PULLING BACK THE CURTAIN ON PBMS: A PATH TOWARDS AFFORDABLE PRESCRIPTION DRUGS

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ABSTRACT

Prescription drug prices in the United States continue to rise with no end in sight. Individuals are foregoing other needs to pay for their medicines while healthcare companies continue to rake in enormous profits. In this Essay, I discuss how Americans can reverse this oppressive drug pricing trend. As both a pharmacist and a member of Congress, I explain why drug prices are so high from a unique perspective, and illuminate what patients and Congress can do to bring prices down and advocate for a better system. After discussing various actors involved with prescription drug pricing, this Essay then focuses on Pharmacy Benefit Managers ("PBMs") as the clandestine menace of the healthcare industry. This Essay utilizes first-hand stories from patients, pharmacists, and doctors to illustrate why PBMs need to be exposed and held accountable. Most importantly, this Essay will provide a legislative framework for making lower drug prices a reality.

I. INTRODUCTION

Over the next decade, the Centers for Medicare and Medicaid Services ("CMS") projects that spending for retail prescription drugs will be the fastest growth health category.[1] In 2019, 52% of American adults reported that healthcare costs have delayed their day-to-day activities.[2] During the 2020 presidential election, one survey found that 74% of Democratic voters in Blue Wall states believed a top priority of Congress should be lowering the cost of prescription drugs.[3] During my experience running a pharmacy, I

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[1] Craig Hanna & Cori Uccello, *Prescription Drug Spending in the U.S. Health Care System*, AM. ACAD. ACTUARIES (2018), https://www.actuary.org/content/prescription-drug-spending-us-health-care-system [https://perma.cc/VL9Z-MZRX].

[2] *See* Megan Leonhardt, *Rising Health-Care Costs Stall Americans' Dreams of Buying Homes, Building Families and Saving for Retirement*, CNBC (Nov. 4, 2019, 1:28 PM), https://www.cnbc.com/2019/11/04/health-care-costs-are-preventing-many-americans-from-hitting-life-milestones.html [https://perma.cc/REX5-BLWZ].

[3] *See* ASHLEY KIRZINGER, CAILEY MUÑANA, MOLLYANN BRODIE, CHARLIE COOK, AMY WALTER, JENNIFER DUFFY & DAVID WASSERMAN, BLUE WALL VOICES PROJECT 27 (2019), https://files.kff.org/attachment/REPORT-Blue-Wall-Voices-Project [https://perma.cc/6HEE-VYEW].

have also unfortunately witnessed families discussing how to cut costs on groceries to afford prescription medicine.

Pharmacy Benefit Managers ("PBMs") have grown into some of the largest, most profitable companies in our nation.[4] PBMs act as middlemen between pharmacies, drug manufacturing companies, and health insurance plans to administer prescription drug benefits.[5] Using their size, leverage, and negotiating power, PBMs play a large role in determining which prescription drugs are covered by insurance plans and how much they cost, while keeping themselves mostly hidden from the American public.[6]

This Essay identifies PBMs as a root cause of high prescription drug costs. Behind the curtain, PBMs play an outsized role in the perilous state of the current American prescription drug market. As everyone from pharmacy owners to patients to taxpayers are victimized by the predatory practices of PBMs, this is inherently a human issue. I hope to expose the hidden actor of PBMs to the American public and encourage Congress to address this problem.

Stories from patients, pharmacists, and doctors have already inspired some congressional action to rein in PBMs' predatory practices. For example, bipartisan coalitions introduced the Ensuring Seniors Access to Local Pharmacies Act,[7] which would require transparency of PBM contracts, prohibit patient steering to in-house or PBM associated pharmacies, and allow seniors in Medicare Part D plans to use pharmacies of their choice.[8] Additionally, the Pharmacy DIR Reform to Reduce Senior Drug Costs Act[9] would ensure that clawbacks, or price concessions issued by PBMs, are assessed at the point of sale to eliminate the retroactive nature of Direct and Indirect Remuneration ("DIR") fees.[10] Congress has also sent several letters to the Biden administration,[11] but no action has been taken to stop PBMs.

It is time to finally lower drug prices in America, and, together, we can make a difference.

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[4] *See* PBM Accountability Project, Understanding the Evolving Business Models and Revenue of Pharmacy Benefit Managers 3 (2021), https://b11210f4-9a71-4e4c-a08f-cf43a83bc1df.usrfiles.com/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf [https://perma.cc/YWR6-HHLZ].

[5] *See id.*

[6] *See id.*

[7] H.R. 2608, 117th Cong. (2021).

[8] *See id.*

[9] S. 1909, 117th Cong. (2021).

[10] *See id.*

[11] *See, e.g.*, Letter from Earl L. "Buddy" Carter, U.S. Representative, House of Representatives et al. to Xavier Becerra, Sec'y, U.S. Dep't Health & Hum. Servs. (Mar. 16, 2022), https://buddycarter.house.gov/uploadedfiles/dir_reform_letter_to_hhs_3.16.22.pdf [https://perma.cc/95NR-G9QT].

II. The Rise in Drug Prices

Drug prices in America are on the rise.[12] According to GoodRx Health, drug costs rose 33% between 2014 and 2020.[13] A recent report by the Congressional Budget Office shows the average net price of branded pharmaceutical products in Medicare Part D increasing from $149 in 2009 to $353 in 2018.[14] A study by the non-partisan, non-profit RAND Corporation suggests drug prices in the United States are 2.56 times higher than other modern nations.[15] And Americans are spending a larger percentage of their total income on healthcare and drugs than in years past.[16]

Insulin provides an illustrative example: diabetic patients pay an average of $300 for a vial of insulin.[17] A vial of insulin contains 1,000 insulin units, and, depending on the type of diabetes an individual has and his or her weight, he or she may require upwards of 100 insulin units a day.[18] Simple math suggests diabetic patients could spend over $1,000 a month on insulin alone. As a result, patients often must choose between their health and their wallets. No American should have to make that choice.

Reducing drug prices has consistently polled as a top issue for American voters.[19] According to a poll released in October 2021 by the Kaiser Family Foundation, 83% of Americans say the cost of prescription drug prices is unreasonable.[20] The same poll says 26% of Americans have a hard time affording their medications, and 78% of Americans think pharmaceutical companies are to blame for the high prices.[21] A different poll released by

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[12] *See* Tamara Hayford & David Austin, Cong. Budget Off., No. 57050, Prescription Drugs: Spending, Use, and Prices 13 (2022), https://www.cbo.gov/system/files/2022-01/57050-Rx-Spending.pdf [https://perma.cc/9ELE-HTYS].

