money in a dark, transparent situation, why not jump in? So that doesn't mean anything. And the key thing, though, is by undermining the system and undermining that line of delivery that I think pharmacists represent as part of our health care delivery system, then I think you really do take away part of the system.

And there are people who are—who definitely would love nothing other than to just have major control over a mail in pharmacy market, and thereby have less, even less kind of delivery system for us. So, Mr. Balto, at your time at the FTC, did they deal with spread pricing and other areas?

Mr. BALTO. No. These problems have become phenomenally worse. And again, because you create an environment that is sort of a petri dish for all of this anticompetitive conduct, lack of competition, lack of transparency, and conflicts of interests, they just have gotten phenomenally worse because you—and then you don't regulate. And, you know, this is just—it is a real fertile environment for this kind of anti-competitive conduct. And——

The CHAIR. And what is the conflict of interest?

Mr. BALTO. The conflict of interest is that they make more money by securing higher rebates when they are supposed—and which results in higher list prices when they are supposed to be seeking lower list prices. That is the conflict of interest. And if you are a payor—again, I do represent some payors. If you are a payor and you want that rebate information, no way. Absolutely not.

Then you want to bring your auditor in and have your auditor check. They limit who can audit. They limit the kind of information you can audit. This isn't like other markets, you know—I mean, they just come out, and, you know, and they just come up with new and novel ways of preventing the market from working effectively.

And by the way, when you think about State regulation and PBMs trying to require State regulation akin to the transparency provisions that you included in the Medicare Modernization Act,

the PBMs fight those tooth and nail. They know darkness is the best environment for them to engage in anti-competitive conduct.

The CHAIR. Well, why can't we do something right now about that, about making sure that there is a transparent market as it relates to these rebates?

Mr. BALTO. We can. You know, there are transparency provisions that, you know, that Congress can consider enacting so that at the very least the plan sponsors have the information so they can properly audit and make sure that they are getting the benefit of the rebates that are being secured.

The CHAIR. Thank you. Thank you, Mr. Chairman.

Senator BLUMENTHAL. Thanks, Senator Cantwell. I have just a few more questions and we have a vote that we will be beginning. I am not sure of the exact time. I want to talk about 340(b) health programs. This is a Federal law, there is a Federal law that provides for discounted drugs to health care providers who serve a high number of low income individuals, community health centers.

Some of them are federally qualified community health centers. They are safety net providers who serve some of the lowest income patients. They are one type of provider that benefits from 340(b) drug discounts. I have talked to a number of them in Connecticut and have heard that PBMs are inappropriately siphoning off these discounts and pocketing them.

Rather than allowing the discounted savings to go to the community health center and the patients they serve, the PBMs force them into contracts with lower reimbursement rates, denying the community health center and its patients the benefit of the discount and instead keeping it. Mr. Scott, have you heard about such practices?

Mr. SCOTT. Senator, at the association, we don't have a position around these 340(b) questions. Our companies have different business models and deal with 340(b) pharmacies in different ways. I will say, what is important for the processing, from the processing standpoint is having those claims modifiers as they do in the Medicaid program, to be able to understand which drugs are 340(b) drugs and which are not so that we can make that distinction.

Senator BLUMENTHAL. Well, will you commit to work with the Committee in making sure that the community health centers, and the patients get the benefit of the discounts?

Mr. SCOTT. I will be happy to continue to work with you on that and other issues. And Mr. Chairman, if I could just take one more minute. I am sorry that Senator Cantwell had to leave. A number of her thematic questions were around this question of transparency. And I just want to make sure that there is a sort of complete understanding of how that transparency exists in the marketplace today.

And taking it in a bit of a reverse order, important to understand that our companies, in Part D plans already report a lot of this information to CMS when it comes to the Medicare program, and we have supported legislation to make that information available to you in Congress through MedPAC, your Congressional advisors.

Congress actually enacted new transparency requirements recently that will kick in at the end of this year. So a lot a whole lot of additional commercial market reporting to HHS, Department

of Labor, the Treasury Department on rebates, fees, impact on out-of-pocket costs, premiums, and the like.

Most importantly, when it comes to the clients, the customers who hire us, and the consumers that they serve, for the client base, it is essential that they are informed, able to shape their contracts, get the information that they want. We want informed choice and so that they can best manage cost and manage risk.

And for the consumer and the physician who is prescribing their drug, it is essential that they understand what is covered, how expensive it is going to be, what the out-of-pocket is going to be. So that information is available right on hand through tools that our companies provide, electronic tools, real time benefit tools, so that that information is on hand and the prescribing decision can factor in those costs questions specific to the consumer.

So we are happy to continue to work with you to make sure you have the information you need.

Senator BLUMENTHAL. Thank you. I assume, then, that you would support the Prescription Pricing for the People Act of 2021?

Mr. SCOTT. And can you refresh that? That is calling for further FTC examinations——

Senator BLUMENTHAL. Would require an FTC study.

Mr. SCOTT. You know, we have actually engaged, and I think that the scope of the study that is contemplated there makes sense because it looks not only at PBMs, but other parts of the supply chain as well, which to me is really important for getting under the hood and understanding these questions.

Senator BLUMENTHAL. I take that as a yes?

Mr. SCOTT. We would not be opposed to that study, Senator.

Senator BLUMENTHAL. OK. That is not exactly the answer that I was looking for. I would like your endorsement of a study. You said you are for more transparency.

Mr. SCOTT. If that legislation is enacted as move forward, we would not oppose it. If that study is commenced, we would engage in making sure we provided information. We—as I articulated before, there is a lot of reporting that already happens in the marketplace. If more is required for better understanding here at the Committee or——

Senator BLUMENTHAL. Here we are. What is really required is more facts, more transparency, more sunlight on a process that is invisible to a lot of consumers. And to go back to where we began, most consumers have no idea what a PBM is. They don't know what a pharmacy benefit manager is, which is the reason why currently we have absence of competition, potential conflicts of interest, and excessive profits, and prices higher than they should be in prescription drug.

PBMs are not the only cause of drug price inflation and excessive pricing. But they are integral to this system. In fact, they are part of an increasingly integrated, uncompetitive system involving PBMs owned or owning insurers and constraining pharmacies in the amount of information they give to consumers.

That is just one slice of a broken system. And the effort to repair the system often runs into armies of lawyers and lobbyists hired by those actors that currently profit from it. So I am seeking to enlist the PBMs.

If they are blameless they should cooperate fully in uncovering every aspect of this system, full transparency, and endorsing full throatily a study into the entire system, including PBMs. I hope for the cooperation of PBMs in the work that we have ongoing. I will be submitting additional questions for the record. We are at the end of the time we have for this hearing.

And the hearing record will remain open for two weeks. Any Senators that would like to submit questions for the record should do so by May 19. We ask that your responses be returned to the Committee as quickly as possible, and in no case later than two weeks after you receive them. I apologize that we are going to have to end this hearing.

There is a lot more to discuss here, and I hope that we will continue this conversation. I appreciate all the witnesses, Mr. Balto, Professor Feldman, Professor Garthwaite, and Mr. Scott, thank you so much. This has been a very valuable session and I hope to continue it. Thank you. This hearing is concluded.

[Whereupon, at 11:50 a.m., the hearing was adjourned.]

A P P E N D I X

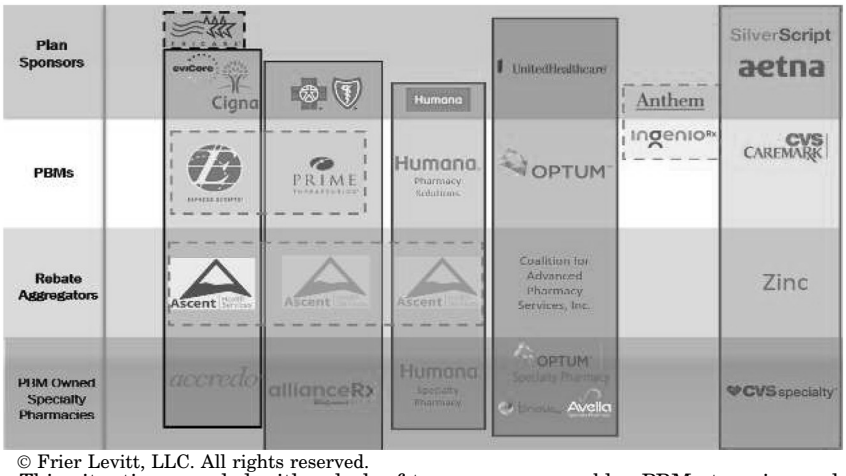
PREPARED STATEMENT OF FMI—THE FOOD INDUSTRY ASSOCIATION

On behalf of the food industry and the many thousands of supermarket pharmacies operated by our member companies, we at FMI—the Food Industry Association thank Chairman Blumenthal, Ranking Member Blackburn and the Senate Commerce Subcommittee on Consumer Protection, Product Safety, and Data Security for holding this hearing to further discussion around this important topic. FMI strongly agrees with the Subcommittee that pharmacy benefit managers (PBMs)—from how they operate to the lack of transparency surrounding their operations—have contributed to higher drug prices for consumers. For years, PBMs have leveraged their concentrated market power and lack of oversight to the detriment of supermarket pharmacies and other providers, health plans and consumers. With that in mind, FMI strongly supports the Federal Trade Commission (FTC) moving forward with a 6(b) study of the PBM industry, including the relationship between large PBMs and pharmacies and the impact of PBM anticompetitive practices on both drug prices and pharmacies, and we ask the Subcommittee to help ensure this is a major priority for the FTC. We wish to highlight for the Subcommittee the following information, which reflects not only FMI's insight, but also the expertise of FMI's Pharmacy Operations Task Force.

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

PBMs were originally formed in the late 1960s, initially to assist with processing claims. Insurance plans were offering prescription drug benefits and PBMs filled out the paperwork, ensuring that reimbursements were passed along to pharmacies. Over time, PBMs portrayed themselves as cost-reducers who could form large patient networks, negotiate discounts from drug companies and pharmacies, and pass savings through to health plans and consumers. They claimed to be simple intermediaries between the health care entities. However, today's reality is very different as the PBM industry has grown and consolidated rapidly in recent decades. For perspective, in 1989, roughly 60 million prescription drug customers had their coverage administered by PBMs. Currently, however, PBMs control nearly 80 percent of the market share for prescription drug access and around 180 million prescription drug customers. Additionally, these PBMs are also vertically integrated with health insurance companies, rebate aggregators and retail, specialty and mail-order pharmacies, giving them unprecedented power.



This situation, coupled with a lack of transparency, enables PBMs to enjoy multiple hidden revenue streams from other stakeholders throughout the health care system. The hidden revenue streams include, but are not limited to, the difference between the amount a pharmacy is reimbursed and the amount the PBM bills to the health plan (spread pricing), post-adjudication fees that are charged to pharmacies and often referred to as Direct or Indirect Remuneration Fees (DIR fees), and manufacturer rebates that pharmaceutical companies pay to have their drugs placed on preferred formularies. The post-adjudication DIR fees are described by the PBMs as "performance-based pharmacy incentive" fees designed to incentivize pharmacies to perform better, yet there is typically no transparency to the process and pharmacies are not told what metrics are being used.

Importantly, this market concentration empowers the PBMs to offer supermarket pharmacies of all sizes take-it-or-leave-it contracts. The pharmacy must either accept the PBM's mandated contract terms (including, among other things, allowing the PBM to set prices for certain drugs unilaterally and then later impose retroactive DIR fees based on an opaque methodology), or give up the ability to serve the many customers whose health plans contract with the PBM; importantly, this would include existing customers who have longstanding relationships with their pharmacists. Furthermore, given PBMs also operate their own pharmacies, FMI pharmacy members are effectively forced to accept contractual terms from their direct competitors—a clear conflict of interest.

PBMs Leverage Concentrated Market Power to Force Pharmacies to Accept Below-Cost Pricing and Other Financially Oppressive Practices

PBMs' profit model is dependent upon their ability to dictate prices and impose upon pharmacies arbitrary and often below-cost reimbursement terms for generic drugs through maximum allowable cost ("MAC") price lists. Unlike with on-patent drugs, where PBM reimbursements typically are based on the actual prices paid by drug wholesalers to manufacturers, PBM reimbursements to pharmacies for generic drugs are based on PBMs' "proprietary" MAC lists, which bear no necessary relation to pharmacies' acquisition costs. Additionally, one of the many ways PBMs profit is by maximizing the difference between what they pay pharmacies for a drug and the inflated amount they charge a health care plan for that same transaction. To take just one reported example, an Iowa county was billed by its PBM $198.22 for a drug that the PBM reimbursed the dispensing pharmacy just $5.73—a markup of more than 3,400 percent.[1]

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 MAC pricing. Even FMI's

[1] Robert Langreth *et al., The Secret Drug Pricing System Middlemen Use to Rake in Millions,* Bloomberg, Sept. 11, 2018.

largest members—Fortune 500 companies with efficiencies, expertise in supply chain logistics, and economies of scale—struggle to operate financially viable pharmacies.

Below-cost pricing is just one way that PBMs systematically leverage their market power. They also impose on pharmacies unfair and exorbitant retroactive DIR fees. PBMs charge these fees to pharmacies without warning or market justification weeks or months after the pharmacy dispenses a drug to a beneficiary. The Centers for Medicare & Medicaid Services ("CMS") tracks DIR fees and recently reported an increase in such post-sale fees charged to pharmacies by PBMs of more than 107,000 percent from 2010 to 2020.[2] There is no competitive market justification for such an exponential growth in these fees. As with MAC pricing, PBMs tout these post-sale fees as disincentives to "poor performance" by pharmacies. In reality, however, they are just another example of PBMs leveraging their market power to maximize their profits. Charges for "poor performance" far exceed incentive payments to pharmacies intended to reward "high performance." As a result, beneficiaries pay higher costs and drug prices become even less transparent. Additionally, FMI members cite these retroactive fees as a key reason for their pharmacies' financial struggles, forcing some to close their pharmacies altogether.

Moreover, with DIR fee reform proposals being considered by policymakers, PBMs have started including contingencies in their pharmacy contracts that would allow them to impose upon pharmacies even more aggressive rates and less favorable reimbursement terms if retroactive DIR fees become prohibited. Case in point, the following clause was recently included by a PBM in a take-it-or-leave-it contract that was offered to an FMI member. Although it cleverly does not reference "DIR fees," that is clearly the focus:

> *Change in Law. In the event [guidance is released] that prohibits or materially alters the economics of a Participating Sponsor's Program (the "Change in Law"), the parties agree to promptly renegotiate the effected provisions of this Schedule, to the extent feasible, in order to preserve the relative economics of the Members, the Participating Sponsor, and Provider to that which existed immediately prior to such Change in Law.*

Although PBMs claim the purpose of DIR fees is to encourage better health outcomes by incentivizing pharmacies to perform better, this clause clearly demonstrates that DIR fees are being used as a profit stream.

PBM contracts often require the pharmacy to relinquish ownership to all data and information sent from the pharmacy to the PBM. The data and information transmitted represents essentially the entire record of the dispensing event and claim(s) for coverage and reimbursement. This not only gives PBMs access to a pharmacy's competitively sensitive information, it also enables the PBMs to utilize the information to manipulate reimbursements and fees while steering patients to PBM-affiliated pharmacies.

In addition, PBMs typically include broad confidentiality language in their contracts to prohibit pharmacists from discussing their own drug costs, services, business practices, or the undefined term "other information" contained in the contract or provider manuals with third parties.

PBM Practices Are Driving Food Retailers Out of the Pharmacy Business

Unlike independent pharmacies, FMI members that operate supermarket pharmacies are not dependent solely on their pharmacy operations for survival. Therefore, PBM abuses may not threaten to force integrated food retailers to close their doors. Instead, PBM practices make it likely that food retailers will be forced to continue leaving the pharmacy business—either by outsourcing their pharmacy operations to the biggest players in the market, or worse, by abandoning pharmacy operations altogether.

Neither of these scenarios is merely hypothetical as several FMI members have already sold their pharmacy operations to PBM-operated chains. The number of pharmacies in supermarkets decreased by more than seven percent between 2007 and 2017[3], while food and mass-market retailers accounted for more than 45 percent of the pharmacy closures during the year from July 2018 to July 2019.[4] Super-

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[2] *Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs*

[3] Sharon Terlep & Jaewon Kang, *The Pharmacist Is Out: Supermarkets Close Pharmacy Counters,* Wall St. J., Jan. 27, 2020.