[13] *See* Tori Marsh, *Prices for Prescription Drugs Rise Faster than Prices for Any Other Medical Good or Service*, GoodRx Health (Sept. 17, 2020), https://www.goodrx.com/healthcare-access/drug-cost-and-savings/prescription-drugs-rise-faster-than-medical-goods-or-services [https://perma.cc/NL2P-5QYY].

[14] *See* Hayford & Austin, *supra* note 12, at 16.

[15] *See* Andrew W. Mulcahy, Christopher M. Whaley, Mahlet Gizaw, Daniel Schwam, Nathaniel Edenfield & Alejandro U. Becerra-Orthenelas, RAND Corp., International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies 26 (2021), https://www.rand.org/pubs/research_reports/RR2956.html [https://perma.cc/8GS6-JBWA].

[16] *See* Danielle K. Roberts, *The Deadly Cost of Insulin*, Am. J. Managed Care (June 10, 2019), https://www.ajmc.com/view/the-deadly-costs-of-insulin [https://perma.cc/3W8V-HBW3].

[17] *See* David Lazarus, *Column: Soaring Insulin Prices Reveal Clout, and Greed of Healthcare Middlemen*, L.A. Times (Nov. 30, 2021, 6:00 AM), https://www.latimes.com/business/story/2021-11-30/lazarus-healthcare-insulin-prices [https://perma.cc/YPC6-6VER].

[18] *See* SingleCare Team, *Insulin Prices: How Much Does Insulin Cost*, SingleCare (Jan. 27, 2020), https://www.singlecare.com/blog/insulin-prices/ [https://perma.cc/ER65-4KM6].

[19] *See* Liz Hamel, Lunna Lopes, Ashely Kirzinger, Grace Sparks, Audrey Kearney, Mellisha Stokes & Mollyann Brodie, *Public Opinion on Prescription Drugs and Their Prices*, Kaiser Fam. Found. (Oct. 18, 2021), https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/ [https://perma.cc/K37C-DU7H].

[20] *See id.*

[21] *See id.*

Morning Consult and Politico revealed that 50% of Americans think bringing down prescription drugs should be a priority.[22] Clearly, this is important issue to Americans.

There are competing and complex explanations for why drug prices are so high. Many Americans think it is because pharmaceutical companies jack up prices and pocket those profits.[23] The above statistics might even suggest this to be true. But this argument blatantly ignores other entities within the American healthcare system and the tactics they use to increase prices and pocket greater profits. The American healthcare system is too complex to put the blame on a single entity. I've experienced the complexities of this system myself for over thirty years as a pharmacist, independent pharmacy owner, and now member of Congress on the House Energy and Commerce Health Subcommittee. There is more than meets the eye to this story, and I strive to reveal how hidden "middlemen" in the pharmaceutical supply chain are the ones to blame for these drastic price increases.

A. Generic Drugs vs. Branded Drugs

1. Where does the money come from?

Before examining the middlemen within the supply chain and how they raise drug costs, it is important to discuss the pharmaceutical marketplace, how generic drugs and branded drugs differ, and how the marketplace profits off of them.

Generic drugs are unbranded products that compete with the original, branded innovator drug when exclusivity and legal patents expire for the branded product.[24] In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Act"),[25] which established a pathway for expedited approval at the Food and Drug Administration ("FDA") for generic drugs that are exact copies of branded products already on the market.[26] The FDA relies on its determination that the original branded product is safe and effective to approve new generic drugs.[27] Be-

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[22] *See* Gaby Galvin, *Curbing Drug Costs Should Be a Top Priority for Congress, 1 in 2 Voters Say*, MORNING CONSULT (May 5, 2021, 6:00 AM), https://morningconsult.com/2021/05/05/drug-pricing-top-priority-congress-poll/ [https://perma.cc/KXA5-E835].

[23] *See* Marisa Fernandez, *Drug Companies Keep Raising Prices*, AXIOS (Jan. 14, 2021), https://www.axios.com/drug-price-increases-new-year-2021-cf1fce6d-3c82-456f-9a6c-6b5144b4f061.html [https://perma.cc/E2PN-84ZD].

[24] SUZANNE M. KIRCHHOFF, AGATA BODIE, KAVYA SEKAR & SIMI V. SIDDALINGAIAH, CONG. RSCH. SERV., R44832, FREQUENTLY ASKED QUESTIONS ABOUT PRESCRIPTION DRUG PRICING AND POLICY 2 (2021), https://sgp.fas.org/crs/misc/R44832.pdf [https://perma.cc/6J7Y-CPYY].

[25] 21 U.S.C. § 355(j).

[26] *See id.*

[27] *See* AGATA DABROWSKA, CONG. RSCH. SERV., IF11075, FDA AND DRUG PRICES: FACILITATING ACCESS TO GENERIC DRUGS 1 (2019), https://sgp.fas.org/crs/misc/IF11075.pdf [https://perma.cc/24VJ-CJQS].

cause the generic drugs are exact copies of the original product, the companies developing them avoid costly research and development investments, clinical trial costs, and the risk of a drug not being safe or effective.[28] Essentially, the Hatch-Waxman Act created competition in the marketplace by giving consumers a choice among different generic and brand-name products when in need of treatment.[29]

The Hatch-Waxman Act was a success: today, generic drugs account for most of the drugs sold in the United States—about 90% of all dispensed medications.[30] These generic products are usually very cheap, accessible at every pharmacy, and have lower out-of-pocket insurance costs for consumers compared to branded products.[31] The intense competition between generic drugs and branded drugs has caused generic drug prices to drop by more than 60% since 2008.[32] Thus, generic drugs are increasingly becoming very affordable.[33] But despite the high market share, generic drugs account for only 26% of total drug spending, meaning 74% of all spending on drugs is spent on branded drugs.[34] The high share of spending on branded drugs is explainable, and there is a good reason for it: branded drugs are often very new to the market. They require years, sometimes decades, of investments into research and development to create, and they treat specific, often rare, health conditions for a small subset of the population.[35]

New drug development does not come cheap. According to the Congressional Budget Office, the pharmaceutical industry spent $83 billion in 2019 on research and development.[36] That is ten times more than what the industry spent in the 1980s, when adjusted for inflation.[37] Drug companies can expect to spend between $1 billion and $2 billion for every new product they attempt to bring to the market.[38] A recent study published in the Journal of Health Economics estimates that it costs drug makers $2.6 billion to get a

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[28] *See id.*

[29] *See id.*

[30] HAYFORD & AUSTIN, *supra* note 12, at 10.

[31] *See* DABROWSKA, *supra* note 27, at 1.

[32] *See* U.S. DEP'T HEALTH & HUM. SERVS., UNDERSTANDING RECENT TRENDS IN GENERIC DRUG PRICES (2016), https://aspe.hhs.gov/reports/understanding-recent-trends-generic-drug-prices [https://perma.cc/Y72T-7YVH].