[4] Xil Consulting, *Payers and PBMs Profit from Obscure Pharmacy Fees, While Seniors See No Relief in Prescription Costs* (Feb. 11, 2020)

market 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 some rural communities, where closures are more prevalent and more detrimental to a community's access to health care. The closure of pharmacies in recent years has created "pharmacy deserts" in some underserved urban communities as well.

PBMs' Concentrated Market Power Harms Health Care Plans and Beneficiaries

As employers that sponsor plans to provide health care coverage to their employees, FMI members also see how PBM practices exploit inherent conflicts of interest to the detriment of health care plans and beneficiaries. For example, PBMs are often 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 may be incentivized to obtain more expensive drugs, to the extent their rebates correlate with the cost of the drugs they include on formularies. FMI members' health plans typically 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 compensation.

Additionally, since PBMs own and have financial interests in pharmacies, they frequently steer patients to those outlets as the sole source for pharmaceuticals. By steering patients to their own pharmacies, PBMs reduce competition and have additional incentive to provide patients with more expensive drugs. As CMS has recognized, "[m]arket competition is best achieved when a wide variety of pharmacies are able to compete in the market for selective contracting with plan sponsors and PBMs," not when PBMs can simply direct patients to themselves.[5]

Conclusion

PBMs have been allowed to operate without oversight, shrouded in secrecy. Increased regulation and transparency are necessary to help curb existing and prevent future abusive practices, while controlling consumers' drug costs and preserving their access to supermarket pharmacies. Moreover, the Supreme Court's *unanimous decision* in the case of *Rutledge v. Pharmaceutical Care Management Association*—which reaffirmed the states' rights to regulate PBMs—provides a strong vote of confidence to achieve greater oversight of PBMs.[6]

Again, FMI thanks the Subcommittee 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 me at *pmatz@fmi.org* or (202) 452–8444.

Sincerely,

PETER MATZ,
Director, Food and Health Policy.

[5] 83 Fed. Reg. 62,176 (Nov. 30, 2018)

[6] Brief for FMI as Amicus Curiae, p. 9–17, Leslie Rutledge v. Pharmaceutical Care Management Association, available at *https://www.supremecourt.gov/DocketPDF/18/18-540/134582/20200302123959805_18-540%20tsac%20FMI.pdf*

PATIENTS FOR AFFORDABLE DRUGS NOW™

Statement for the Record by Patients For Affordable Drugs Now

U.S. Senate Committee on Commerce, Science, and Transportation
Subcommittee on Consumer Protection, Product Safety, and Data Security

Hearing on "Ensuring Fairness and Transparency in the Market for Prescription Drugs"

May 5, 2022

Patients For Affordable Drugs Now is the only national patient organization focused exclusively on policies to lower drug prices. We are bipartisan and independent. We don't accept funding from any organizations that profit from the development or distribution of prescription drugs.

Prescription drug prices are set by pharmaceutical companies, and our organization is dedicated to passing comprehensive reforms that will hold drug companies accountable by giving the federal government leverage over prices through negotiation and by implementing penalties on companies that price gouge. The comprehensive set of solutions passed by the House of Representatives last year and now before the Senate would finally authorize Medicare to negotiate prices directly for some of the most expensive prescription medicines, including insulin; institute a hard cap on out-of-pocket drug costs for Medicare beneficiaries and limit copays on insulin for millions of Americans to $35 each month; and limit annual price increases to no more than the rate of inflation. The Senate should advance and pass these provisions immediately.

But drug companies are not the only actors in the drug pricing supply chain, and there is ample evidence that pharmacy benefit managers (PBMs) do not always act to minimize prices and costs for patients as intended under U.S. policy. Our concern about the impact of PBMs — and the need for more oversight and accountability — is why we submitted the following comments in response to the Federal Trade Commission's solicitation for public input on the business practices of PBMs. Our comments urge the FTC to investigate PBMs in order to highlight specific areas needing reform and potential solutions. But, even while the FTC pursues its work to examine PBM practices, Congress can act now to increase accountability for PBMs by requiring transparency into the secret actions of PBMs, giving the FTC the necessary tools to regulate PBMs, and passing legislation to ensure that PBMs are accountable first to their beneficiaries, rather than their shareholders.

We're grateful for the Subcommittee's attention to lower drug prices, and we submit the following comments for the record in the hope that they will elucidate the patient perspective on PBMs and their impact on drug access and affordability.

Patients For Affordable Drugs Now Comments In Response to the Federal Trade Commission's "Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers"

Introduction

Patients For Affordable Drugs Now is pleased to offer these comments in response to the Federal Trade Commission's "Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers."

Patients For Affordable Drugs Now is the only national patient organization focused exclusively on policies to lower drug prices. We are bipartisan and independent. We don't accept funding from any organizations that profit from the development or distribution of prescription drugs.

Today, pharmacy benefit managers (PBMs) administer prescription drug benefits for more than 266 million Americans, or 80% of the population. While drug prices are set by manufacturers, there is ample evidence that indicates the profit-driven and secretive practices of PBMs play a major role in the cost of and access to drugs for our patient community. In order to better understand PBMs' impact on patients — and to guide future government and industry reforms — we urge the Federal Trade Commission to conduct a study of PBMs.

PBMs Are Shrouded In Secrecy

PBMs are supposed to act as intermediaries, leveraging the buying power of insurers, employers, and government purchasers in order to capture savings, which at the end of the day are supposed to accrue to the benefit of patients and consumers. But because the business practices of PBMs are shrouded in secrecy, policymakers and the public are left in the dark about the amount of savings actually passed on to payers and patients through lower premiums and out-of-pocket costs. While PBMs claim to be utilizing their bargaining power on behalf of patients, they are simultaneously fighting to ensure their rebate practices stay hidden from view. As a result, a patient cannot know if the preferred drug on the formulary is placed there because it is the best, most cost-effective option or because it is the one for which the PBM received a substantial rebate. Without further transparency and accountability, PBM decision-making and its impact on patients will remain a mystery.

Are Patients Actually Paying More For Some Drugs Because Of Rebate Practices?

Because larger rebates can be exchanged for more favorable formulary placement, PBM rebate practices may in fact incentivize drug companies to raise list prices in order to be able to provide deep enough rebates to gain and maintain placement. This ongoing cycle demonstrates how rebate practices can contribute to ever-increasing list prices.

Pay-for-position rebate practices also lead to higher costs for patients. A PBM may receive a substantial rebate from a brand-name drug company in exchange for placing that brand-name drug — instead of a

less expensive generic option — in a preferred tier. Because patient cost-sharing is most often based on the full, non-discounted price of the drug, this structure exposes insured patients to higher costs even though an equally effective, more affordable option may exist. The impact on uninsured patients is even more severe because they must pay the entire, rebate-inflated list price without the benefit of insurance coverage to absorb some of the costs. The relationship between rebates and higher out-of-pocket costs has been substantiated in academic research.

PBM Practices May Be Used To Block Competition

Our drug pricing system is designed around the expectation that the market entry of generic and biosimilar drugs will generate competition and promote affordability. Unfortunately, PBM practices may make it difficult or impossible for generic and biosimilar drugs to gain uptake in the market. Current incentives in the negotiations between drugmakers and PBMs leave contracts vulnerable to gaming.

For example, as part of drug manufacturer Teva's effort to delay generic competition for its blockbuster multiple sclerosis drug Copaxone, the company developed a higher concentration version of the drug and began efforts to switch patients to this dosage before the existing dosage faced generic competition. The House Committee on Oversight and Reform uncovered documents that show that Teva pressured PBMs "by tying contractual rebates on [the previously marketed concentration] to adding [the newly developed concentration] to their formularies." The participating PBM conceded, seeking the sizable rebates in question. Teva's efforts to impede generic competition resulted in considerable costs to our health system and kept affordable alternatives out of reach for patients. In addition, in 2017, Pfizer filed a lawsuit accusing Johnson & Johnson of offering PBMs larger rebates to incentivize them to place its blockbuster rheumatoid arthritis drug Remicade in a favorable formulary position instead of Pfizer's new biosimilar competitor, Inflectra. Both examples illustrate instances in which drug companies worked in tandem with PBMs to hinder market penetration of more affordable generic and biosimilar medications.

PBMs Put Shareholders First, Not Patients

PBMs have become some of the most profitable players in the health care sector. In 2021, PBMs handled more than $422 billion of gross drug revenues in the United States. The profitability of PBMs has risen in recent years as a result of vertical mergers between PBMs, insurance companies, and pharmacies. Almost 90% of those gross revenues in 2021 moved through the "Big Three" alone — CVS, Express Scripts, and OptumRx. The gross profit of PBMs grew 12% between 2017 and 2019, increasing from $25 billion to $28 billion. Because they are profit-driven entities with a duty to shareholders but without a fiduciary responsibility to beneficiaries, additional transparency could clarify whether their practices best serve patients or shareholders. We believe U.S. law and policy should be amended to give PBMs a fiduciary responsibility to beneficiaries, requiring them to put beneficiary health and financial interests first.

Lack Of Competition Leads To Profits Over Patients

Concentration in the PBM industry is yet another factor that appears to contribute to a drug pricing system where profits come before patients. Because three large PBMs have a stranglehold on the market, these companies have a disproportionate impact on what medications patients have access to. For example, at

the end of last year, CVS Caremark announced that it would no longer cover the blockbuster anticoagulant Eliquis in 2022 and would instead cover only warfarin and Xarelto. This decision had enormous implications for patients since CVS Caremark has the largest market share (34%) of any PBM. As a result, many patients were forced to switch products in order to remain on a covered drug. For some medications — especially biologics — a forced switch can carry with it significant health and safety implications for the patient. Patient choice can be further limited by PBMs, like CVS Caremark, that own retail pharmacies and may be directing or requiring beneficiaries to fill prescriptions with their retail affiliates.

Recent mergers have also made the lines between PBMs and insurance companies increasingly difficult to distinguish. This trend creates conflicting incentives stemming from the fact that PBMs are typically more profitable than insurance companies. Insurers, which are typically motivated by cost-containment, may pivot to direct patients to treatments with higher rebates instead of acting in the best health and financial interests of their beneficiaries. This dynamic could exacerbate all the aforementioned effects that PBMs have on patients and their costs.

Conclusion

PBMs were created with the stated purpose of negotiating on behalf of patients. Today, PBMs handle more than $420 billion and cover more than 266 million lives. Nevertheless, their work is shrouded in secrecy, so their practices remain unclear and their effects on patients are at best uncertain — and at worst deleterious. The Federal Trade Commission should investigate PBMs in order to reveal the practices and effects of these large and growing entities. Such an investigation could be critical for identifying problem areas and an important step in building a foundation for policymakers to utilize as they seek to develop appropriate legislative solutions to ensure PBMs can best serve consumers.

Commissioner NOAH PHILLIPS,
Commissioner CHRISTINE WILSON,
Federal Trade Commission,
Washington, DC.

May 5, 2022

Dear FTC Commissioners Noah Phillips and Christine Wilson,

Pharmacy Benefit Managers (PBMs) work to jack up the price of life-saving drugs like insulin, steal from community pharmacies until they go bankrupt, and turn pharmacy care—one of the most important (and often only) sources of health care for rural patients—into a living nightmare.

FTC Commissioner Noah Phillips and Commissioner Christine Wilson, please stop blocking efforts to open an investigation into PBMs.

Signed,

2,406 of your constituents, including:

Katelyn, C (20002)
Paula, B (99517)
Kimberly, D (17981)
Ron, P (97402)
James, F (97520)
Russell, N (53705)
Norm, S (92399)
Jennifer, I (18704)
Mary, C (6516)
Katherine, B (93711)
Sandy, D (19958)
Christine, A (28374)
Debra, C (85044)
Carol, K (19317)
Shelley, S (23693)
Frank, B (90630)
Sherry, M (92056)
Stephanie, F (6002)
Mary, K (21044)
Nancy, S (50229)
Steve, T (8518)
Tiffany, R (80031)
Elizabeth, G (33647)
Lindsey, B (53110)
Vicki, F (20912)
Julia, E (32257)
Helen, L (17408)
Charles, F (30033)
Mimi, B (60031)
Clayton, M (98133)
Querido, G (95445)
Mary, I (30814)
Brad, W (80214)
Kamona, J (78744)
William, R (60148)
Jonathan, H (60622)
Subrina, W (23321)
Richard, Y (90066)
Heidi, W (80631)
Allan, H (95445)
Mary, R (21227)
Kaci, A (99354)
Mark, N (94960)
B., E (91361)
Layne, T (39120)
Donald, J (66762)
Dion, E (62040)
Elizabeth, S (53211)
Kevin, D (66604)
Steven, L (96789)
Candace, W (72701)
Kristin, R (89523)
Shai, W (98465)
Ellen, M (27102)
Charity, G (66215)
Erin, C (19930)
William, M (22042)
William, D (34613)
Steven, C (33594)
Jeremy, L (46052)
Jim, S (22152)
James, H (89149)
Patti, W (85254)
Christina, K (2130)
Michael, B (78705)
Jorge, C (90015)
David, G (85024)
Leslie, S (63105)
Rosa, L (92260)
Kristine, Z (32084)
Shirley, S (93030)
Deborah, E (85704)
Cynthia, S (60649)
Shawn, M (45439)
Eleanor, C (22192)
John, B (84111)
William, W (2478)
Rebecca, W (87108)
Henry, S (30344)
Angela, R (23185)
Ron, K (58481)
Teri, C (87112)
Brenda, T (37040)
Marie, M (90403)
Andrew, A (60534)
Frances, G (32963)
Leslie, O (79106)
James, J (20602)
Patrick, T (96706)
Ra'id, K (98105)
Barbara, P (11553)
Francine, L (11930)
Cynthia, S (2445)
Miranda, B (98115)
Ronald, B (54313)
Matthew, B (41014)
Raymond, K (32162)
Diana, P (12204)
Sophia, K (98146)
Mary, C (33707)
B j, P (87715)
Joy, G (11208)

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Kelvin, E (15061)
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Pedro, H (39211)
Linda, L (21403)
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Rob, S (90265)
Leslie, C (23229)

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Sandra, M (53211)
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Chris, F (48154)
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Elliot, C (44313)
Nicole, E (55122)

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Katlyn, S (98125)
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Paul, H (78745)
Murray, B (96134)
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Jose, D (32822)
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James, F (45840)
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Deidre, B (30080)
Jerry, B (48381)
Kris, S (84629)
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Igor, T (11375)
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Debra, M (60563)
Tracy, H (92393)
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Robert, L (32244)
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Hugh, M (46383)
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Virginia, J (1060)

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Aaron jaocb, L (83704)
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David, F (80128)
Brinna, C (25526)
Brandon, C (19713)

FEDERAL TRADE COMMISSION
Washington, DC, May 5, 2022

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

Hon. ROGER WICKER,
Ranking Member,
Committee on Commerce, Science, and Transportation,
United States Senate,
Washington, DC.

Hon. RICHARD BLUMENTHAL,
Chairman,
Subcommittee on Consumer Protection, Product Safety, and Data Security,
Committee on Commerce, Science, and Transportation,
United States Senate,
Washington, DC.

Hon. MARSHA BLACKBURN,
Ranking Member,
Subcommittee on Consumer Protection, Product Safety, and Data Security,
Committee on Commerce, Science, and Transportation,
United States Senate,
Washington, DC.

Dear Chair Cantwell, Ranking Member Wicker, Chairman Blumenthal, and Ranking Member Blackburn:

I write to express my strong support for the Senate's ongoing work and upcoming hearing on pharmacy benefit managers (PBMs) entitled, "Ensuring Fairness and Transparency in the Market for Prescription Drugs." [1]

I believe that PBMs play a critical and under-examined role in determining the price and availability of prescription drugs to patients at the pharmacy counter and clinic, and I am concerned that certain incentives and the surrounding lack of transparency means that PBMs' interests may not always align with patients and others who pay for prescription drugs. I am also concerned that PBMs' vertical integration and dominant market position may allow them to under-reimburse independent pharmacies and steer business to PBM-owned mail-order and specialty pharmacies, which may threaten the long-term viability of independent pharmacies in both urban and rural communities.