[33] *See* Rachel Schwartz, *The Generic Drug Supply Chain*, ASS'N FOR ACCESSIBLE MEDS. (Oct. 16, 2017), https://accessiblemeds.org/resources/blog/generic-drug-supply-chain#:~:text=with%2089%20percent%20of%20all,the%20U.S.%20health%20care%20system [https://perma.cc/GE6C-Q9ZM].

[34] *See id.*

[35] *See* KIRCHOFF ET AL., *supra* note 24, at 29.

[36] TAMARA HAYFORD & DAVID AUSTIN, CONG. BUDGET OFF., 57025, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 1 (2021), https://www.cbo.gov/publication/57126 [https://perma.cc/N26M-2NUP].

[37] *Id.*

[38] Jonathan Gardner, *New Estimate Puts Cost to Develop a New Drug at $1B, Adding to Long-Running Debate*, BIOPHARMA DIVE (Mar. 3, 2020), https://www.biopharmadive.com/news/new-drug-cost-research-development-market-jama-study/573381/ [https://perma.cc/LGH3-S8X9].

drug to market.[39] Despite the billions of dollars drug makers invest in new products, there is no guarantee a new drug will ever make it to pharmacy shelves. The FDA approves only about 9% of all drugs that start clinical trials, proving new drug development to be an extremely risky venture.[40]

Drug companies must charge a price that recoups the billions of dollars in developmental costs, payroll, overhead, financial losses from non-approved drugs, and other expenses—all before taking any profit. These companies take immense risk to create life-saving medicines, experiencing a 91% fail rate on their investments. We must preserve the incentive of modest profits for these companies to take such risks—risks that bring us life-saving medicines.

2. Where does the money go?

Americans may assume most of the money they spend on drugs goes back to the drug manufacturer. That is not the case. In fact, drug manufacturers receive just 37% of dollars spent on prescription drugs.[41] This number has decreased by 17 percentage points since 2013.[42] Similarly, branded drug list prices have now declined for the fourth straight year.[43] This means, year after year, manufacturers are actually decreasing, not increasing, their listed drug prices.[44]

If drug prices listed by manufacturers continue to decrease, then what explains the increased drug costs for consumers at the pharmacy counter? The answer is middlemen, or PBMs. In 2020, total gross expenditures for branded medications reached $517 billion. [45] Brand manufacturers retained just 31% of this spending, while middlemen retained 69%.[46]

To summarize, yes, drug prices at the pharmacy counter are rising. But the data shows drug manufacturers are dropping their drug prices, while middlemen in the supply chain are taking substantially more profits every single year. My experience as a pharmacy owner has led me to believe that the main culprits for the rise in drugs costs are PBMs.

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[39] *See* Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 20 (2016).

[40] *See* Press Release, Biotechnology Indus. Org., New Study Shows the Rate of Drug Approvals Lower Than Previously Reported (Feb. 14, 2011), https://archive.bio.org/media/press-release/new-study-shows-rate-drug-approvals-lower-previously-reported [https://perma.cc/3K7F-5YGX].

[41] Andrew Brownlee & Jordan Watson, *The Pharmaceutical Supply Chain, 2013–2020*, BRG (Jan. 7, 2022), https://www.thinkbrg.com/insights/publications/pharmaceutical-supply-chain-2013-2020 [https://perma.cc/A5EN-MEVN].

[42] *Id.*

[43] *See* John A. Murphy, III, *Brand Name Drug Prices Fell in 2021 — Again.*, BIO (Jan. 7, 2022), https://www.bio.org/blogs/brand-name-drug-prices-fell-2021-again [https://perma.cc/H6DC-DDYQ].

[44] *See id.*

[45] Brownlee & Watson, *supra* note 41, at 5.

[46] *See id.*

B. PBMs

The drug supply chain encompasses six main entities: manufacturers, distributors, retailers or pharmacies, PBMs, health insurance plans or government-run insurance, and patients.[47] Manufacturers make a drug, distributors purchase those drugs and ship them to retailers and pharmacies, and the medication is then dispensed to the patient by a pharmacist. These entities provide services that are visible to patients.[48]

Health insurance plans and PBMs operate as virtual entities in the supply chain. Health insurance plans pay a portion of the cost of the dispensed medication. They decide which pharmacies are part of their network—entities your health plan contracts with to provide you with medical benefits. Health plans make money by charging patients premium payments and yearly deductibles.

PBMs operate as middlemen, and they operate exclusively in the United States.[49] They were originally created to perform administrative functions for insurers related to consumer drug benefits.[50] Today, they negotiate costs and reimbursements with pharmacies, drug manufacturers, and insurance plans to establish drug formularies, or lists of generic and branded medications that insurers will cover and pay for according to a consumer's health insurance contract.[51] PBMs also manage the flow of financing in the drug supply chain by providing reimbursements and payments to all entities.[52]

PBMs claim they are directly responsible for lowering the costs of drugs.[53] The Pharmaceutical Care Management Association ("PCMA"), the PBM industry association that lobbies lawmakers in Washington, D.C., has an entire webpage dedicated to explaining the value of PBMs.[54] They claim discounts and rebates, paid by pharmaceutical companies and negotiated by

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[47] *See* JULIE SOMERS & ANNA COOK, CONG. BUDGET OFF., NO. 2703, PRESCRIPTION DRUG PRICING IN THE PRIVATE SECTOR 5–11 (2007), https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/01-03-prescriptiondrug.pdf [https://perma.cc/68A7-9M6Q].

[48] *See id.* at 1–2.

[49] *See* Jeff Lagasse, *Pharmacy Benefit Managers Operate with Lack of Transparency, Expert Finds*, HEALTHCARE FIN. (Sept. 19, 2018), https://www.healthcarefinancenews.com/news/pharmacy-benefit-managers-operate-lack-transparency-expert-finds [https://perma.cc/5FYM-LCGV].

[50] *See* Cole Werble, *Pharmacy Benefit Managers*, HEALTH AFFS. (Sept. 14, 2017), https://www.healthaffairs.org/do/10.1377/hpb20171409.000178/ [https://perma.cc/8FSC-4KZQ].

[51] *See* Ana Gascon Ivey, *A Guide to Medication Formularies*, GOODRX HEALTH (May 19, 2020), https://www.goodrx.com/insurance/health-insurance/medication-formulary [https://perma.cc/GU7W-BAS6].

[52] *Pharmacy Benefit Managers and Their Role in Drug Spending*, COMMONWEALTH FUND (Apr. 2019), https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending [https://perma.cc/8C5F-NFQ3].

[53] *See The Value of PBMs*, PHARM. CARE MGMT. ASS'N, https://www.pcmanet.org/the-value-of-pbms/ [https://perma.cc/ZL7H-2TL5].

[54] *Id.*

PBMs, ultimately lower patient costs.[55] They claim PBMs build pharmacy networks to provide drugs at discounted rates.[56] And they claim PBMs work to increase generic drug utilization and patient medication adherence.[57]

PBM lobbyists spread these messages throughout Congress' halls. In the first nine months of 2021, PBMs spent $5.9 million to convince lawmakers these claims are true.[58] This was a 20% increase over the same period in 2020.[59] They are spending this money for good reason. PBMs have been under increased scrutiny by states and the federal government for their business dealings.[60] In 2021, over 100 bills were introduced across the country that targeted PBMs.[61] Congress and the Biden and Trump administrations have taken action on PBMs as well. I will discuss these actions in more detail later.

Unfortunately, the lack of transparency in PBM business practices has allowed them to institute practices that harm consumers' medication access and to increase drug costs.[62] The key to their lack of transparency: vertical mergers.

PBMs have vertically integrated, creating healthcare conglomerates that control pricing with little competition.[63] The three largest PBMs are CVS Caremark, Express Scripts, and OptumRx.[64] CVS Caremark is integrated with Aetna's insurance plan and CVS Pharmacy.[65] Express Scripts is merged with Cigna's insurance plan and Express Scripts' mail-order pharmacy.[66] OptumRx is merged with United Healthcare's insurance plan and runs its own

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[55] *Id.*

[56] *Id.*

[57] *Id.*

[58] David McKay, *To Be, or Not to Be . . . a Fiduciary: That Is the Question for PBMs*, Benefits Pro (Feb. 14, 2022), https://www.benefitspro.com/2022/02/14/to-be-or-not-to-be-a-fiduciary-that-is-the-question-for-pbms/?slreturn=20220123185822 [https://perma.cc/A3SH-GRHL].

[59] *Id.*

[60] Gaby Galvin, *Pharmacy Benefit Managers Are Feeling a Push from States to 'Turn the Lights on' to Their Business Practices*, Off. Mont. State Auditor, Comm'r Sec. & Ins. (Aug. 26, 2021), https://csimt.gov/news/pharmacy-benefit-managers-are-feeling-a-push-from-states-to-turn-the-lights-on-to-their-business-practices/ [https://perma.cc/M3DJ-TC3G].

[61] *Id.*

[62] *See id.*

[63] Adam J. Fein, *Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?*, Drug Channels (Dec. 12, 2019), https://www.drugchannels.net/2019/12/insurers-pbms-specialty-pharmacies.html [https://perma.cc/6JF6-BTYR].

[64] *See* Matej Mikulic, *U.S. Prescription Market: Market Share of Pharmacy Benefit Managers 2020*, Statista (June 16, 2021), https://www.statista.com/statistics/239976/us-prescription-market-share-of-top-pharmacy-benefit-managers/ [https://perma.cc/2GUP-8EUM].

[65] Fein, *supra* note 63.

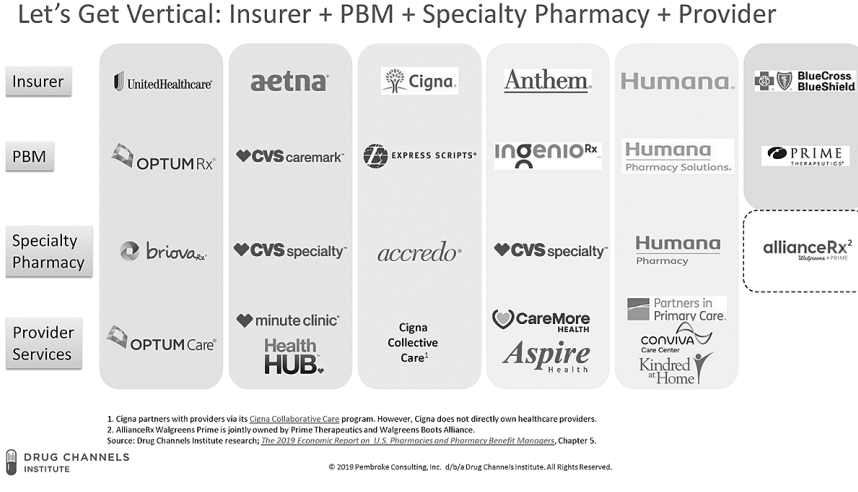
[66] *Id.*

mail-order pharmacy.[67] The big three PBMs control almost 80% of the market.[68]

PBMs comprise the only entity in the drug supply chain that knows what everyone is paying and what everyone is profiting. Yet they operate in a black box with no transparency. PBMs use this lack of transparency to take profits from the rest of the supply chain—resulting in much higher drug prices.

The chart below, from Drug Channels Institute, shows the extent of vertical integration involved.[69] Note that the integration includes mergers with health providers too, not just insurers and pharmacies. This integration presents opportunities for PBMs to lock competing pharmacies, insurers, or even providers out of the market. With less competition, PBMs can continue raising prices and stealing profits from other entities, again leading to increased drug costs.

FIGURE 1:



PBMs have also merged with specialty pharmacies, which were established to manage the extreme growth of specialty medication use and the extra precautions required to dispense them.[70] Specialty medications are

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[67] *Id.*

[68] Jake Frenz, *Industry Voices—Why It's Time for PBM Rebates to Come to an End*, FIERCE HEALTHCARE (Apr. 8, 2019, 10:42 AM), https://www.fiercehealthcare.com/payer/industry-voices-why-it-s-time-for-pbm-rebates-to-come-to-end [https://perma.cc/W9F2-BJBV].

[69] Fein, *supra* note 63.

[70] *See* ANNA ANDERSON-COOK & JARED MAEDA, CONG. BUDGET OFF., NO. 54964, PRICES FOR AND SPENDING ON SPECIALTY DRUGS IN MEDICARE PART D AND MEDICAID 1 (2019), https://www.cbo.gov/system/files/2019-03/55011-Specialty_Drugs_WP.pdf [https://perma.cc/EZ88-DTME].

complex drugs that treat chronic, difficult to treat, or rare conditions.[71] These medications are driving large spikes in health spending in recent years.[72] They often have high prices and usually require special handling, storage, additional training for pharmacists, and intensive patient monitoring.[73] Specialty medications accounted for 53% of all drug spending in 2020—up from 27% in 2010.[74] Roughly 75% of all drugs under development right now are specialty medications—mostly oncology and autoimmune medications.[75] PBMs have realized the potential for profitability with specialty medications. It is estimated that dispensing specialty medications accounted for nearly one-third of PBM profits in 2019.[76] In 2020, specialty pharmacies are estimated to have dispensed $176 billion in medications, an increase of 9.1% since 2019.[77]

CVS owns CVS Specialty, Express Scripts owns Accredo, and OptumRx owns BriovaRx.[78] In 2018, only 900 United States pharmacies had a specialty pharmacy accreditation.[79] It is estimated there are more than 60,000 pharmacies in the United States.[80] PBMs that own specialty pharmacies partake in a little-known practice called "patient steering," where the PBM forces patients, through their insurance network, to use a specialty pharmacy the PBM owns.[81] The PBM unilaterally decides what medications will be covered as part of a patient's drug formulary.[82] This presents an opportunity for PBMs to spike costs because patients have limited options to access the medication elsewhere.