Addressing dominant intermediaries such as PBMs has been a top priority during my tenure at the FTC.[2] In line with this priority, FTC staff has been working since last year to use the FTC's 6(b) authority to conduct an inquiry into PBMs, and I am hoping that the Commission will vote to initiate a study as soon as possible.[3] Given the life-and-death stakes of this work, I believe the FTC has a moral imperative to act swiftly.

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[1] *Ensuring Fairness and Transparency in the Market for Prescription Drugs: Hearing Before the Subcomm. on Consumer Protection, Product Safety, and Data Security of the S. Comm. on Commerce, Sci., and Trans.,* 117th Cong. (May 5, 2022), *https://www.commerce.senate.gov/2022/5/ensuring-fairness-and-transparency-in-the-market-for-prescription-drugs.*

[2] Memorandum from FTC Chair Lina M. Khan to Commission Staff and Commissioners Regarding Vision and Priorities for the FTC, at 3 (Sept. 22, 2021), *https://www.ftc.gov/system/files/documents/public_statements/1596664/agency_priorities_memo_from_chair_lina_m_khan_9-22-21.pdf* ("The second area I'd like us to prioritize addressing is dominant intermediaries and extractive business models.").

[3] Remarks of Chair Lina M. Khan Regarding the 6(b) Study on Pharmacy Benefit Managers (Feb. 17, 2022), *https://www.ftc.gov/news-events/news/speeches/remarks-chair-lina-m-khan-regarding-6b-study-pharmacy-benefit-managers.*

As part of this effort, the FTC has issued and recently extended a Request for Information seeking public comments on PBM business practices.[4] Hundreds of unique comments have been submitted to date on how PBMs are impacting patients, doctors, and pharmacists. The comments touch on a range of issues, including Direct and Indirect Remuneration (DIR) fees, inadequate pharmacy reimbursements, unnecessary prior authorizations and step therapy requirements, detrimental formulary exclusions, and the steering of patients to PBM-owned pharmacies.[5]

While the FTC will continue its work in this important area, I also welcome legislative action on PBMs, including efforts to ensure that these intermediaries are serving the interests of American patients and contributing to a fair and accountable prescription drug system.

Sincerely,

LINA M. KHAN,
Chair,
Federal Trade Commission.

[4] Solicitation for Public Comments on the Impact of Prescription Benefit Managers' Business Practices, FTC–2022-0015, *https://www.regulations.gov/docket/FTC-2022-0015/comments* (last visited May 5, 2022).

[5] *Id.*

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May 11, 2022

The Honorable Richard Blumenthal
Chair, Senate Commerce, Science & Transportation Subcommittee on Consumer Protection, Product Safety, and Data Security
SH-706
120 Constitution Avenue NE
Washington, DC 20002

The Honorable Marsha Blackburn
Ranking Member, Senate Commerce, Science & Transportation Subcommittee on Consumer Protection, Product Safety, and Data Security
SD-357
50 Constitution Avenue NE
Washington, DC 20002

Re: *Submission for the record: Ensuring Fairness and Transparency in the Market for Prescription Drugs*

Dear Chair Blumenthal and Ranking Member Blackburn:

On behalf of the Board of Directors of the Community Oncology Alliance (COA), I want to express our thanks for the hearing you held last week on *Ensuring Fairness and Transparency in the Market for Prescription Drugs*. Senator Blumenthal cited one example of a cancer patient from Connecticut who was unable to get her drugs on a timely basis. Unfortunately, this is not a one-off event. Cancer patients and their oncologists are in a constant, daily fight with pharmacy benefit managers (PBMs) to get their critical drugs on a timely basis, especially when PBMs mandate that the drugs be delivered by their own mail-order pharmacies.

I could go on and on about the abuses cancer patients face at the hands of PBMs but will let the attached five volumes of "horror stories" speak to real-life Americans battling with PBMs.

I submit this letter with attachments to the record of the hearing *Ensuring Fairness and Transparency in the Market for Prescription Drugs.*

Thank you.

Sincerely,

Ted Okon
Executive Director

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Delay, Waste, and Cancer Treatment Obstacles:

The Real-Life Patient Impact of Pharmacy Benefit Managers

Over 15 Years *of* Making a Difference in Cancer Care

There is growing awareness of the problems and pitfalls with Pharmacy Benefit Managers (PBMs) in the United States health care system. Contracted by insurance carriers to negotiate on their behalf with pharmaceutical companies, these 'middle men' corporations have quietly become an unavoidable part of our nation's health care system. Controlling at least 80 percent of drug benefits for over 260 million Americans, PBMs have the power to negotiate drug costs, what drugs will be included on plan formularies, and how those drugs are dispensed. Oftentimes, patients are required to receive drugs through PBM-owned specialty pharmacies.

However, while the role PBMs play in the U.S. health care system is complex and under scrutiny by policymakers and the public, with much of the debate focusing on economics, little discussion takes place of the impact PBMs have on patients.

This paper is the first in a series that will focus on the serious, sometimes dangerous, impact PBMs are having on cancer patients today. These are real patient stories but names have been changed to protect privacy.

AN AVOIDABLE DEATH?

Derek, a young husband, was diagnosed with advanced melanoma with brain metastases. Prognosis was grim, yet a ray of light appeared in the form of a new drug prescribed by his doctor. Proven to have the potential of significantly extending life, the drug offered Derek and his wife real hope. Located in his doctor's office was the clinic's pharmacy, where this potentially life-prolonging medication was simply waiting on the pharmacy shelf— but not for Derek. Derek's PBM mandated that Derek purchase his meds from one of their own mail-order specialty pharmacies. The clinic immediately faxed to the PBM all the necessary information for receiving prior authorization, and for the next ten days, Derek and his wife waited to hear that the prescription had been approved. Upon receiving the go-ahead, they then faxed the prescription to the PBM's specialty pharmacy, and sat back to wait again.

One week later, the drug still had not appeared; instead, the couple was notified that they first had to remit the drug's $1,000 co-pay, an amount they were unable to afford. Derek's wife now began arranging co-pay assistance, but she had to deal with the matter on her own at this point, because Derek had been admitted to the ICU. Several days later, she received approval for co-pay assistance, and forwarded the information to the PBM's pharmacy, which then FedExed the drug to Derek. The medication finally arrived— only there was no one to take them. By this time, Derek could no longer swallow pills, and sadly, shortly after, he died.

The most common and devastating issue that cancer patients face with PBMs is the fact that they must wait, for weeks or even months, to obtain medication that they could have received within 24 hours, had they been permitted to get it at the point of care from their oncologist. Beyond the stress and aggravation incurred, delays in receiving medication often translate into delayed treatment and worsening of the patient's condition, and in the most tragic of cases, possibly contributing to the patient's death.

TREATMENT DELAYED DUE TO PHARMACY RESTRICTIONS

Bill was prescribed an oral medication that works to prevent his cancer cells from replicating, thus reducing the growth and spread of the disease. His oncologist faxed the prescription to the specialty pharmacy indicated by Bill's PBM. Unfortunately, this particular pharmacy does not carry the medication prescribed, and so they forwarded the script to another specialty pharmacy that does carry it. However, that pharmacy does not accept Bill's insurance.

So, the prescription was forwarded again to yet another specialty pharmacy, which is the preferred pharmacy of Bill's insurance company. However, they don't carry the medication either. By this time, ten days have passed since the medication was first prescribed. Bill's physician, attempting to expedite things, now sends the prescription to a fourth specialty pharmacy that does carry the meds, and personally calls the insurance provider to explain the situation and ask for immediate approval. Five days later, and more than two weeks since the initial prescription was made, Bill receives his medication.

Agreements between insurance carriers and PBMs, which may be part of the same corporation, grant them full authority to determine where patients may or may not purchase their medication. This is carried out regardless of the detrimental effect it often has on patient health and wellbeing. In such a system, one must wonder whether the objective of curing patients from terminal disease has been usurped by that of achieving financial gain.

MEDICATION DELAYED 6 WEEKS DUE TO PBM SPECIALTY PHARMACY INDIFFERENCE

Carol was battling metastatic colon cancer. Unable to receive the same chemotherapy Carol had been treated with initially, her oncologist prescribed a medication to help stop the cancer from spreading any further. Her physician sent all documentation necessary to the specialty pharmacy mandated by Carol's PBM.

One week later, when Carol's oncologist phoned the PBM-mandated pharmacy to check on status of the prescription, again, they were told that nothing had been done— they refused to process the prescription without knowing Carol's current weight. Rather than calling Carol or the doctor to ascertain the necessary information, they had simply done nothing.

Another week went by, and the doctor called in again to check on the prescription. This time she was told that there was a form the doctor needed to fill out, in order to request Prior Authorization from the PBM. The doctor couldn't understand why they hadn't simply sent the form to her— or told her about it a week ago, when she had called. Eventually the doctor received the form, filled it out and submitted it, as Carol continued to wait and her cancer continued its lethal advance. Ultimately Carol received the medication— a full six weeks after it was initially prescribed, the most terrible irony being that had she been allowed to receive the pills at the site of care, she would have had them within a day.

Another serious issue patients and doctors face with PBMs and specialty pharmacies is their passive attitude towards patient care. Time and again, patients and doctors wait for medication that will never arrive. One small detail missing in the documentation is enough to delay its delivery, and the specialty pharmacy staff, who do not see themselves as partners to patient care, also do not see it as their responsibility to take any action to hasten the process.

LIFE-SAVING TREATMENT POSTPONED

Barbara, who was battling brain cancer, was prescribed two drugs: one a form of chemotherapy and the other an antiemetic that would alleviate the symptoms of nausea caused by the chemo. Both were to be taken in conjunction with the radiation treatments scheduled to begin six days later.

At Barbara's clinic, well aware of the urgency of the situation, the nurse on call faxed Barbara's prescriptions over to her PBM-mandated specialty pharmacy, and at the same time, applied for prior authorization from Barbara's PBM. Five days later the nurse called over to the pharmacy, asking for an update, since neither she nor Barbara had heard anything. The pharmacy worker informed the nurse that the prescriptions had indeed arrived and they were now about to enter them into their system to see if prior authorization was necessary.

The nurse was nonplussed— why had the prescriptions not been entered five days earlier, when they were sent and received by fax? And what if the nurse had not called to follow up; how much longer would it have taken? Most importantly, how is it that the PBM-mandated pharmacy staff, who are dispensing medication aimed to keep people alive, do not see it as their duty to provide customers with the very best and fastest service possible? Barbara's radiation treatments, scheduled to begin the next day and already delayed nearly a week, now had to be postponed until the medication could be received.

Multiple cases are reported in which doctors must reach out to PBM-mandated specialty pharmacies to enquire about the status of medication— only to find that while the pharmacy has received the patient's prescription, it's been just sitting on someone's desk, untouched, with no concern for the person on the other end, who is being treated for a life-threatening condition.

PATIENT DENIED MEDS DUE TO TECHNICAL GLITCH

Carl, battling prostate cancer, was prescribed an oral chemotherapy drug to help control his disease. Under his insurance plan, however, the co-pay costs for the medication came to over $4,000 per order. Carl simply could not afford to pay such an exorbitant amount. Fortunately, the pharmaceutical company that manufactures the drug has a co-pay program of its own, for eligible patients, making the drug affordable. Furthermore, the in-house pharmacy at the clinic where Carl receives his treatment benefits from this arrangement, and is able to acquire these and other cancer drugs for the low patient co-pay of $20.

The clinic phoned Carl's PBM on his behalf, explained the situation and asked them to accept the pharmaceutical company's co-pay as a 'secondary insurance.' Their request was promptly denied, as the PBM explained that their system did not have the capability to add in a secondary insurance. When asked if they could then simply authorize the clinic to fill the prescription instead, as they had it right there, this was also refused. Unwilling to believe that his patient was not going to receive this medication because it could not be entered into the PBM's computer system, Carl's physician made repeated calls to the PBM, speaking to one supervisor after another. Ultimately, he was forced to admit defeat, and Carl was denied a treatment that might have extended his life.

Patients who receive medication at their treating physician's in-house pharmacy benefit from the fullest in personal care and attention, and have access to a team that will strongly advocate on their behalf. Patients who are forced to deal with PBMs and specialty pharmacies, on the other hand, are often relegated to numbers and statistics, and if their case requires special attention or extra effort, their needs are likely to go unmet.

BUSY SIGNALS AND PBM SPECIALTY PHARMACY PROTOCOLS DELAY DRUG DELIVERY

PBM specialty pharmacies require patients to schedule delivery of their medications by phone, which seems, on the surface, a simple enough task. John, who was undergoing chemo for bone cancer, tried for an entire week to get through to his specialty pharmacy and schedule the next delivery of his medication, but no matter what time of day he called, the line was always busy. Finally, one day before he was supposed to start a new chemo cycle, and with no medication left, John called the clinic in frustration, and asked if they could intervene in some way.

Calling the specialty pharmacy, John's clinic was able to speak with a representative. "You are lucky you got through! " she was told by the rep. "Our lines are so busy, we cannot make outbound calls because all of our lines are used up. " Their luck ran out fairly quickly however; as the clinic staff member was not on John's list of 'approved' contacts at the pharmacy, she was unable to speak on John's behalf and schedule delivery of the medication. And with the lines tied up throughout the day, the specialty pharmacy rep was unable to call John to verify. The clinic staff hung up, and had to call John back to tell him his only recourse was to continue trying to call in and hope that he will eventually reach someone— before it becomes too late to matter.

Another reason for delays in receiving medication from a PBM specialty pharmacy is the difficulty in adhering to their complex bureaucratic protocols. Pharmacies insist on speaking to the sick patient firsthand, hearing them name the drug, and confirming their shipping details before they will send the medication. However, patients often miss these calls, which are most often automated, and which stop after three missed attempts. In many cases, even when the patient answers the phone, they cannot confirm the name of the drug, causing another cycle of delay to begin.

SPECIALTY PHARMACY TRIES TO STEAL A PATIENT

For two days, a PBM specialty pharmacy had been calling and faxing a doctor's clinic, which offers a pharmacy to provide integrated care to the patients it treats. The specialty pharmacy was claiming that one of the clinic's patients, William, had requested that his lung cancer medication be transferred to their pharmacy, and was demanding the clinic's immediate compliance in the matter.

Surprised by the news, the physician contacted William to enquire about his decision, only to discover that this was the first time William had heard of the matter. "Please do not transfer it anywhere else! " William asked. " I want to get it filled through the dispensary. I did not ask for this. I love being able to get this right away and with no hassles. I was on an oral chemo before and it was filled by a specialty pharmacy and I always was getting it late, missed a few days of medication sometimes and had numerous phone calls from them. They never seemed to know what was going on with my medication."

At first it may seem surprising to hear of a specialty pharmacy resorting to lies in order to steal business from an in-house dispensary. On deeper examination, however, it would seem just the next step in a long line of unethical behaviors resulting from the industrialization of the pharmacy system and the dehumanization of patients seeking medical care.

PATIENT AND CARE PROVIDERS GET THE RUNAROUND

Diana, a patient with metastatic breast cancer living in Ventura County, California, needed to refill her oral medication. On a Thursday, the clinic staff called in to the PBM specialty pharmacy to refill it on her behalf. The specialty pharmacy representative promised to expedite the process and overnight the medication, at no additional cost.

On Monday morning, the staff member walked into her office to find several faxes, e-mails and voicemails from Diana's family, friends and assisted living staff. Apparently, they had received a phone call from the specialty pharmacy on late Friday afternoon, saying that the drug was out of stock in their pharmacy, and suggesting that she call around to local pharmacies to try and find some. Over the weekend, Diana's family and friends called every pharmacy in the county, before starting on those in Los Angeles and Santa Barbara, all with no success.

Hearing the news, the clinic staff immediately contacted the drug manufacturer, who gave her the name of another specialty pharmacy to try. She faxed over the prescription, and then followed up over the next few days, each time being told that the script was being processed. Near the end of the week, the new specialty pharmacy called her to say that they were unable to fill the prescription for at least another month, as it had already been filled by the initial specialty pharmacy— the one that had said they were out of stock. The staff member now called back the first specialty pharmacy, asking that they reverse their claim; however, they reported that the medication had already been shipped out via UPS. Tracking it down, the staff member discovered that indeed the medication was on the truck, ready for delivery.