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[71] Bijal Nitin Patel & Patricia R. Audet, *A Review of Approaches for the Management of Specialty Pharmaceuticals in the United States*, 32 PharmacoEconomics 1105, 1105 (2014).

[72] *See* Rabah Kamal, Cynthia Cox & Daniel McDermott, *What Are the Recent and Forecasted Trends in Prescription Drug Spending?*, Peterson-Kaiser Fam. Found. Health Sys. Tracker (Feb. 20, 2019), https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/ [https://perma.cc/74PF-8J5K].

[73] *See* Anderson-Cook & Maeda, *supra* note 70, at 1.

[74] Murray Aitken & Michael Kleinrock, IQVIA Inst., The Use of Medicines in the U.S. 4 (2021).

[75] CVS Health, Drug Trend Report 2019 8 (2020).

[76] *See* Fein, *supra* note 63.

[77] Adam J. Fein, *DCI's Top 15 Specialty Pharmacies of 2020: PBMs Expand Amid the Shakeout—While Walgreens' Outlook Dims*, Drug Channels (May 4, 2021), https://www.drugchannels.net/2021/05/dcis-top-15-specialty-pharmacies-of.html [https://perma.cc/7VD6-LCGU].

[78] *See* Adam J. Fein, *PBM-Owned Specialty Pharmacies Expand Their Role in—and Profits from—the 340B Program*, Drug Channels (July 21, 2020), https://www.drugchannels.net/2020/07/pbm-owned-specialty-pharmacies-expand.html [https://perma.cc/K5SP-8VAP].

[79] *See* Adam J. Fein, *The Specialty Pharmacy Boom: Our Exclusive Update on the U.S. Market*, Drug Channels (Apr. 23, 2019), https://www.drugchannels.net/2019/04/the-specialty-pharmacy-boom-our.html [https://perma.cc/B9K9-TFLR].

[80] Pete Hatemi & Christopher Zorn, Pharm. Care Mgmt. Ass'n, Independent Pharmacies in the U.S. Are More on the Rise than on the Decline 2 (2020).

[81] *See Patient Steering*, Nat'l Cmty. Pharmacists Ass'n (2022), https://ncpa.org/patient-steering [https://perma.cc/84PE-AWZJ].

[82] Paul B. Ginsburg & Steven M. Lieberman, *Government Regulated or Negotiated Drug Prices: Key Design Considerations*, Brookings (Aug. 30, 2021), https://www.brookings.edu/essay/government-regulated-or-negotiated-drug-prices-key-design-considerations/ [https://perma.cc/W3ZX-83WJ].

Studies about specialty pharmacies in certain states have indicated that the big three PBMs are involved in this type of "steering" behavior. One report from the Florida Pharmacy Association and the American Pharmacy Cooperative in February 2020 studied the behavior of PBMs in relation to a diverse group of pharmacies in the state of Florida.[83] A *Pharmacy Times* review of the report found that PBMs often require "generic specialty drugs to be dispensed at their affiliated pharmacy and the reported payments to these pharmacies far exceeded their [cost of dispensing]."[84] The report also found that claims "dispensed at affiliated or specialty pharmacies are being reported with a weighted average margin over acquisition cost of up to $200 per claim" within Florida.[85]

Other states have studied this behavior and come to similar conclusions. The Ohio Pharmacists Association and 46brooklyn Research, a drug-pricing analytics firm, authored a 2019 report[86] discussing PBM operations in Ohio. Antonio Ciaccia, co-author of the report, commented that the data suggests that in Ohio:

> [i]n the case of specialty drugs and [Medicaid managed care organization ("MCO")]-owned specialty pharmacies, inappropriate profiteering and self-dealing are not just risks, but realities. When those entities who are tasked with containing costs also profit off the cost, it begs the question of whether or not there are adequate incentives to contain costs at all.[87]

The vertical integration of PBMs, insurers, and the rest of the healthcare delivery system increasingly presents opportunities to raise prices and increase profits.[88] In my opinion, PBMs are filled with conflicts of interest and incentives to raise prices, not decrease them.

There are some independently owned specialty pharmacies operating, and they present customers with a high degree of quality service and competitive prices.[89] In 2018, 44% of all independent pharmacies dispensed spe-

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[83] *See* 3 Axis Advisors, Sunshine in the Black Box of Pharmacy Benefits Management (2020), https://cdn.ymaws.com/www.floridapharmacy.org/resource/resmgr/docs_2020_legislative_session/fl_master_master_5.0_delieve.pdf [https://perma.cc/Z68U-7NEJ].

[84] Aislinn Antrim, *Florida Pharmacy Association Report Outlines Concerns About PBM, MCO Manipulations,* Pharmacy Times (Feb. 5, 2020), https://www.pharmacytimes.com/view/florida-pharmacy-association-report-outlines-concerns-about-pbm-mco-manipulations [https://perma.cc/2HPX-BUP7].

[85] 3 Axis Advisors, *supra* note 83, at 9.

[86] 46brooklyn Rsch., New Drug Pricing Analysis Reveals Where PBMs and Pharmacies Make Their Money (2019), https://www.46brooklyn.com/research/2019/4/21/new-pricing-data-reveals-where-pbms-and-pharmacies-make-their-money [https://perma.cc/R24K-ENCN].

[87] Darrel Rowland, *PBMs Accused of Exploiting Specialty Drugs*, Columbus Dispatch (Apr. 24, 2019), https://www.dispatch.com/story/news/politics/government/2019/04/24/pbms-accused-exploiting-specialty-drugs/5347089007/ [https://perma.cc/F9DJ-YBUG].

[88] *See id.*

[89] Elizabeth Seeley & Surya Singh, *Competition, Consolidation, and Evolution in the Pharmacy Market*, Commonwealth Fund (2021), https://www.commonwealthfund.org/publi-

cialty drugs, but not all were accredited specialty pharmacies.[90] Unfortunately, with PBMs' immense control over the specialty pharmacy business, it becomes harder every day for these community pharmacies to compete.