The cost in hours wasted per patient, per medicine, multiplied by the millions of people living with cancer today in the US, is astronomical. This is in addition to the high toll that the resultant stress takes on patients and their caregivers, as they race through bureaucratic hoops and set off on what often prove to be wild goose chases.

THOUSANDS OF DOLLARS IN WASTED MEDICINE

Laura was prescribed a regimen of drugs to treat her multiple myeloma. She was supposed to take it for three weeks, and then take a break for a week. After two weeks on the medication, Laura began exhibiting symptoms of toxicity, so her oncologist lowered her dosage. However, her specialty pharmacy had already sent her another bottle of the medication in its initial, stronger dosage, to be used the following month. Unable to be returned, the $12,000 worth of medication had to be taken into the clinic and destroyed.

Numerous instances are reported in which patients' therapies have changed, but the specialty pharmacy continues to send the medicine anyway. For expensive anti-cancer drugs and therapies each wasted delivery can be worth tens of thousands of dollars. Each time, the medicine must be brought in and destroyed— a shameless waste of money, time and medicine.

About the Community Oncology Alliance

The Community Oncology Alliance (COA) is the only non-profit organization dedicated solely to preserving and protecting access to community cancer care, where the majority of Americans with cancer are treated. COA helps the nation's community cancer clinics navigate a challenging practice environment, improve the quality and value of cancer care, lead patient advocacy, and offer proactive solutions to policymakers. To learn more, visit www.CommunityOncology.org

May 2017

Unaccountable Benefit Managers:

Real Horror Stories of How PBMs Hurt Patient Care

Over 15 Years *of* Making a Difference in Cancer Care

There is no shortage of horror stories associated with the increasingly large role that Pharmacy Benefit Managers (PBMs) play in the United States' health care system. With their numerous offshoots and service lines, PBMs have managed to take on an oligopolistic presence that adversely impacts patients receiving treatments, their health care providers, and everyone else in between.

Originally created to lower prescription drug costs, it has become clear that these multibillion dollar PBM corporations have transformed into gargantuan and almost completely unaccountable arbiters of the care that cancer patients receive. As this story series demonstrates, the dangerous combination of PBM unaccountability, opacity, and lack of oversight have resulted in benefit managers that are focused on their profits and not patient care.

This paper is the second in a series from the Community Oncology Alliance (COA) that focuses on the serious, sometimes dangerous, impact PBMs are having on cancer patients today. These are real patient stories but names have been changed to protect privacy.

PBM KNOWS BETTER THAN THE DOCTOR?

A community oncology and hematology clinic in Pennsylvania was being forced to use a specific PBM specialty pharmacy for their patients' oral chemo prescriptions, despite the practice having its own in-office dispensary. They had actually applied to the PBM two years earlier for the right to dispense drugs; however, approval was still "pending."

Frank was one of the clinic's patients battling rectal cancer. His oncologist prescribed an appropriate medication and submitted it to the PBM specialty pharmacy for filling. Soon after, the PBM called the clinic and announced that approval was denied for the submitted diagnosis, however if the oncologist were to change the diagnosis to one of several other cancers, they would then approve it. The clinic responded by noting that this would be a fraudulent change, that they refused to comply with it, and would be reporting it to the State of Pennsylvania. Within ten minutes of that call, Frank's medication was approved without any changes.

Edward was another of the clinic's patients, also battling rectal cancer. He had been prescribed the same drug, with a specific dosage, to be taken twice daily, seven days a week, for five weeks. However, when the medicine arrived, the PBM specialty pharmacy had changed the dosage and instructions. This was done despite the fact that a pharmacy is forbidden to change prescription instructions without the approval of the prescribing physician. To make matters even worse, the quantities sent to Edward were incorrect, even for the adjusted regimen.

Chris was another patient at the practice battling with rectal cancer and prescribed the same medication with the same dosage. He too found that his prescription had been changed by the PBM specialty pharmacy—from seven days per week to five days per week. When the PBM specialty pharmacy called Chris to schedule shipment he refused because the instructions were different from those he'd been given at the doctor's office. At this point, the PBM specialty pharmacy called the patient's physician, who had to reinstate the original prescription.

Because of the constant, unauthorized changes to the details of prescriptions made by oncologists, this practice worries that patients' care is in danger. And these changes are not isolated to just this PBM or practice—specialty pharmacies seem to be playing it fast and loose with the oncologists' directed treatment plans. Details, such as number of dosages and their size, are crucial life-and-death matters, and PBMs and their specialty pharmacies should not be changing them.

NEARLY A MONTH OF DELAYS

James, a 73-year old husband, father and grandfather, had been battling metastatic non–small cell lung cancer (NSCLC) for a while, when his oncologist prescribed a new medication that was FDA approved for cases like James', in which the cancer was "locally advanced or metastatic."

On November 13th, James' doctor submitted a request for prior authorization to the PBM. The first sign that things were not as they should be was when the request was denied—in a way that made absolutely no sense; they were demanding the results of his blood tests for jaundice. His doctor was incensed. How could the PBM deny someone an FDA-approved medication that was indicated for their illness and prescribed by an oncologist? They resubmitted the request, and for the next three weeks, waited in vain for the determination, with the doctor occasionally calling for status, only to be disconnected or told to call back.

On December 4th, as the doctor waited on hold with James' insurance company, James' family called to say that James had died. They would never get a chance to see if the medicine would have prolonged his life.

PBMs, by giving decision-making power to administrative workers with no medical background and little to no patient contact, have created a system that often results in treatment delays and, in worst-case scenarios, the patient's untimely death. In contrast to this, when patients are permitted to purchase their medication from a physician-owned pharmacy, they are spared the crippling bureaucracy of the PBM system.

REFILLING MEDICATION TO TREAT THE DECEASED

A practice in California began receiving request after request from a particular PBM for prior authorization to initiate a refill—what was unusual was that they were for a variety of expired prescriptions. What was going on? None of the practice's patients had been prescribed these drugs recently. In fact, some were for drugs that patients had stopped taking months earlier, while others were for patients who had died.

The practice was puzzled at first, but then came to the following conclusion: "It seems they [the PBM] are just going through their files, and when a prior authorization expiration date pops up for prescriptions filled through their pharmacy at one time, they are automatically sending out prior auth requests."

An amusing anecdote on the surface, stories such as this reveal the wholesale approach taken by the PBMs, in which patients are viewed not as individuals in need of medical care, but rather as a potential market of consumers. Spread across the entire health care system with drug benefits managed by PBMs for millions of patients, this scenario also potentially means millions, if not billions, of dollars of wasted costs in cancer medications.

THE BUREAUCRACY KNOWS BETTER THAN DOCTORS' ORDERS?

George, a patient with multiple myeloma, was prescribed two specific medications that work in conjunction with each other. It was thus a great surprise when the specialty pharmacy refused to send his medication, saying that they wanted to discuss with his oncologist the drug interaction between the two medicines. His oncologist was also perplexed; it was common knowledge that these two drugs are always prescribed together, as the second medicine provides a key part of the maintenance for the first drug, a fact that was not only clinically known but actually spelled out clearly on the manufacturer's website. George had also been on the medication combination for nearly 18 months at that point without problems.

After over a month of delays, the oncologist and PBM finally got this sorted out, but George's fiasco wasn't over. The specialty pharmacy then caused further delay, as they insisted upon speaking again to the doctor, this time to ascertain how many refills were needed. The irony of this was that this particular medication cannot be refilled, so it was simply additional time wasted, while George's treatment cycle was again delayed.

PBM specialty pharmacies have a long list of complex bureaucratic protocols. While they may be designed to prevent mistakes and ensure patient safety, the result is just as often unnecessary, time-consuming delays that in fact endanger the patients they are trying to protect.

MANY PATIENTS… ONE PBM SPECIALTY PHARMACY FULL OF PROBLEMS—A PRACTICE DOCUMENTS CHRONIC DELAYS

A community oncology clinic became so fed up with the problems and delays their patients faced in dealing with a PBM specialty pharmacy that they opened a dedicated file to document each case.

Michelle, a patient at a Florida community oncology practice, had arranged for the PBM specialty pharmacy to ship her medication to one of their local branches, for easy pickup. However, when Michelle arrived at the store, she discovered that they had thrown away her prescription. She now had to request a new prescription from her doctor, get a new prior authorization from her insurance carrier, and then have the medication shipped again—all of which resulted in a two-week delay of treatment.

Diane, another patient at the clinic, had her prescription faxed to the same PBM specialty pharmacy. The pharmacy confirmed it had received the prescription. However, 50 days later, the medication had still not arrived. Clinic staff called the pharmacy, who then claimed they had never received the prescription. By the time it was all sorted out, Diane had been left two months behind in treatment.

The following month, another patient of theirs, Juan, came home to find that his medication had been delivered and left in the middle of the road. Exposed to the Florida heat and rain, the drugs were ruined and had to be reordered—subjecting him to another round of authorizations, delay of his life-saving treatment, and unnecessary cost for the health care system.

No system is perfect. But when a PBM specific pharmacy is repeatedly documented making life-threatening mistakes with no accountability, and cancer patients are forced to remain with them, unable to choose another pharmacy, it would seem that something needs to change.

NEARLY THREE WEEKS OF BROKEN PROMISES AND SHIPPING DELAYS

On January 12th, the clinic treating Liane, a cancer patient, submitted a prescription to her PBM's preferred specialty pharmacy. On January 19th, the day Liane was scheduled to begin treatment, her insurance company notified the clinic that even though they already had prior authorization, they were now requiring a new prior authorization.

Liane was understandably upset by the news; why had the insurance company not contacted them a week ago, when the prescription was first sent? This would now delay her treatment unnecessarily. Later that day, the clinic's pharmacist ascertained that the additional approval required was related to the medication's cost, which had been put under a separate review. Over the next five days, the clinic's authorization specialist, Barbara, was in constant contact with the PBM, who assured her that the medication would be going out at any moment.

A week later, Barbara discovered that this was not true, for when she finally reached a PBM supervisor, Barbara learned that authorization was still pending. She was told that it could take another seven business days or more, before a decision was made.

Barbara's call must have made a difference however, because later that day the PBM faxed over a form to the clinic, to be filled out and returned to them. The following day approval was granted, albeit for the mail order specialty pharmacy. It took another two days for the specialty pharmacy to receive the prescription, another day to process it, and then the pharmacy contacted the patient to arrange for shipping. All together it took nearly three weeks from the original prescription being submitted to the PBM for the patient to receive it.

"Approval of your medication is pending" may well join the list of phrases that savvy consumers have long-since stopped believing, such as "Your call is important to us" and "The check is in the mail." Too many patients and physicians have been promised things too many times by PBM and specialty pharmacy reps, only to find those promises unfulfilled or completely contradicted.

DATA MIGRATION OR PATIENT NEGLECT?

Cathy was one of the fortunate ones; after seven and a half years, she was among the 22% of patients diagnosed with Stage IV cancer who had made it past five years. Unfortunately, Cathy's survival was dependent upon the specialty pharmacy her PBM had mandated she use—despite the fact that her oncologist had an in-house pharmacy that she would prefer to use. The problem was that every month, Cathy had to engage in a battle with the PBM pharmacy just to obtain her oral chemo medication.

As an example, on October 12th, Cathy called the PBM specialty pharmacy to verify that they were planning to over–night the oral chemo medication to her, so she could stay on schedule. The PBM specialty pharmacy told her that her oncologist had not sent in the renewal subscription. Cathy then called the pharmacy manager at her oncologist's office, who assured her that the prescription had indeed been faxed over one week earlier.

Trying to help Cathy out, the practice pharmacy manager then called up the PBM specialty pharmacy, who placed her on hold until they eventually located the script, which indeed had arrived a week before. "Why was the medicine not shipped? " the pharmacy manager asked. "Data migration," she was told; this meant that the PBM specialty pharmacy was in the middle of reorganizing its filing system, and had failed to take proper precautions to ensure that no patient care information was lost or misplaced along the way.

Had Cathy not called up the specialty pharmacy, she would never have received her medicine in time. Furthermore, the pharmacy manager at her oncologist's office informed Cathy that while she had been talking with the PBM specialty pharmacy, another patient had called her with the exact same issue. Every month, without exception, Cathy has had difficulty getting the medicine shipped on time from the PBM specialty pharmacy. No matter what, whenever her oncologist calls it in, the PBM specialty pharmacy manages to misplace the order.

Customer satisfaction, integrity, and commitment are important qualities for any profession or field. Yet, they are even more crucial in those professions that deal directly with people's lives. As PBM specialty pharmacies deal in products that have the potential to lengthen the time another person has on Earth, there must be a different standard to which their employees are held, and clearly indifference, apathy and carelessness should have no place.

PATIENT AND CARE PROVIDERS GET THE RUNAROUND

One serious complication that often results from chemotherapy and radiation treatments is a condition called neutropenia, in which there is a significant reduction of the white blood cells that provide essential first line of defense against infections. Neutropenia can lead to sepsis, organ failure, and death; however, it need not progress this far, if properly treated in time.

Marvin, a cancer patient being treated by a community oncology clinic, had developed neutropenia, and his oncologist prescribed a medication that helps the body to produce more white blood cells. His PBM indicated that, in order for Marvin to receive this particular medication, it had to be mail ordered from a specific PBM specialty pharmacy.

The clinic where Marvin was being treated faxed the prescription over to the specialty pharmacy on February 27th. Three days later, they called to check on status, and were told that the prescription was in the 'benefits verification stage,' in which the PBM pharmacy confirms that the patient's insurance provider will indeed cover the medication's costs. The clinic asked if prior authorization was required, but the PBM specialty pharmacy representative was unable to say; she promised to call back with that information. Two days later, having heard nothing, the clinic called again, and a PBM specialty pharmacy representative told them that indeed prior authorization was required. That same day, the clinic arranged for prior authorization, called the PBM specialty pharmacy back, told them the medication had been approved, and requested that they now call the patient and arrange for delivery. The PBM specialty pharmacy representative refused, however, stating that the prescription was still 'being processed.'

Having had enough, the clinic manager asked to speak with a supervisor, who under pressure, agreed to deliver Marvin's medication on March 7th. However, the date came and went, without any medicine being delivered; nor did Marvin or his clinic receive any phone calls from the PBM or specialty pharmacy, to let them know about or explain the additional delay. When the clinic called back the next day, the PBM specialty pharmacy representative told her that the medication was out of stock, but they would arrange for delivery on March 9th.

Because of the PBM delays and runaround, Marvin's neutropenia continued to go untreated for nearly two weeks, leaving him vulnerable to any number of infections and diseases that his body was unable to fight off on its own.

Dealing with PBM bureaucracy often feels like being trapped on a merry-go-round, with no way off. Every issue is handled by a different person or entity, each with its own agenda and protocols, and there is no one person who has a bird's-eye view of the patient's situation. Nor is there any accountability or certainty that the promises made will be met.

PBM SPECIALTY PHARMACY INDIFFERENCE DELAYS MEDICATION FOR TWO MONTHS

Darla had been taking a medication to treat her thyroid cancer since June. Then, in January her insurance provider changed to a new PBM, although they assured Darla that she would be able to continue filling her prescription at her doctor's in-house pharmacy. However, when it came time for her January refill, the PBM denied the clinic authorization to fill the script, saying it had to be filled at their own specialty pharmacy.

Despite being a federal government-supported plan under Obamacare, which mandated that the PBM consent to any

"willing provider," Darla never received her January refill. By the time the PBM contacted her for benefits verification, an entire month had gone by. Another week passed, and then another, without Darla ever receiving her medication.

Six weeks later, on March 7th, the PBM called Darla to schedule delivery, but there was more to come. Now her case was passed on to the PBM clinical department, where they needed to verify the dose, diagnosis, allergies, and drug interactions, despite the fact that Darla had been on the medication already for nearly ten months.

Once everything was verified, someone at the PBM realized that the medication was being used off-label. They called up Darla's oncologist, who confirmed that the patient had received prior authorization back in June to use the drug for thyroid cancer. He also asked the PBM specialty pharmacy representative for an explanation as to why it had taken so long to get Darla her medicine, and why there had been so many lags in communication, but the PBM representative had none to offer. As the call came to an end, the physician asked if Darla could now finally get her medicine. "No," the specialty pharmacy representative said. "Now we forward to the payment verification center. Once complete, it will be forwarded to the dispensing center. Then we can ship it out."

If Darla had been allowed to purchase her meds from the in-office pharmacy at her oncologists practice, she would have had them within 48 hours at the most. With the PBM specialty pharmacy, it took closer to two months.

Even when PBM specialty pharmacies are unable to provide a patient with the necessary medicine, they still will not release that patient so he or she can purchase it where it is available. The greed is so deep that they would rather risk a patient's life than allow another pharmacy to profit in their stead.

About the Community Oncology Alliance

The Community Oncology Alliance (COA) is the only non–profit organization dedicated solely to preserving and protecting access to community cancer care, where the majority of Americans with cancer are treated. COA helps the nation's community cancer clinics navigate a challenging practice environment, improve the quality and value of cancer care, lead patient advocacy, and offer proactive solutions to policymakers. To learn more, visit www.CommunityOncology.org

September 2017

Bureaucracy, Deadly Delays, and Apathy:

Pharmacy Benefit Manager Horror Stories — Part III

Over 15 Years *of* Making a Difference in Cancer Care

The dire consequences of having Pharmacy Benefit Managers (PBMs) within the United States' health care system continue to be seen, especially by the millions of cancer patients across the nation who must interact with them to access life-saving drugs.

Initially established as a way for insurance companies to outsource the management of drug benefits, PBMs have slowly morphed from simply handling prescription transactions to managing pharmacy benefit plans, negotiating with drug manufactures for discounts, and determining which drugs a patient will receive and from whom they will receive them. It's even reached the point where PBMs have become so bold as to usurp physicians' treatment decisions without consulting or notifying them of their actions.

This paper is the third in a series from the Community Oncology Alliance (COA) that focuses on the severe impact PBMs are having on cancer patients today. The stories are all real and provided by community oncology practices; only the patient names have been changed, to protect their privacy.

The vast number of horror stories from PBM abuses that are being reported by COA and others, shows the devastating result these institutions are having on patient care. From medication never sent or never received and mistaken dosages, to insurmountable red tape erected between the patient and their treatment, the problems are numerous and lead to one incontrovertible conclusion: action must be taken to stop PBM abuses.

PBM-PHARMACY ERROR NEARLY KILLS PATIENT

Carla, a colorectal cancer patient, was prescribed a common oral medication that has been on the market for nearly 20 years. Carla's PBM mandated that she fill the prescription at a large, well-known specialty pharmacy. Each time, the pharmacy had the medicine auto-shipped to Carla, with no patient contact or instructions.

Carla's oncologist prescribed the medication to be taken in rounds with the following specific instructions: 'two weeks on, one week off.' The PBM mail-order pharmacy, unfortunately, neglected to include the 'one week off' part of the instructions on the label. After her third refill, Carla ended up in a hospital's intensive care unit, fighting for her life.

Carla's experience was the straw that finally broke the camel's back, and the practice established its own oncology pharmacy with a pharmacist-managed program. However, many of their patients are still required to purchase their drugs from PBM-mandated, mail-order specialty pharmacies.

PBM pharmacies have been repeatedly documented making life-threatening mistakes; yet patients are forced to remain with them, unable to receive their medication at their physician-managed pharmacy, where they would receive the close, personalized care and monitoring that would easily prevent such potentially fatal occurrences from happening.

A PBM BUREAUCRACY FAILS TO HELP PATIENTS

Dylan had been on a specific medication for several years to manage his chronic cancer. Each time, he would simply fax the refill script to his pharmacy and the prescription would be filled with no glitches. Dylan's new insurance policy, however, required him to now fill his prescriptions at a specific PBM specialty pharmacy.

As usual, the clinic treating him faxed his refill prescription over to the new pharmacy in mid-May and Dylan waited for his medication to arrive. He waited and waited. In fact, over

the next few weeks, Dylan's wife began calling the pharmacy on a daily basis, asking them when the medication would arrive. Each time, she was told there was some issue delaying delivery, but that it would be resolved in just a day or two, not to worry. Every few days, she would call back to say it had still not arrived, only to have the same conversation with a different person.

Finally, after over a month of waiting, Dylan's wife asked his oncology clinic to intervene and one call from them determined the actual problem. Apparently, the prior authorization for the medication had expired, something no one at the specialty pharmacy had bothered to inform Dylan, and no one his wife had spoken to had bothered to check what the real issue was holding up delivery. The clinic handled the situation, arranging for authorization and for the medicine to finally be shipped.

Patients and practices often find their efforts to be futile in trying to overcome the massive bureaucracy morass they face with PBM-mandated specialty pharmacies. This creates a costly burden on the physician offices throughout the country, who must now take up the task of contacting pharmacies, resubmitting medication approval, locating missing prescriptions, questioning holdups, and more. But what of the thousands of patients out there with no one in their corner, who are forced to fight these battles on their own?

ONE-SIZE FITS ALL IS NO WAY TO TREAT A CANCER PATIENT

About a year ago, Darlene was diagnosed with multiple myeloma and prescribed a particular medication. Single and living alone, Darlene decided she would continue to work full-time while being treated for the disease.

The first hurdle Darlene met was getting her 21-day supply of medication filled by the mail-order pharmacy mandated by the PBM. The pharmacy called her while she was in a meeting at work and insisted that she listen to the mandatory recital of the "Patient Understanding." They promised it would take no longer than five minutes, yet forty-five minutes later, having been transferred to four different representatives as part of the process, Darlene finally hung up the phone.

While confused and upset, Darlene also felt relieved that the PBM ordeal was over, and all she had to do now was to wait for the medication to arrive. She could not have been more wrong. Although Darlene had made it very clear that she arrives home every day from work at 4:30pm, two days later Darlene arrived home to find a note on her door that UPS had tried to deliver her medicine at 2pm. She spent the rest of the day trying to locate the medicine.

After a great deal of effort, Darlene managed to schedule future deliveries of her medication for Saturdays before 1pm. Darlene is hard of hearing, so that Saturday, she sat in her front room from 8am to 1pm, afraid to even go to the bathroom lest she miss the knock on the door. At 2pm, she opened her front door and found a note from the UPS driver that he had attempted to make the delivery but found no one at home. Again, she had to chase down the package and finally ended up retrieving her drugs from a drop center twenty-five miles away from home.

As time went on, Darlene's situation only worsened, becoming more and more time-consuming for this elderly woman who was already contending with a fatal cancer. Each time she attempted to speak to a PBM representative to resolve the issue, she was passed to a new person who refused to listen to what Darlene had to say, but rather droned on repetitively that Darlene must "follow procedures" or she would not receive her medication.

Not every cancer patient has a vast network of family and friends who are there to assist them in their time of need. Often the elderly, or those living alone without close friends nearby, are forced to handle everything by themselves. While a physician-managed pharmacy would be able to adjust to such a patient's needs and assist them in easily accessing their medication, PBM mail-order pharmacies are not set up to handle the requirements of individuals. Patients must comply with their procedures and regulations, regardless of the personal cost.

POTENTIALLY FATAL DELAY IN DELIVERY

Bertrand was diagnosed with renal cell carcinoma and prescribed a specific oral medication by his doctor. The oncology clinic sent out his prescription to the PBM-mandated specialty pharmacy on February 4th. Four days later, the clinic called the pharmacy to follow up, and was told that the pharmacy was waiting for additional information from Bertrand. Ten days later, they called again to see where things stood, and were told that while the pharmacy had tried to call the patient and schedule delivery, they had been unsuccessful in reaching him. The

patient's clinic asked why the pharmacy had not tried to call the patient's doctor; were they not aware that Bertrand was suffering from renal cell carcinoma, and that it was quickly progressing without medication?

Another eleven days passed — nearly one month from the initial prescription — and Bertrand informed the clinic that the medication had still not arrived. The clinic once again called the pharmacy and were told that the pharmacy had closed the patient's account there, having been unable to reach him and verify his information in order to schedule shipment. The clinic then called Bertrand and asked him to contact the pharmacy in order to re-open his account and immediately schedule delivery.

Nearly forty days since being prescribed the medication, Bertrand had still not received it. The oncology clinic ultimately filed a formal complaint with the insurance company and is waiting for a resolution. Meanwhile, Bertrand continued to wait, though his cancer did not; in fact, between Stage I and Stage IV of renal cell carcinoma, five-year survival rates go from 90% down to 10%.

Time and again, patients wait for medication from PBMs that will never arrive — because of a small detail missing in the documentation, or a situation that requires the specialty pharmacy worker to take some proactive measure. These workers, with their passive attitude towards patient care, unfortunately, do not see themselves as partners to the process, nor do they see it as their responsibility to shorten the time needed to deliver patients' medication.

COMPLETE INDIFFERENCE TO A SITUATION'S URGENCY

Lorraine, a multiple myeloma patient, was being denied by her insurance company the medication prescribed by her doctor. A worker at the clinic where she was being treated called Lorraine's PBM to sort the matter out. She got through to a company representative and began reviewing the situation until, at some point, the call was disconnected. Upon calling back, the worker had to start all over from the beginning with a different customer service representative.

A few days later, she called the PBM a third time, reaching yet another representative, who seemed unable to understand the situation. The clinic worker asked to speak to a supervisor, yet she turned out to be even more abysmal than the prior three representatives, both in terms of her attitude and her inability to understand the situation. The supervisor transferred the matter over to someone in appeals.

Now, the clinic worker found herself speaking to a fifth employee of the PBM who became even more aggressive, and questioned the worker's role in the doctor's office and her right to be making the call. When the worker began to conference the doctor in, so he could participate in the phone call, the PBM representative hung up on them.

As a last resort, the worker tried reaching someone in the PBM investor relations department, and had the call transferred over to the executive escalation team. She began by emphasizing the urgency of the matter; the longer it took to get Lorraine her medication, the worse her prognosis. She added that their office would be contacting both Medicare and the Insurance Commissioner's office in Maryland, to complain about the unprofessional handling of the matter with a patient's life on the line. Within twenty-four hours, there was a case worker assigned to Lorraine's case, yet no knowledge yet of how long it would be before — or even if — Lorraine would receive authorization for the lifesaving treatment she needed.

Dealing with PBM bureaucracy often feels like being trapped on a merry-go-round with no way off. Every issue is handled by a different person or entity, each with its own agenda and protocols. Patients must wait for weeks or even months, to obtain medication that they could have received within twenty-four hours, had they been permitted to get it at the point of care from their oncologist. These delays often translate into delayed treatment and worsening of the patient's condition, and in the most tragic of cases, possibly contribute to the patient's death.

BUREAUCRACY LEAVES A PATIENT IN LIMBO

Janine, a 22-year-old woman with Hodgkin's lymphoma, was prescribed a specific medication for fertility preservation. Her clinic's representative contacted the PBM specialty pharmacy to determine if prior authorization was required for the drug, and what Janine's co-pay would be.

The PBM pharmacy representative rudely responded that Janine's doctor needed to follow the proper procedures: send in the prescription and wait the necessary two days before obtaining the benefits information. The clinic representative explained that they only wanted the benefit information in order to make a treatment decision; that without knowing the co-pay they didn't know if Janine

could afford the medication, and therefore didn't know whether or not to prescribe it.

The response was that the PBM specialty pharmacy could in no way help in this, nor could they refer them anywhere for more information. As a result, the clinic's hands were tied; they had no idea if the insurance company would authorize the medication, and if not, if Janine would be able to afford them on her own.

PBM specialty pharmacies have a long list of complex bureaucratic protocols, but shouldn't they be able to help patients and practices make cost saving decisions? Unfortunately, PBM bureaucratic protocols are often harmful to the very patients they are meant to help.

ONE DANGEROUS MISTAKE AVERTED… HOW MANY AREN'T?

Maria was a colon cancer patient prescribed several rounds of chemotherapy. For her first round of treatment, all went smoothly; she was permitted to fill the drug prescription right there at her clinic's physician-run pharmacy. However, for the second round of treatment, her insurance company mandated that she use one of the large, well-known PBM specialty pharmacies.

The problems began when the specialty pharmacy delivered Maria's medicine late, which delayed the beginning of her second treatment round. The following month, things worsened. Maria had suffered profound side effects from the medication, causing her oncologist to lower the dose for her third round of treatment. When Maria called the pharmacy, however, they said they had no record of the new prescription on file — though it had been sent and received.

Confusingly, shortly after the call, the PBM pharmacy called Maria back and said the medicine was about to be shipped. Upon her inquiry, the pharmacy informed her of the dosage; it was the same dosage and instructions as the previous two rounds, which had caused the intolerable side effects. Maria proceeded to spend the next several hours on the phone with the pharmacy to correct the situation. In addition, her physician's office called and spent time clarifying the matter with them. Had Maria been any less vigilant, her health could have been severely compromised by such sloppy drug administration.

With PBM specialty pharmacies being run completely separately from the point of care and physicians, patients must be extremely vigilant at all times to ensure they receive the correct medication. For cancer patients who are already dealing with a life-threatening disease and a range of debilitating side effects of the toxic medications they are on, this additional burden can be very costly — and for some, simply not feasible.

TOTAL INDIFFERENCE TO PATIENT'S PROGNOSIS

James was a patient in his late 50s, suffering from advanced renal cell carcinoma. On May 18th, his oncologist prescribed a particular medication, and they began a two-week wait for his insurance company to approve usage. Upon receiving approval, the doctor's office sent the prescription over to James' PBM-mandated pharmacy, with a request that it be handled ASAP, as the patient's situation was dire.

One week after making the urgent request and having heard nothing, the practice followed up to ascertain the status of his prescription. A few days later, a response came back from the pharmacy that they had attempted to contact James twice, but had not succeeded to reach him. They asked the doctor's office to have the patient call the pharmacy himself. The office asked the pharmacy if and when they had been planning to contact them, to notify them that there was an issue with delivering James' medication. The pharmacy responded that their policy is to try phoning the patient three times, and then they either contact the prescribing doctor's office or simply mail the prescription back to the patient.

While the PBM bureaucracy failed to try to remedy the situation, James' cancer continued to spread, untreated, leaving him no closer to receiving his medication than he had been three weeks earlier. As for the PBM pharmacy, they seemed completely unconcerned, despite the fact that the five-year survival rate for advanced renal cell carcinoma goes from 53% down to 8%, if it passes from Stage III to Stage IV.

Time and again, doctors reach out to PBM-mandated specialty pharmacies to enquire about the status of medication— only to discover that the process is stuck, and no one at the pharmacy feels any sense of urgency, despite the fact that the patient in question is being treated for a life-threatening condition in which time is of the absolute essence.

THE HORROR IS NOT LIMITED TO CANCER DRUGS

Carl was prescribed regular injections of anticoagulant medication. The initial prescription was sent off to the local branch of a major pharmacy and filled without issue. Three weeks later, however, when Carl tried to refill his medication, the pharmacy charged him a $700 co-pay. They explained that they could not offer refills; they must go through his PBM-mandated specialty pharmacy. Now there was an emergent situation because Carl needed those syringes immediately.

Carl paid the high price to obtain four syringes, which was all he could afford, while his doctor contacted the insurance company, who said that if the local pharmacy would call them, they could offer an override. The doctor called the pharmacy with the terrific news, only to hear them refuse the request, outright. "We don't have time for this," they said. "If the customer wants an override, he needs to make the call himself."

Several hours later, Carl received a call from the local pharmacy, saying that they had spoken with his insurance company, and that the mail-order pharmacy will need a new prescription. No word about the override — they hadn't even bothered to enquire about it while on the phone with the insurance company. Three hours later, the mail-order pharmacy sent Carl's doctor a request… only it was for a refill on medication used to prevent side effects caused by chemo and radiation — not for the anticoagulant meds that Carl actually needed.

At this point, Carl was twenty-four hours away from being out of medication. Adding to the absurd irony of the situation, Carl's doctor actually had an in-house pharmacy that stocked the necessary medicine. However, while the pharmacy was once part of the network of Carl's insurance company, in 2011 their contract had been cancelled, as they presented competition to the PBM's specialty pharmacy.