As a Member of Congress seated on the House Energy and Commerce Health Subcommittee, I have warned my colleagues repeatedly that vertical integration of PBMs, insurers, and other health entities is going to raise prices and limit medication access. Three years ago, I sent a letter to the Federal Trade Commission ("FTC") warning against the merging of these companies and tipped off the Department of Health and Human Services ("HHS") that these mergers were going to cause problems for consumers.[91] In that letter, I stated that PBMs maintain a number of conflicts of interest that inhibit their ability and incentive to keep drug costs low.

Congress established the FTC in 1914 through passage of the Federal Trade Commission Act.[92] The agency is tasked with investigating and preventing unfair competition, or lack thereof, and protecting consumers from lies and deceptive business practices.[93] The FTC is also tasked with enforcing various antitrust laws, or laws that regulate the organization of businesses to promote competition and prevent monopolies.[94]

Contrary to the FTC's congressionally mandated mission, it has allowed the mergers discussed previously to occur. In my letter, I pointed out to the FTC that PBMs control prescription drug coverage for over 238 million Americans.[95] The three largest PBMs control approximately 89% of those prescription drug benefits.[96]

PBMs have stated that their role in the marketplace is to control costs.[97] However, patients' out-of-pocket costs increased 169% from 1987 to 2008.[98]

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cations/issue-briefs/2021/aug/competition-consolidation-evolution-pharmacy-market [https://perma.cc/4HE8-XN4P].

[90] *See* PDM Healthcare, *Independent Pharmacies, Chains Enter Specialty Pharmacy*, 7 PDM Healthcare Health Indus. Link 4 (2016), http://www.pdmhealthcare.com/HIL.aspx?story=HIL704_12 [https://perma.cc/4QTP-PYX6].

[91] *See* Earl L. "Buddy" Carter, Comment Letter to the Federal Trade Commission on Competition and Consumer Protection in the 21st Century Hearings, Project Number P181201; the State of Antitrust and Consumer Protection Law and Enforcement, and Their Development, Since the Pitofsky Hearings (Aug. 20, 2018), https://www.ftc.gov/system/files/documents/public_comments/2018/08/ftc-2018-0048-d-0083-155238.pdf [https://perma.cc/3NLT-S4NF].

[92] 15 U.S.C. §§ 41–58.

[93] *A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority*, Fed. Trade Comm'n (May 2021), https://www.ftc.gov/about-ftc/mission/enforcement-authority [https://perma.cc/AE42-2S7N].

[94] *Guide to Antitrust Laws*, Fed. Trade Comm'n, https://www.ftc.gov/advice-guidance/competition-guidance/guide-antitrust-laws [https://perma.cc/5ZAP-R8UE].

[95] *See* Comment Letter, *supra* note 91, at 2.

[96] *Pharmacy Benefit Managers*, Nat'l Ass'n Ins. Comm'rs (Mar. 16, 2021), https://content.naic.org/cipr_topics/topic_pharmacy_benefit_managers.htm [https://perma.cc/BRJ3-F4MA].

[97] *Pharmacy Benefit Managers and Their Role in Drug Spending*, *supra* note 52.

[98] Nat'l Cmty. Pharmacists Ass'n, The PBM Story 8 (2017), http://www.ncpa.co/pdf/PBM-Storybook-6pg.pdf [https://perma.cc/UDQ2-PKVL].

Employers experienced a 1,553% increase in drug benefit costs over that same time for employer-sponsored insurance benefits offered to employees.[99] Fast forward to 2018, recent data shows nationwide spending on prescription drugs reached $335 billion, up from only $30 billion in 1980.[100]

If PBMs argue they keep drug costs low, then the question naturally arises: why have drug costs gone up so much? PBMs have developed a complex business model of rebates, fees, gag clauses, and other practices that allow them to drive up prices and profits.[101] For example, if a drug manufacturer wants patients to have access to their product, they may be instructed by the PBM to set a higher list price on the medicine in order to deliver a bigger rebate to the PBM.[102] If the drug manufacturer refuses, the PBM could just exclude the medicine from their drug formulary—denying patients access.[103] PBMs also have no incentive to negotiate contracts with pharmacies outside of their integrated business. Independent pharmacists can try to negotiate business contract with the PBM for network access, but they are often told by the PBMs that the contract is non-negotiable. I experienced this at my own pharmacy business.

These practices prevent competition from entering the marketplace and allow PBMs to further consolidate. Furthermore, PBMs are seated in the middle of the drug marketplace, allowing them to control the drug manufacturer rebate, plan formulary, fee paid to the pharmacists, and the price of drugs to the patients.[104] They maintain control of the flow of money with little to no transparency. PBMs have no fiduciary duty to employers, insurance plans, or patients. They are therefore able to negotiate all aspects of drug delivery without any responsibility to disclose any benefits they receive preventing patients, manufacturers, pharmacists, and even plans from determining their true value in the market. To this day, there are no laws or regulations that require PBMs disclose any of their business dealings, despite a HHS proposal to move forward with reforms that would address the growing impact of DIR fees on drug prices.[105]

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[99] *Id.*

[100] HAYFORD & AUSTIN, *supra* note 12.

[101] *See* Lauren Vela, *Reducing Wasteful Spending in Employers' Pharmacy Benefit Plans*, COMMONWEALTH FUND (Aug. 30, 2019), https://www.commonwealthfund.org/publications/issue-briefs/2019/aug/reducing-wasteful-spending-employers-pharmacy-benefit-plans [https://perma.cc/8AEE-CHXF].

[102] *See* MATHEMATICA POL'Y RSCH., INC., THE ROLE OF PBMS IN MANAGING DRUG COSTS: IMPLICATIONS FOR A MEDICARE DRUG BENEFIT 16 (2000), https://www.kff.org/wp-content/uploads/2013/01/the-role-of-pbms-in-managing-drug-costs-implications-for-a-medicare-drug-benefit.pdf [https://perma.cc/9FGC-34BY].

[103] *See id.*

[104] *See* Mark Meador, *Squeezing the Middleman: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry through Regulation*, 20 ANNALS HEALTH L. 77, 78–79 (2011).

[105] *See* Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Correction, 87 Fed. Reg. 1842 (proposed Feb. 25, 2022) (to be codified at 42 C.F.R. §§ 422–23), https://www.federalregister.gov/documents/2022/02/25/2022-03966/medicare-program-contract-year-

The FTC received my letter but did not investigate PBM business practices. I never received a response from the agency. I followed up with FTC Chair Lina Kahn in December 2021 over the phone. The Chair told me the FTC would be conducting investigations and taking action against PBMs. As of January 2022, they still have not done so.