Even when PBM specialty pharmacies are unable to provide a patient with the necessary medicine, and even when the situation is urgent to the point of life and death, they still will not release that patient so he or she can purchase it where it is available. The greed is so deep that they would rather risk a patient's life than allow another pharmacy to profit in their stead.

About the Community Oncology Alliance

The Community Oncology Alliance (COA) is the only non–profit organization dedicated solely to preserving and protecting access to community cancer care, where the majority of Americans with cancer are treated. COA helps the nation's community cancer clinics navigate a challenging practice environment, improve the quality and value of cancer care, lead patient advocacy, and offer proactive solutions to policymakers. To learn more, visit www.CommunityOncology.org

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Danger, Delay, Denial:

Pharmacy Benefit Manager Horror Stories — Part IV

The cautionary tale of the Pharmacy Benefit Manager (PBM) system is a lesson not yet learned. The United States' health care system continues to be strangled by the dark presence of these ever-growing corporate middlemen, siphoning off billions of dollars in profits while leaving behind pain, suffering, anxiety, and despair for the millions of cancer patients.

This is the fourth paper in a series from the Community Oncology Alliance (COA) that focuses on the very real and negative impact PBMs continue to have on cancer patients today. This impact threatens to grow even stronger under recent proposals put forth by the Centers for Medicare & Medicaid Services and in President Trump's Blueprint. Rather than heed warnings about abusive PBMs and limit their influence, the current administration has proposed to do the exact opposite and increase the role PBMs play in our health care.

Today, while PBMs are contracted to handle Medicare Part D, which includes self-administered medications such as pills, they are not involved in Medicare Part B, which covers all doctor- administered drugs, such as infused chemotherapy. The government is now proposing a slew of changes, including that some, or all, of Part B medications be shifted to fall into Part D. It has also dictated that insurance middlemen, some of which own PBMs, can require step therapy for Part B medications in Medicare Advantage.

These proposals have been put forth to lower drug prices. Unfortunately, they ignore the vast evidence that the incompetence and greed of middlemen has not only failed to reduce drug prices but has ironically caused them to increase thanks to the network of shadowy rebates and discounts siphoned off by these middlemen. And, as these horror stories clearly demonstrate, this has all been done at the expense of cancer patients.

The following PBM horror stories have been provided to COA by community oncology practices. While patient names have been changed to protect privacy, the terrifying stories and details are unfortunately very real.

BUREAUCRATIC MADNESS AND A GAME OF TELEPHONE

Donald, an electrical engineer, husband and father of two college students, had been diagnosed with colorectal cancer and was scheduled for radiation treatments. His doctor prescribed an oral chemotherapy to be taken alongside the radiation and faxed the prescription off to Donald's PBM-mandated specialty pharmacy. Three days later, the pharmacy contacted Doreen at the clinic treating Donald, to clarify his prescription. Doreen handled the matter without delay, and then, four days later, called to ask when the medicine had shipped… only to discover that due to 'issues' it had not yet gone out.

The pharmacy transferred Doreen to the Medicare department, and after a lengthy wait, a representative came on, to whom Doreen explained that Donald was in fact not a Medicare patient. After another lengthy wait, the silence was broken only by the occasional interjection of "One moment," the representative explained that regardless of the patient's coverage, this particular medication ordered for him needed to be 'released' from the Medicare Part B department.

The representative informed Doreen that the next step was for her to call Donald and ask him to call them – the pharmacy – to schedule delivery, as the pharmacy was not able to make outbound calls. However, she said, another option was for Doreen to bring Donald in on a third-party call and then wait on the line while the pharmacy verified the entire shipping process with him.

A very frustrated Doreen hung up and called Donald to explain the situation. By now it was Friday afternoon, and Donald was scheduled to begin radiation treatments on Monday, accompanied by the oral medication. It was looking more and more unlikely that Donald would have his medication in time. Adding to the absurdity of the situation was the fact that Doreen had plenty of the medication Donald needed – right there in the in-house pharmacy, and could easily have filled Donald's prescription herself, had the PBM allowed her to do so.

Countless times, bureaucratic PBM delays mean that patients must postpone treatment – or begin, but without the right combination of medicine – that will give them their best chance at battling this devastating disease. Yet, even when the situation has become a matter of life and death, patients have no recourse other than to wait it out, as the bureaucratic machinery of the PBM is not programmed to make any kind of exception.

SHAMELESS BLAME GAME WHILE THE PATIENT SUFFERS

James, a third-grade teacher in his early 40s, has lived with leukemia for many years, keeping it in remission with a daily oral medication. In November, his insurance provider notified James' doctor that a new prior authorization was required to continue receiving his medication. There was no time to lose; James had just finished his last bottle and needed an immediate refill. The authorization was immediately obtained, and the clinic forwarded it on to the PBM-mandated specialty pharmacy.

Four weeks went by, yet no medication arrived. Brenda, a clinic worker, contacted the specialty pharmacy, and a voice on the other end stated that a new prior authorization was needed. Confused, Brenda again faxed the approval letter to the pharmacy, while continuing to wait on hold. After a considerable wait, the pharmacy worker came back on the line and told Brenda that this letter was already in the patient's file, but that a new prior authorization was needed.

What on earth for? Brenda wondered to herself, as she hung up the phone. They were in February, so perhaps it was because the previous prior authorization had been sent in 2017? Yet, according to the insurance company, the old prior authorization was still in effect. She called the specialty pharmacy back, and this time a different representative answered. He looked up James' case and stated that all was well; in fact, the medication should arrive in just a few days.

Brenda hung up and called James to let him know he should expect his medication any day now. Answering the phone, James told Brenda that for the past four weeks, going without medication, he'd been frantically calling the pharmacy on a regular basis, trying to order it. They had told him each time that they'd been unable to contact Brenda, despite many attempts, and that his being without medication was due to the clinic's negligence.

Meanwhile, during those same four weeks, while James' blood counts were reaching horrific levels, Brenda was able to fill five prescriptions of the same drug for other patients, whose PBM allowed them to receive their medications in-house.

Dealing with PBM bureaucracy can be frustrating to say the least. Getting the runaround… being told one thing by a representative, only to have that information contradicted the next moment by someone else… having the person on the other end of the phone lie to you… these are the things patients and clinic workers meet time and again. And, as if lying about the status of a drug's delivery wasn't bad enough, to add insult to that situation by implying the delay is the fault of the very people treating the patient, is unconscionable.

TROLLING FOR BUSINESS

The pharmacist of an in-house clinic at a community oncology practice was going over patient files one day when the phone rang.

The caller politely introduced herself as an employee of a well-known PBM specialty pharmacy, and then abandoned all niceties as she proceeded to ask why the pharmacist was filling a prescription for a patient that by all rights belonged to them. The in-house pharmacist pulled up the

file for the patient in question, who was battling advanced stage ovarian cancer. Not seeing any conflict of interest, he requested further details.

In clipped tones, the caller explained that his filling of this script was "outside of the manufacturer's contract, and illegal." Unfazed, the pharmacist responded by saying that there was no law preventing them from filling it. At this point, realizing that her strong-arm tactics were getting her nowhere with the pharmacist, she changed tactics; perhaps the doctor would be an easier target. "Did the patient's physician intentionally send the script to you?" she asked, to which the pharmacist replied, "Of course he did. Our pharmacy is located inside of the practice."

With no wiggle room left, the caller said that she would be informing the patient of all this, and abruptly ended the call. The pharmacist was left to marvel at the audacity of trying to intimidate him into handing over a patient – and the corporation that clearly couldn't care less about what was best for her.

When that corporation's income is derived from 'trolling' the system to collect more profit-generating patients receiving treatment for life-threatening ailments, we realize things have gone way too far. At some point, something must be done to rectify the perverse profit-motives and incentives behind the corporate PBM approach patient care.

CAN'T BE BOTHERED TO GET THE PRESCRIPTION RIGHT

Annabelle, a retired cosmetician and widow, had been diagnosed with Philadelphia chromosome-positive + chronic myeloid leukemia. Her community oncologist tried her out on 180mg of a particular medication, and Annabelle's response was highly positive. Her blood work showed immediate improvement, and she showed no significant side effects.

The doctor wrote out a prescription for the medication, which according to Annabelle's PBM had to come from their mandated mail order specialty pharmacy. As the medicine does not come in pills of 180 mg, the prescription clearly stated: one 100 mg tablet and one 80 mg tablet. Nevertheless, over the following months, each time Annabelle had her prescription renewed, she was given either 100 mg or 80 mg – never both. This meant that she was not only taking the wrong dosage, but also her dosage was changing each month, according to the whim of the pharmacy and whoever happened to be filling her prescription.

Annabelle did not do well with the incorrect dosing; her laboratory results showed dangerous levels in her blood work, again.

Despite the clinic's repeated attempts to get the PBM to deliver the right medication, the PBM specialty pharmacy refused to take the necessary measures to ensure that Annabelle received the proper dosage. When the doctor tried to have the script filled in the in-house pharmacy at his clinic, it was denied. Meanwhile, Annabelle continues to be improperly dosed, impacting her opportunity for remission.

This story exemplifies the constant dangers patients are in at the hands of incompetent, faceless PBM pharmacy workers. Removed several times from the patients they are meant to serve, their inattention to crucial detail is not what we should expect from a company in the business of caring for patient lives.

PBMs STANDING IN THE WAY OF TIMELY STANDARD OF CARE TREATMENT

Rhonda, a 55-year-old wife, mother, grandmother, nurse, world traveler and self-described Disney expert had been diagnosed with Her2-negative breast cancer. She was receiving treatment at a local community oncology center. Her physician prescribed treatment and attempted to fill it on the same day at the in-house pharmacy; however, the co-pay was too high for Rhonda's limited means.

The clinic's financial assistance coordinator went to bat and, six days later, had secured a co-pay card from the drug manufacturer. Two days later, however, when the practice tried to fill Rhonda's script, her PBM rejected the use of the co-pay card at the practice pharmacy. Instead, the PBM required the script to go out to its own specialty pharmacy. Not wanting to delay her treatment, the practice quickly faxed the prescription over.

Another six days passed before the specialty pharmacy notified the clinic that the prescription must first go

through the specialty pharmacy connected with the patient's PBM, regardless of who would ultimately fill it. The clinic staff filled in all the additional forms and handled all new bureaucratic measures, and then proceeded to wait. Three days later, a clinic RN called the specialty pharmacy to ask for an update. The representative who answered told her that all was well, and that no prior authorization would be needed. She then placed her on hold. Ten minutes later, the representative returned, only to say that actually prior authorization was needed. With the greatest of patience, the nurse filled out all the new forms and faxed all relevant records necessary for the prior authorization, over to the specialty pharmacy.

Later that day, the pharmacy contacted the RN to inform her that the prescription had been denied, based on the patient's Her-2 positive status. The RN again sent the patient's records to the pharmacy, highlighting the fact that she was, and had always been, since she was first diagnosed Her-2 negative. Two days later, the medicine finally arrived.

All-together, Rhonda's therapy was delayed 19 days, which, had she been permitted to fill her prescription in-house, would never have happened. In total, the clinic staff spent five hours dealing with red tape.

Worst of all, Rhonda never had the opportunity to take the first pill. The night before the medication arrived at her home, she was hospitalized for complications of her metastatic disease. After a lengthy hospital stay she was discharged home to hospice.

While the physicians caring for Rhonda were busy trying to "march to the beat of the PBM's drum", this sweet, young, vibrant woman's window of opportunity closed. How many other scenarios involving pointless deterioration, hospitalization, and death from PBM incompetence are there? When reflecting on the life and care of the patients, PBMs should not be part of the conversation.

WOULD IT KILL YOU TO WAIT?

In 2012, a 45-year-old salesman named Bill was diagnosed with colorectal cancer. Bill had a good job working for a large office supply manufacturer based in the Midwest, a loving wife and two small children, and he decided to fight with everything he had. Following surgery, Bill was treated with IV chemotherapy, but with negligible results. The cancer progressed over the next year, and his doctor changed to a different IV chemotherapy. This time his response was very good, and for the next four years things were fairly quiet.

In 2017, tests showed that Bill's cancer was back, and this time he was treated with yet a third kind of IV chemotherapy. His response seemed good at first, but by the following year, the cancer had progressed to Stage IV and metastasized to his liver. At this point, Bill's oncologist ordered an oral medication specially prescribed for relapsed or metastatic colon and rectal cancers.

Bill's physician at the community oncology practice sent the prescription over to the in-house pharmacy to fill. Unfortunately, according to Bill's new insurance plan, his prescription could only be filled by a PBM-mandated pharmacy. Despite the facts that Bill's Stage IV cancer was aggressive, that his doctor wanted to get him started on the medication that very same day, and that the medication was sitting on the shelf of the in-house pharmacy, Bill had to wait. Even the option sometimes given to have a 'one-time fill' that would let him get started while waiting for the PBM pharmacy to mail him his medication was denied. Thus, with the drug's prohibitive list price (over $10,000/month), Bill had no option but to wait.

The doctor sent his prescription on to the new pharmacy, along with Bill's contact details, so that they could arrange for delivery. Meanwhile, Bill went to his clinic and received detailed in-person counseling on how to take the drug, since it was a somewhat complicated regimen. There were specific directions on how to take the medication, what side effects to expect, and how to ensure the proper dosing. The latter could be confusing, since the drug is taken in multiple tablets twice daily on days 1-5 and 8-12 of a 28-day cycle.

After seven full days of waiting to start his therapy regimen, Bill finally received his medication in the mail. Opening the box, he began to read the label, and found to his great surprise, that it stated: "take once a day." Picking up the phone, Bill checked in with his oncologist

to report the change in instructions. The clinic pharmacist confirmed that the instructions were wrong, and reached out to the PBM pharmacy, which promised to contact Bill about clearing up the matter.

Bill received a call from the PBM-mandated pharmacy representative, who apologized for having sent the wrong prescription with the wrong amount of medication. They assured Bill he would receive an additional supply of medication. First, however, they asked Bill to please return the medication he had been sent, so it could be properly labeled. Now Bill, with Stage IV metastatic cancer and his treatment already having been delayed a week, was being asked that rather than take his life-saving medicine, he ship it back to the warehouse for proper labeling and reshipping.

This was not the last time the PBM pharmacy impacted and delayed Bill's care. Later, when it came time to refill his medication, Bill's treatment was again delayed. The PBM pharmacy, it seemed, decided that before filling his prescription, it had to first clarify the dosage. It then claimed to have had difficulties in contacting Bill's community oncology clinic, despite having been provided with all the correct contact details. Ultimately, Bill had to call his local clinic and ask for the in-house pharmacist to call the PBM to confirm dosage, before they would ship it out. And while he waited, his cancer was allowed to progress, unchecked.

One of the most dangerous parts of PBM-mandated pharmacies is the distance between the pharmacy and patient. In this, we are speaking not only of geographical distance, but also of when patients are forced to wait for medicine to be shipped, rather than walk across a hallway to purchase it. More to the point, however, is the situation in which the patient becomes a name or number on a call sheet, rather than an actual human being facing a life-threatening illness; rather than a patient for whom there is care and endearment. That distance is at the core of many PBM mistakes and apathy.

About the Community Oncology Alliance

The majority of Americans battling cancer receive treatment in the community oncology setting. Keeping patients close to their homes, families, and support networks lessens the impact of this devastating disease. Community oncology practices do this while delivering high-quality, cutting-edge cancer care at a fraction of the cost of the hospital setting.

The Community Oncology Alliance (COA) advocates for community oncology and on policy issues that affect patient care. Our members include patients in active treatment, cancer survivors, caregivers, family members, medical and oncology professionals, and members of the general community. For more than 15 years our members have advocated for smart public policy that ensures the community cancer care system remains healthy and able to provide all patients with access to local, quality, affordable cancer care. Learn more at www.CommunityOncology.org

April 2019

Dangerous Health Care Middlemen & Bureaucracies:

Pharmacy Benefit Manager Horror Stories — Part V

The Pharmacy Benefit Manager (PBM) industry lobby claims that it successfully achieves drastic price reductions on medications. They say this comes from PBMs negotiating with competing drug companies and by "encouraging consumers to use the most cost-effective drugs."

Setting aside clear evidence that secretive PBM rebates and fees are actually driving drug prices higher, the last claim should give all Americans pause. How exactly does a PBM "encourage" a treating physician to use cost-effective but life-saving drugs? How do they know what is right for each individual patient and disease? What tactics or methods do PBMs use to do this? And are the changes in the patients' best interests, or simply to save money for PBM profit margins?

Unfortunately, time after time, PBMs have been exposed for abusing their position to do this, getting between the patient with cancer and their physician to dictate care. All too often, the PBM bureaucracy does this by simply and heartlessly delaying or denying make patients' access to needed medications. Perhaps most egregiously for patients facing a ticking clock of cancer, PBMs deny prescribed treatments and demand that patients first fail on a list of 'approved' drugs before receiving the medication that their physician prescribed in the first place.

For patients with cancer, this intrusion into their care plans is painful, potentially life-threatening, and unnecessarily stressful. For oncologists it is yet another bureaucratic burden placed between them and caring for a patient, wasteful of scarce health care resources, and insulting to the doctors that went to medical school and prescribe treatment plans.

These and other monstrous by-products of the PBM system are further exposed here, as the Community Oncology Alliance (COA) presents the fifth in a series that focuses on the very real and negative impact PBMs continue to have on patients with cancer today. The infuriating stories presented here are real but made anonymous with personal details changed to protect the privacy of the patients.

A NARROW WINDOW FOR TREATMENT

Brian, a married social worker with two young children, was in his early 30s in February 2014, when he was diagnosed with a relatively rare form of cancer in his appendix. Brian underwent surgery and chemo at a large hospital system, and for the next few years, his life went back to normal.

In late 2017, however, Brian suffered a relapse. He underwent surgery to remove all traces of the cancer, and his oncologist followed up with a round of chemotherapy. Despite the metastasis, Brian's doctors thought he had a good chance at survival, and recommended that he immediately begin a six-month regimen of oral medication to help keep the cancer at bay. He was young, strong, and had everything to live for; they were optimistic the cancer might never return.

On February 8th, Brian's oncologist sent a prescription for the pills to the local pharmacy his clinic worked with. They informed him that while they had the medicine in stock, Brian's insurance and PBM prohibited them from filling the prescription. Instead, they forwarded the prescription to a PBM-mandated specialty pharmacy to receive prior authorization.

The PBM-mandated specialty pharmacy granted the prior authorization, but was also unable to fill the prescription, so it was forwarded to yet another PBM specialty pharmacy. By this point, 11 days had passed. After another few days of silence, the second PBM pharmacy sent a message that they were unable to fill the prescription; it had to be done by the first PBM specialty pharmacy. It seemed that no one really knew who was responsible or able to fill the script.

On February 23rd, the same day that Brian finally received his oral anti-cancer medications, he was rushed to the emergency room for severe pains in his abdomen. There they discovered he had contracted an infection that necessitated surgery to repair his abdominal wall. The pills in his hand were no longer relevant.

Today, Brian must remain on chronic antimicrobial therapy pills to ward away abdominal infection; should he stop, they might easily return. Unfortunately, this precludes any further chemotherapy, and Brian's once promising prognosis has been replaced by one far direr. In effect, Brian missed his very narrow window and it is likely that he will never get well again.

Oncologists are on the front lines treating patients with cancer who have complex needs – they know the exact state of their patients, and how very precious even a day can be. PBMs and their mandated specialty pharmacies are several times removed from the exam room, and as a result, their lack of urgency and inability to cut through bureaucratic red tape can easily become an indirect – or even direct – cause of patient suffering.

NOT A HEALTH CARE PROFESSIONAL? YOU DON'T STAND A CHANCE

After having survived her battle with thymus cancer in 2015, Rachel was surviving with several autoimmune disorders, including myasthenia gravis, a condition in which the body attacks its own neuromuscular connections. After utilizing several immunosuppressants, Rachel has managed to keep the illness in remission for the past two years, by taking a wonder drug that works as an immunosuppressant, maintaining a low volume of antibodies in her system.

An advanced oncology certified nurse at a community oncology clinic, Rachel knows her condition well and how to stay healthy. For two years she has been taking her medication faithfully every day, working to care for her patients, and living life as normally as could be.

Then, at the beginning of 2019, her employer changed insurance carriers. When it came time one Friday for Rachel to refill her meds, she went to the local pharmacy to pick them up, only to be told that there were 'issues. 'The pharmacist was confused and said he would look into it.

Two hours later, the pharmacist called to say that from now on, Rachel must obtain her medication through the PBM's specialty pharmacy. She immediately called the new pharmacy's number, where she waited a long time until she was connected. After trying fruitlessly to locate Rachel in the system, he put her on hold for ten minutes. When someone else finally came back online, Rachel had to tell her entire story from the beginning. This happened several times, with Rachel's blood pressure rising exponentially. It was Friday afternoon, and she had six pills left – enough for two days.

Rachel hung up the phone; this had been a dead end. Falling back on a trick she had learned after dealing with countless PBM bureaucracies on behalf of patients, Rachel called the member services number on the back of her insurance card. After being passed around from representative to representative, she reached "Brian," who promised to establish a new member's account for her. However, as to her refills, he insisted he first needed to call her doctor to get prior auth.

Rachel began to see red. It was Friday afternoon, and her neurologist's office was closed. Trying to remain calm, Rachel explained to Brian that she still had several refills left. Brian promised he would contact her pharmacy and have the refills transferred over. "Call me in the morning," he said. Saturday morning, at 7:30 am, she called the specialty pharmacy, where she was told that no one named Brian had been in touch, and there was nothing in the computer about her issues. However, this new representative was the real deal. She handled everything over the next few hours, and arranged for the meds to arrive by Monday – which they finally did – just as Rachel's pills had run out.

Infinite patience coupled with buckets of determination and self control seem to be de rigueur when it comes to dealing with PBM Specialty Pharmacy bureaucracies holding one's life-saving medicine hostage. If it was this difficult for a seasoned, tough-as-nails advanced oncology nurse to get her own meds, what is going to happen to the other 99.9% of the population?

CLERICAL ERRORS MARRIED WITH INCOMPETENCE

Paula was a very intelligent company executive battling breast cancer. Her oncologist prescribed a particular medication and she faced no issues in having it filled or refilled the first time. When it came time for the second refill, however, she met a PBM roadblock. Despite several calls to the PBM, and speaking with several different people, all the patient could get them to explain was that there were insurmountable "insurance issues." Not knowing what else to do, she came into the oncologist's office so they could call the PBM together to resolve the matter.

After a long wait on hold, the doctor and his patient finally reached a representative who informed them that they were unable to fill the prescription because it could have a negative interaction with another medicine she was currently taking. The doctor and the woman looked at each other for a moment, before asking the rep, "What medicine?" The patient was not taking any other medication. This was, however, not what the PBM had in their records. It took quite a bit of additional convincing by the patient and her doctor before the PBM would believe them, and agree to provide authorization.

By this point, due to clerical error and the absence of anyone to take responsibility, the patient had already gone 10 days off of her regimen, something which never should have happened.

Practices report that they spend an absolutely 'ridiculous' amount of time trying to obtain prior authorizations from PBMs – well beyond any reasonable expectancy. Even getting to the point where there is another human being on the other end of the phone to talk to is an achievement in and of itself. This, of course, is only the beginning of the PBM process that is fraught with errors and poor record keeping, all of which can add up to dozens of hours of staff time wasted dealing with bureaucracy, and drag on over days, weeks, even months. In the meantime, patients with cancer are left waiting without the treatment that they need.

PBMs SERVING THEIR OWN BOTTOM LINE

Gordon, a retired FBI agent with a distinguished record of security service on behalf of the United States, was diagnosed with an aggressive form of lung cancer. Proving resistant to the drug regimen his oncologist initially prescribed, the cancer metastasized to his brain, and he was immediately started on radiation therapy. It was at that point that his doctors made an important discovery: Gordon's cancer had the EGFR mutation, which indicated he would do better with oral medication than infusion chemotherapy. More importantly, there was a new drug that had just been approved by the FDA as the first-line treatment for EGFR-mutated non-small cell lung cancer. This gave Gordon and his cancer care team a window of hope.

Gordon's oncologist prescribed the new medication, but the PBM denied authorization, providing the name of an alternative drug they wanted him to try first. His doctor argued that his original prescription would be better for the patient; It had been shown to have far higher efficacy for patients whose cancer had metastasized to the brain. The PBM argued back that it had been initially approved for a different EGFR mutation than the one Gordon had. His doctor argued back that this was irrelevant, as it was effective for Gordon's mutation as well, and was now FDA approved.

Back and forth, the fight went on for an entire month, with the doctor providing data and rationale to support his clinical decision making. Meanwhile the cancer grew inside Gordon, unchecked. He began to feel increasingly fatigued, and a man who had remained very active throughout his cancer battle began to deteriorate.

Ultimately, after more than 30 days of wasted time, the PBM approved the doctor's original prescription. Upon beginning the regimen, Gordon's condition began to slowly improve, but it never should have been allowed to reach such a low state.

Again and again, we see PBMs playing doctor, choosing to authorize one medication and not another, for reasons that have nothing to do with patient care. From pushing the drugs from pharmaceutical companies with which they have made sweetheart deals, to demanding patients be

prescribed lower-cost medication, their actions are profit-driven and often in complete contradiction to what the patient actually needs to get well.

PBM APATHY LEAVES BOY IN DANGER OF BLEEDING TO DEATH

Diagnosed with hemophilia, 15-year old Jason had to simultaneously contend with his blood's inability to form clots and the danger of bleeding uncontrollably. Jason's oncologist had him on a once-daily oral medication that can slow the spread of his cancer by blocking a specific protein the disease needs to thrive.

One day, Jason missed his footing on the stairs at home. Falling, he hit his thigh and developed a significant hematoma, common with hemophiliacs. He now urgently needed a specific recombinant factor injection to help his blood clot, and quickly.

Jason's oncologist quickly prescribed the necessary self-injected medication to be taken at home. Prior authorization was received, however the PBM handling Jason's case refused to allow the practice's pharmacy to fill the script, so they forwarded it to the PBM-mandated pharmacy. Unfortunately, they could not fill the prescription, and without informing Jason or his doctor, they outsourced the prescription to yet another pharmacy.

Recognizing the urgency of the situation, Jason's mother, a full-time nurse, stepped in to see how things could be expedited. She made numerous phone calls, verifying that the pharmacy she used to work with before her insurance changed had the medication in stock and, due to a contract with the PBM, was able and willing to ship it out the next day. Not wanting to lose out on the business, the original PBM-mandated pharmacy stepped in and vetoed the plan, stating that as it had already been ordered from them, there could be no cancellations.

Adding another layer of unnecessary problems to the mix, the PBM suddenly claimed that there had been no prior authorization filed for the prescription. Undeterred, the practice pharmacist spent hours trying to get it all done as soon as possible, so that Jason could get the medicine he needed.

Finally, just when it felt like the situation was starting to be resolved, the PBM pharmacy representative on the phone belatedly realized that the medication in question was for injection and stopped the process. Prescriptions for injections, she said, had to go through a different department. Unfortunately, it was now 5 pm on a Friday and the PBM offices were closed for the weekend, so they would have to wait to submit the prescription until Monday. Because of his hemophilia, young Jason was now in danger of developing a dangerous complication that could require emergency surgery and a long hospital stay if not treated immediately.

With no alternative, the doctor sent Jason to the hospital emergency department to receive the necessary injection. While this prevented any life-threatening occurrences, it incurred an enormous expense for his family and insurer, one that could easily have been avoided. Due to the astonishing bureaucracy, a patient fell through the cracks, with no one outside his personal doctor standing up to take responsibility or showing the slightest concern.

Patients do not walk off the pages of a textbook or an encyclopedia of illnesses and their recommended treatment. Each case is individual and ought to be treated as such, in a thoughtful, intelligent, holistic manner. Additionally, patients do not stop treatment just because it is the weekend or after the phone lines shut down. The more control PBMs are given over patient care, the more sweeping and infuriating their bureaucracies become, and, ultimately, the more dangerous their decisions and actions prove to be.

WOULD YOU LIKE SOME KIDNEY FAILURE WITH YOUR CANCER?

In the Fall of 2012, Trisha, a medical software instructor in her early 60s, suffered renal failure and was rushed to the hospital. Diagnosed with Multiple Myeloma, she underwent dialysis and was referred, by her community oncologist, to a Myeloma specialist at the nearby hospital system. The specialist recommended a particular regimen of chemotherapy to keep the disease in check, and Trisha was released.

A few months later, tests revealed that the cancer was progressing. Her chemo was clearly not working; a new

medication had to be tried. This would not be simple, for following Trisha's renal failure, her kidneys had never returned to normal. This meant her doctors had to be extremely careful about what drugs they prescribed, as certain medications for Myeloma are known to take a heavy toll on the kidneys.

Trisha's oncologist, in consultation with the hospital specialist, decided to prescribe a particular drug that could slow the progression of her disease, without having any adverse effects on her already stressed kidneys. Her oncologist sent in the prescription to the PBM mandated specialty pharmacy, which promptly sent back a notice denying the request.

At first, the pharmacy said that prior authorization was needed. Her doctor said, "No problem," and instructed the in-house clinic to fill out all the necessary forms and fax them over. This was followed by a second denial, which stated that the patient did not meet "the proper requirements" to receive the requested drug. What were those requirements? Trisha had to first have tried two other drugs, one after the other, and to prove that either her body had been unable to tolerate them, or that they had failed to slow the cancer's advancement.

Of those two drugs that the PBM demanded Trisha try - and fail - first, one was the very same drug she had been prescribed the previous year that had already failed to slow the cancer's progression. The second was a medication that, had she taken it, would have seriously damaged her kidneys and likely put her back into renal failure.

Over the next two months, Trisha's oncologist appealed the PBM's decision, and a long series of communications ensued between the oncologist, the Multiple Myeloma specialist, and the PBM specialty pharmacy. Trisha, meanwhile, watched with increasing anxiety as her myeloma protein markers quadrupled, indicating that the cancer was gaining ground. The appeal turned into a letter of medical necessity, and ultimately, after more than two months of delay, the correct medicine was finally approved by the PBM.

PBMs have been given enormous amounts of control over what doctors may and may not prescribe. They try to strong-arm doctors into prescribing the medicine that the PBMs choose, even though they have never met the patient, and often have no medical background to support the decisions they are making.

PBM DELAY TACTICS VICTIMIZE PATIENTS

Belinda, a kindergarten teacher and mother of two, was fighting thyroid cancer. Her oncologist had her on a particular medication that was approved for off-label use on thyroid cancer; she'd been taking the medication for seven months and was doing well.

In January, Belinda's insurance carrier moved to a new PBM, which required her to fill her prescriptions at their mandated specialty pharmacy. They assured Belinda that it would be no trouble for them to continue filling her medication. So, that same month, when it came time for Belinda's refill, her oncologist sent the e-prescription directly to the new pharmacy, and called Belinda to confirm.

When Belinda tried to pick up the prescription, however, the PBM-mandated pharmacy said they were unable to process it "at that time." She waited an entire month before being contacted by the PBM pharmacy to verify benefits and schedule delivery. After another week went by with no medication, a very frustrated Belinda called her oncologist to see if they could dispense the medication directly to her. Unfortunately, according to Belinda's insurance policy, they were not allowed to do that.

Another week passed, and, after six weeks of delays, the PBM-mandated pharmacy contacted Belinda. They wanted now to schedule delivery – again. The prescription was then sent to PBM's Clinical department to verify dose, diagnosis, allergies, and drug interactions.

At this stage, someone at the PBM finally noticed that the drug was being prescribed for an off-label usage, and called her oncologist to verify the diagnosis. The oncologist spoke to the PBM pharmacist, explaining that the drug had been approved for nearly a year, with the patient taking it all that time, to very beneficial results. It had always been for off-label usage, and the insurance company had always agreed to it. What was the matter?

The PBM pharmacist had no explanation for the time lag, nor was there any documentation to explain why more than two months had passed. At the end of the

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conversation, the doctor asked if Belinda could finally expect to receive her medication now. "No," the pharmacist replied. "Now, we forward the matter to the payment verification center. After that stage, it will be forwarded to the dispensing center. Then we can ship it out."