III. PBM Predatory Tactics

Pharmacies are the nation's most accessible healthcare entities—95% of Americans live within five miles of a pharmacy.[106] There are two main types of pharmacies: independently owned "community pharmacies" and retail pharmacies that are integrated, or owned, by PBMs. [107] The best recognized and largest PBM-owned retail pharmacies are CVS, Express Scripts mail order, and OptumRx mail order.[108] The latter two are virtual pharmacies that ship medications to patients—they are not brick-and-mortar stores.[109]

Independent pharmacists continue to support their patients, but they are being driven out of the market by PBMs.[110] From December 2017 to December 2020, the United States lost more than 2,300 independent pharmacies, while PBMs consolidated more of the market for their own pharmacy business.[111] Every day that the FTC fails to stop PBMs' mergers and anticompetitive practices, more independent pharmacies are put out of business.[112]

PBMs use various tactics to limit patient medication access and increase drug costs to benefit their bottom line: issuing DIR fees, pocketing rebates, spread pricing contracts, and patient steering.[113]

2023-policy-and-technical-changes-to-the-medicare-advantage-and [https://perma.cc/K95F-76ZU].

[106] *See* Rachel Balick, *HHS Releases Plan Aimed at Increasing Adult Immunizations*, Pharmacy Today (May 1, 2016), https://www.pharmacytoday.org/article/S1042-0991(16)30176-1/fulltext [https://perma.cc/WY2C-JU4M].

[107] *See* Patty Taddei-Allen, *Evolution of the Pharmacy Benefit Manager/Community Pharmacy Relationship: An Opportunity for Success*, 26 J. Managed Care & Specialty Pharmacy 708, 708–710 (2020).

[108] *See* Adam J. Fein, *CVS, Express Scripts, and the Evolution of the PBM Business Model*, Drug Channels (May 29, 2019), https://www.drugchannels.net/2019/05/cvs-express-scripts-and-evolution-of.html [https://perma.cc/J4FQ-M2ZM].

[109] *See id.*

[110] *See* Markian Hawryluk, *The Last Drugstore: Rural America is Losing its Pharmacies*, Wash. Post (Nov. 10, 2021, 7:00 AM), https://www.washingtonpost.com/business/2021/11/10/drugstore-shortage-rural-america/ [https://perma.cc/TY6Q-ZDQH].

[111] *See* Press Release, Am. Pharmacists Ass'n, Pharmacy Coalition Praises Legislation to Relieve Patients and Pharmacies from Pharmacy DIR Fees (May 27, 2021), https://pharmacist.com/APhA-Press-Releases/pharmacy-coalition-praises-legislation-to-relieve-patients-and-pharmacies-from-pharmacy-dir-fees [https://perma.cc/JDJ4-ZYLA].

[112] *See* Linette Lopez, *What CVS Is Doing to Mom-And-Pop Pharmacies in the US Will Make Your Blood Boil*, Bus. Insider (Mar. 30, 2018, 4:59 AM), https://www.businessinsider.com/cvs-squeezing-us-mom-and-pop-pharmacies-out-of-business-2018-3 [https://perma.cc/U7RP-R7F9].

[113] *See Uncloaking Pharmacy Benefit Managers to Promote Market Competition*, Barclay Damon (June 20, 2017), https://www.barclaydamon.com/blog/health-care/uncloaking-pharmacy-benefit-managers-to-promote-market-competition [https://perma.cc/U3E4-YAXK].

A. DIR Fees

DIR fees were originally conceived in Medicare Part D as an incentive to lower costs for patients.[114] The original rule defined DIR fees as including: "discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers, pharmacies or similar entities."[115]

The idea was to bring prices down for Medicare patients through incentives. It has since morphed into a tool PBMs use to take more profits. PBMs require that pharmacies fulfill certain metrics when dispensing drugs—often called "performance fees."[116] PBMs are not transparent about how they grade pharmacies to issue these fees, but they are likely based on dispensing rates, medication adherence, and chronic disease management.[117] Pharmacies may be hit with DIR fees if they do not refill medications whether a patient asked for it or not, how many medications they dispensed, or if they dispense drugs that are not on the PBMs' preferred drug formulary list.

DIR fees are not itemized and can be charged a year or more after medications are expensed—a practice that has since also been termed as "clawbacks".[118] There is no transparency on how DIR fees are calculated, yet they are extracted by the PBM from each pharmacy dispensing claim.[119] Pharmacies may not even know if a transaction is profitable for months after it transpired, depending on the DIR fee assessed to the pharmacy by the PBM.[120]

Independent pharmacy owners can be suddenly hit with unplanned expenses from these clawback fees, which are sometimes so high that the business is no longer profitable.[121] These predatory practices make it very difficult for independent pharmacies to remain operational.

According to the CMS fiscal year 2022 budget justification sent to Congress, pharmacy DIR fees under the Medicare program have increased by a staggering 91,500% between 2010 and 2019.[122] Independent pharmacies

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[114] *See* True North Political Solutions, *White Paper: DIR Fees Simply Explained*, PHARMACY TIMES (Oct. 25, 2017), https://www.pharmacytimes.com/view/white-paper-dir-fees-simply-explained [https://perma.cc/JKC3-GPL4].

[115] 42 C.F.R. § 423.308 (2010).

[116] True North Political Solutions, *supra* note 114.

[117] *See id.*

[118] *See id.*

[119] *See id.*

[120] *See id.*

[121] Laurie Toich, *DIR Fees and Independent Pharmacies: What is the Impact?,* PHARMACY TIMES (Feb. 13, 2017), https://www.pharmacytimes.com/view/dir-fees-and-independent-pharmacies-what-is-the-impact [https://perma.cc/RG6W-N36L].

[122] U.S. DEP'T HEALTH & HUM. SERVS. CTRS. FOR MEDICARE & MEDICAID SERVS., JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEE 242 (2022), https://www.cms.gov/files/document/fy2022-cms-congressional-justification-estimates-appropriations-committees.pdf [https://perma.cc/EEN3-53HF].

rarely have negotiating power to stop these fees.[123] They are at the mercy of the PBMs because they rely on in-network status from the insurers the PBM might be merged with. As PBMs make more profit off these fees, the rest of the supply chain is forced to charge higher prices to ensure they make a profit—hurting patients.[124]

Pharmacy DIR reform has strong bipartisan support in both the House and Senate, highlighted in the Pharmacy DIR Reform to Reduce Senior Drug Costs Act.[125] Additionally, in April 2020, 114 members of Congress signed a letter that I wrote to House and Senate leadership, requesting DIR fee reform be brought up for a vote.[126] Unfortunately, such a vote has not yet happened.