Had Belinda been authorized to purchase her medicine from the in-house pharmacy at her doctor's office, the entire process would have taken a single day.

The larger an organization, the more complex the bureaucratic procedures. This is often done under the guise of ensuring safety. However, how far do things need to go before it can be said that the harm to patients has greatly surpassed any intended good? At what point do the PBMs themselves become accountable to a certain standard of care – even in terms of something as simple as response time?

IT IS TIME TO STOP PBM ABUSES!

While much of the debate over PBMs focuses on economics, there is often not enough discussion about the impact PBMs have on patients. The sad fact is that PBMs make more money by delaying or denying patients access to necessary medications. Every pill they stop from being dispensed is money they can pocket. COA has documented real-life patient horror stories from practices and physicians about patients battling cancer who have suffered at the hands of PBMs due to delayed coverage decisions, denial of coverage, arguments with physicians over proper treatment, and failure to receive medications in a timely manner.

Read our other PBM Horror Stories papers at https://www.communityoncology.org/category/horror-stories/

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RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. MARSHA BLACKBURN TO ROBIN FELDMAN

Question 1. Can you elaborate on how PBMs' consolidation within the pharmaceutical supply chain has been able to go unchecked?

Answer. Markets should be fair, open, and efficient. Unfortunately, the PBM market lacks these essential qualities. The level of concentration within the market is concerning, with just three PBMs controlling 80 percent–85 percent of the market.[1]

[1] Neeraj Sood, Dana P. Goldman, & Karen Van Nuys, Follow the Money to Understand How Drug Profits Flow, STAT (Dec. 15, 2017), *https://www.statnews.com/2017/12/15/prescription-drug-profits-pbm/* ("The top three pharmacy benefit managers, which negotiate drug prices on behalf of insurers and self-insured employers, dominate 85 percent of their market."). See also Neeraj Sood, Transcript of Understanding Competition in Prescription Drug Markets: Entry &

Competition issues also arise regarding consolidation between PBMs and other players in the pharmaceutical supply chain, such as PBMs merging with pharmacy chains and specialty pharmacies. A discussion of a variety of competition concerns when PBMs merge with pharmacies can be found in my most recent book,[2] but as one example, PBMs can drive patients towards their own pharmacies. Specifically, some health plan formularies restrict patients from purchasing a 90-day supply of medicine from any pharmacy other than the one owned by a particular PBM—and, of course, it's the PBM that helped write the formulary. Activities such as these can dampen competition at other parts of the pharmaceutical supply chain, as well as reducing patient choice and harming access to medicine.

The negative impact of concentration at many levels of the supply chain for medicine has various causes, but governmental gaps and failures have certainly allowed concentration to go unchecked. These include: 1) the need for regulatory enforcers to take a "second look" post-merger to determine if their competitive predictions proved accurate, take appropriate measures, if not, and to adjust future merger and acquisition protocols accordingly; 2) the failure of insurance regulators and legislators to protest that PBMs have breached their duty to act in the best interest of health plans and, by extension, plan enrollees; and 3) the failure of insurance plans, regulators, and courts to push back against PBMs' baseless reliance on trade secret law to shield their pricing data from public and regulatory scrutiny.[3]

- Is the consolidation in the PBM market ultimately working to lower drug prices for patients?

Answer. A heavily consolidated market is rarely in the interests of consumers. In the PBM market, the Big Three tend to offer the same terms, preventing the customers of those three from having meaningful options and avoiding the challenge of true competition. None of this has been helpful for lowering drug prices for patients.

- What would a competitive PBM market do for the consumer at the counter?

Answer. A PBM's job is to negotiate better prices for the benefit of patients. However, the perverse incentives operating in the PBM market have helped to inflate profits for PBMs instead of appropriately driving down prices for consumers. Although there are many contributors to rising prices, true competition in the PBM market could help drive down the prices that consumers pay at the pharmacy counter, as well as the dollars they pay for insurance plan premiums.

- What are some ways we can spur innovation within the PBM market?

Answer. As noted above, markets should be fair, open, and efficient. To spur competition and innovation in the PBM market, I would recommend four key approaches related to Fiduciary Duty, Transparency, and Concentration:

1) First, clarify that PBMs have a fiduciary duty, certainly to the health plan if not the patients, themselves.
2) Second, clarify that price and price terms in this context are not trade secrets.
3) Third, ensure that competition agencies have the proper tools to reduce concentration in the PBM and related industries. We won't see price improvements until we improve competition.
4) Fourth, encourage regulators to adopt a robust "Second-Look" policy. Rather than relying on crystal-ball predictions of what will happen after a merger or acquisition, competition agencies should establish a system of post-merger review to ensure past decisions had the intended results and to improve future evaluations.

Question 2. What is your view of copay accumulators that prevent patient support from counting toward a patient's deductible or maximum out-of-pocket costs. Do you know where these revenues are going?

Sometimes, a gift is a Trojan horse. It seems like a wonderful offering—even a blessing—but, beware of what lies within. That can be the case with patient assistance programs. And, as I will describe below, the patient is always the one who loses out.

Supply Chain Dynamics Workshop (Nov. 8, 2017), *https://www.ftc.gov/system/files/documents/videos/understanding-competition-prescription-drug-markets-panel-2/ftc_understanding_competition_in_prescription_drug_markets_-_transcript_segment_3.pdf.*

[2] *See* ROBIN FELDMAN, DRUGS, MONEY, & SECRET HANDSHAKES: THE UNSTOPPABLE GROWTH OF PRESCRIPTION DRUG PRICES 46–50 (Cambridge 2019).

[3] *See* Robin Feldman & Charles Tait Graves, *Naked Price & Pharmaceutical Trade Secret Overreach,* 22 YALE J.L. & TECH. 61 (2020) (examining PBM efforts to assert that pricing arrangements should be considered trade secrets).

For patients who are struggling to afford tremendously expensive medication, providing a coupon seems heaven-sent. Even more so if the coupon pays for a life-saving drug. But the costs to the patient, not to mention the health care system, are carefully camouflaged.

With a coupon, or other form of patient assistance program, the brand-name company agrees to pay all, or a signiﬁcant portion, of the patient's out-of-pocket costs. Thus, the patient sees tremendous relief in the form of out-of-pocket costs. But it can be an illusion. The health insurance plan pays for the more expensive, brand-name drug, rather than a less expensive competitor. The extra amount that the plan pays for the drug is then reflected in the cost of the annual premium patients pay. If this happens enough, premiums can rise for everyone in the plan, including the specific patient.

In 2020, a U.S. House Oversight Committee report provided an inside view of how pharma companies themselves think about patient assistance programs. The report examined reams of documents from Novartis, relating to its blockbuster oncology drug Gleevec. The company's documents showed that co-pay assistance programs were a crucial piece of its strategy to encourage patients to stay with the brand-name drug after generics entered the market. The company even calculated that beefing up the strategy 6 months before generics entered the market would be the timing that provided the greatest return on investment by keeping the maximum number of patients attached to the drug before the generics made it to market.

The return on the company's investment was impressive. Company documents showed that the company's patient assistance on the drug provided a return on investment of $8.90 for every dollar spent on the program. When a company is making nine additional dollars for every dollar it hands out with a coupon, the company is not acting out of the goodness of its heart.

In response, health plans have created policies that prevent such programs from counting towards a patient's deductible or out-of-pocket maximum. Their theory is that the patient did not pay that amount out-of-pocket; the pharma company did. These health plan limitations are being called co-pay accumulators or co-pay maximizers. They are intended to save money for the plan which, in the best of circumstances, would flow through to keep the premiums lower for patients. I have not studied, however, whether that actually happens. Nor am I aware of academic studies concluding that these savings do, indeed, flow through to create lower premiums for patients.

In the process of handing out patient assistance, of course, brand companies purchase brand loyalty.[4] The patient—who is now wedded to an expensive brand-name drug, rather than a generic, biosimilar, or less expensive alternative—may be reluctant to change. When the maximum value of the company's coupon is reached, the patient is socked with the extremely high out-of-pocket cost of the drug. That is, yet again, another hidden price that patients must pay.

As always, the patient is caught in the middle of the struggle, and no matter what, the patient seems to lose out.

Question 3. I am concerned that copay accumulators may negatively impact prescription drug access for vulnerable patients. How can we best address this issue to help patients and caregivers?

Answer. As noted in my response to the prior question, the patient is always the one who loses in these struggles. In particular, brand companies can begin handing out copay coupons before the generic or biosimilar has arrived on the market—an effective method for ensuring that patients have continued loyalty when the generic or biosimilar does arrive.[5]

If the health plan and the brand company truly wanted to help a vulnerable patient, the drug could be provided to the patient's health plan at a severely reduced cost with the agreement that the particular patient would enjoy a low out-of-pocket cost. Congress could help by clearing any regulatory hurdles in the way. Moreover, programs such as these should be designed so that they provide a long-term benefit

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[4] Studies show that these patient assistance programs increase brand-name drug sales by 60 percent, mostly by reducing sales to generic competitors. *See* Leemore Dafny, Christopher Ody & Matt Schmitt, *When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization,* 9 Am. Econ. Jl.: Econ. Policy 91, 93 (2017).

[5] *See* U.S. HOUSE OF REPRESENTATIVES, STAFF REPORT: COMMITTEE ON OVERSIGHT AND REFORM, DRUG PRICING INVESTIGATION: NOVARTIS—*GLEEVEC* SELECTED INVESTIGATION DOCUMENTS (2020) (finding that Novartis made significant changes to its copay assistance program for the blockbuster oncology drug Gleevec six months before generics entered the market, offering patients the allure of steep reductions in out-of-pocket payments, a strategy that convinced patients to stick with Gleevec once generics were on the market).

for a vulnerable patient, rather than as a limited-time offering of free samples that reel in a patient, who will then be stuck paying large sums for a long time.

And, of course, the best help for vulnerable patients—as well as access to medicine for all patients—would be to inject transparency and competition into the PBM system. I am heartened to see the Subcommittee's work on these important issues.

RESPONSE TO WRITTEN QUESTION SUBMITTED BY HON. RICHARD BLUMENTHAL TO JUAN CARLOS "JC" SCOTT

Question. As you know, the dynamics of the 340B program are always complicated. There has been a lot going on over the last couple of years with respect to contract pharmacy, and I am hearing often from South Dakotans with concerns about actions taken by both PBMs and manufacturers. At the end of the day, these actions are harmful to the program that is meant to help our hospitals support their communities. Resolving these issues will take some time, so I just ask for your commitment to be willing to be part of the conversation.

Answer. Thank you for taking the time to share your concerns about the 340B program. I appreciate the opportunity to respond, and I am always willing to contribute to the discussion. While PCMA is neutral on the 340B program, we are aligned fully with the program's goal of helping safety-net entities provide better care to vulnerable populations. Our members process claims in support of the program, but PBMs cannot always determine when a claim is related to a 340B transaction, which causes complications for PBMs, pharmacies, manufacturers, and individuals paying for health insurance. To maintain eligibility to sell drugs to state Medicaid programs, manufacturers must agree to participate in 340B. While Medicaid eligibility and 340B participation are linked, the programs are separate, and Federal law prohibits duplicate discounts—mandated Medicaid rebates do not apply to drugs obtained at 340B pricing. To support efforts to avoid duplicate discounts for 340B pharmaceuticals, claims modifiers, like those used in the Medicaid program, are needed to better understand which drugs are 340B and which are not. PCMA welcomes the opportunity to continue working on this and other issues in the 340B program to ensure fairness and transparency in the prescription drug marketplace.

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. MARSHA BLACKBURN TO JUAN CARLOS "JC" SCOTT

Question. (Blackburn) I would like to know what you would see a competitive marketplace be. We know there have been consolidations. Mr. Scott says there are 70 PBMs, but we know we have very few players in this area. So, in a perfect world, how would you structure a competitive PBM marketplace that would, indeed, yield our Medicare enrollees a lower cost? (Blumenthal) I would invite each panelist to respond to that question in writing. It is a big question and at the heart of what we are doing here today.

Answer. To foster a more competitive market for prescription drugs, Congress should focus on increasing competition to promote consumer accessibility and affordability and enhance the value of dollars spent on health care. Last year, PCMA announced a three-part policy platform focused on lowering prescription drug costs by updating Medicare Part D, increasing competition, and moving consumers toward a more value-driven health care system.[1] Our policy platform outlines concrete policy steps to make prescription drugs more affordable for all consumers, and the PBM industry's vision for a health care system that delivers more value to all Americans. If fully implemented, PCMA's policy platform would reduce prescription drug costs, make pharmaceutical care more accessible to all Americans, and save taxpayers $257.5 billion to $398.7 billion over ten years.[2]

The first set of policies propose modernizing Medicare Part D. PCMA suggests specific policy options to make Medicare Part D more affordable, including capping out-of-pocket costs, eliminating misaligned incentives that keep drug prices artificially high, building on Part D's record of choice and competition, allowing plan sponsors access to additional tools for managing costs, repealing the rebate rule to

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[1] PCMA. The Critical Path Forward: Rx Policies to Reduce Patient Costs, Improve Access. June 2021. Available at *https://www.pcmanet.org/pbms-solutions-to-lower-patient-rx-costs-improve-access/*.

[2] PCMA. PCMA's The Critical Path Forward Will Save Taxpayers $255.5 Billion Over 10 Years. July 2021. Available at *https://www.pcmanet.org/wp-content/uploads/2021/07/pcma_criticalpathforward_7-6-21.pdf*.

protect seniors by preventing significant premium increases, and preventing taxpayers from paying substantially more for Part D. Additionally, we support enhancing manufacturer liability throughout all phases of the benefit to ensure that manufacturers bear a fair share of the responsibility to provide American seniors with high-quality coverage.

The second set of policies would prevent patent abuses like patent thickets, evergreening, product hopping, and misuse of citizen petitions that drug manufacturers use to prevent fair competition from generic and biosimilar drugs. As we work together to bring greater savings to Medicare beneficiaries, we must also focus on real solutions to lower drug costs for everyone. Consequently, PCMA supports policies aimed at reducing market distortions, like those aimed at limiting patent and exclusivity abuses that stifle competition and keep drug prices high. We also need solutions to ensure drugs compete fairly, including the production of more cost-effective generics and biosimilars.

The third and final set of policies would foster broader adoption of value-based purchasing and the acceleration of consumer-focused pharmacy care. More health care spending does not automatically result in better outcomes. To promote the use of high-value treatments and reduce the use of those which do not provide the necessary or expected benefit to patients, PCMA proposes policies to accelerate value-based and consumer-centered care. We also support bringing the same value-driven tools used by employers to Medicare and Medicaid and promote the production and use of rigorous evidence of drug performance in the real world. Improving health outcomes requires the treatment of patients based on their individual needs. Therefore, PCMA supports driving a concerted effort to reduce health care disparities and inequities. Value-based care arrangements for consumers would be made possible by granting Part D drug plans access to Medicare Parts A and B claims data, establishing safe harbors for value-based contracting, and allowing Part D and state Medicaid plans greater flexibility to adopt private-sector formulary management techniques.

Question. I have been hearing about new PBM programs called copay accumulators that impact certain patients in high-deductible health plans. These programs prevent patient support from counting toward a patient's deductible or maximum out-of-pocket costs. As a result, patients face sudden and often unexpected higher out-of-pocket costs when their patient assistance runs out, and they discover their deductible has not been met. Can you please explain to me how these programs impact patients?

Answer. Copay accumulator programs are health-plan programs designed to prevent drug manufacturers from using copay coupons to steer or coerce employers, unions, and government programs to pay for expensive, unnecessary brand medications. Under Federal law, the use of copay coupons to obtain healthcare services under Medicare and Medicaid is prohibited as marketing tools to induce a consumer to purchase a particular brand they might not otherwise purchase. Similarly, copay coupons for prescription drugs are an inducement to obtain a particular drug even when a lower-cost therapeutic alternative is available. Therefore, legislation seeking to stop payers from managing their costs by prohibiting the use of accumulator programs would eliminate a crucial tool in their fight against rising drug costs. If drug companies are concerned about patients accessing medications, they should simply lower their prices; this is the simplest, most effective way to reduce patient costs for drugs.

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