B. Rebates

PBMs processed over 90% of all pharmacy claims in 2016.[127] As the middlemen, PBMs are supposed to use their large purchasing power to negotiate for rebates off the manufacturer's drug list price and pass those savings to patients.

Drug list prices are set by manufacturers.[128] They do not take into account any rebates or discounts to which PBMs and insurers agree. Manufacturers then offer rebates, best described as coupons, on their drugs to the PBMs and insurers in exchange for making their drug available to patients.[129] These rebates are then, in theory, supposed to be passed down to the patients at the pharmacy counter or used to cover a patient's out-of-pocket insurance costs. Drug manufacturers willingly offer coupons on their products so patients get cheaper drugs.[130]

PBMs leverage their power to get bigger rebates on drugs from manufacturers, putting even more money into their pockets.[131] Drug manufacturers have no choice in this matter. If they do not offer larger rebates to the PBM,

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[123] Laurie Toich, *supra* note 121.

[124] *Pharmacy Benefit Managers and Their Role in Drug Spending*, *supra* note 52.

[125] S. 1909, 117th Cong. (2021); *see* Gabrielle Ientile, *Pharmacy Associations Praise Bill Seeking to Reform DIR Fees*, Drug Topics (June 2, 2021), https://www.drugtopics.com/view/pharmacy-associations-praise-bill-seeking-to-reform-dir-fees [https://perma.cc/2WTZ-G3Q9].

[126] Letter from Earl L. "Buddy" Carter, U.S. Representative, House of Representatives et al. to House & Senate Leadership (Apr. 27, 2020), https://buddycarter.house.gov/uploadedfiles/dir_letter_to_leadership.pdf [https://perma.cc/7N7C-RXHM].

[127] Susan K. Urahn, Alan Coukell, Ian Reynolds & Alisa Chester, Pew Charitable Trusts, The Prescription Drug Landscape, Explored 40 (2019), https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored [https://perma.cc/Y55C-VHX2].

[128] *See How Are Prescription Drug Costs Really Determined?*, Drug Cost Facts, https://www.drugcostfacts.org/prescription-drug-costs [https://perma.cc/WQA4-P8YS].

[129] *See id.*

[130] *See* Pragya Kakani, Michael Chernew & Amitabh Chandra, *Rebates in the Pharmaceutical Industry: Evidence from Medicines Sold in Retail Pharmacies in the U.S.* 1 (Nat'l Bureau of Econ. Rsch., Working Paper No. 26846, 2020).

[131] *See* Frenz, *supra* note 68.

the PBM can choose to not include their drugs in their list of covered medicines.[132] As PBMs demand larger rebates, manufacturers lose profits and are forced to increase costs to make up for the losses PBMs are pocketing.[133] Patients are on the losing end of this—paying increasingly higher prices for drugs.[134]

On May 4, 2021, the House Energy and Commerce Health Subcommittee, which I am seated on, held a hearing titled, "Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs."[135] Dr. Gaurav Gupta, founder of Ascendant BioCapital, testified to the committee that only 53% of what a patient pays for a drug at the counter makes it back to the drug manufacturer.[136] 47% gets taken by middlemen—largely PBMs.[137] PBMs are convoluting the rebate system, originally designed to decrease costs, in order to increase prices and take a larger portion of the cost increase for themselves.[138]

C. Spread Pricing

PBMs also utilize their power to pigeonhole independently owned pharmacies into predatory business contracts with a reimbursement structure termed "spread pricing."[139] According to the National Community Pharmacists Association, "spread pricing is the PBM practice of charging payers like Medicaid more than they pay the pharmacy for a medication, and then the PBM keeps the 'spread' or difference, as profit."[140] For example, an independent pharmacy in Iowa serviced the local county jail and dispensed a generic bottle of antipsychotic pills for an inmate.[141] The PBM, CVS Caremark, billed the jail $198.22 for the medication but gave the pharmacy

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[132] *See Pharmacy Benefit Managers and Their Role in Drug Spending*, *supra* note 52.

[133] *See* Katheryn Houghton, *States Step Up Push to Regulate Pharmacy Drug Brokers*, KAISER HEALTH NEWS (June 30, 2021), https://khn.org/news/article/states-step-up-push-to-regulate-pharmacy-drug-brokers/ [https://perma.cc/WZB2-HEY3].

[134] *See* Ryan Oftebro, *Op-ed: Addressing Rising Drug Costs for Patients*, STATE OF REFORM (Mar. 4, 2022), https://stateofreform.com/news/washington/2022/03/op-ed-addressing-rising-drug-costs-for-patients/ [https://perma.cc/6LQA-C8W6].

[135] *Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs: Hearing Before the Subcomm. on Health of the H. Comm. On Energy and Commerce*, 117th Cong. (2021).

[136] Prelim. Transcript, *Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs: Hearing Before the Subcomm. on Health of the H. Comm. On Energy and Commerce*, 117th Cong., at 120 (May 4, 2021).

[137] *See* Robert Langreth, David Ingold & Jackie Gu, *The Secret Drug Pricing System Middlemen Use to Rake in Millions*, BLOOMBERG (Sept. 11, 2018), https://www.bloomberg.com/graphics/2018-drug-spread-pricing/ [https://perma.cc/G99A-VATK].

[138] *See* Frenz, *supra* note 68.

[139] Trevor J. Royce, Sheetal Kircher & Rena M. Conti, *Pharmacy Benefit Manager Reform: Lessons From Ohio*, 322 J. AM. MED. ASS'N 299, 299 (2019).

[140] *Spread Pricing 101*, NAT'L CMTY PHARMACISTS ASS'N, https://ncpa.org/spread-pricing-101 [https://perma.cc/2QTM-UGCN].

[141] *See* Langreth, et al., *supra* note 137.

only $5.73.[142] CVS Caremark took $192.49 of profit on the generic medication, and the pharmacy reportedly lost money servicing the county jail for that year.[143]

PBMs use spread pricing tactics quite frequently to reimburse pharmacy claims below the cost of the dispensed drug. Pharmacy owners have little choice but to agree to these contracts, otherwise the PBM will not include them as an in-network pharmacy, likely putting the pharmacy out of business.[144]

Drug costs through Medicaid have increased, yet PBM reimbursements to pharmacies have decreased.[145] States have found that the practice of spread pricing meant Medicaid programs were billed more than what the actual pharmacies were paid for claims.[146] For example, in 2017, PBMs profited $1.3 billion of the $4.2 billion state Medicaid programs spent on drugs.[147]

A few states have audited PBMs to uncover the profits they make from spread pricing contracts in Medicaid drug programs. Maryland found PBMs pocket $72 million annually from spread pricing.[148] Michigan found PBMs overcharged their Medicaid program over $64 million, and Kentucky found PBMs pocketed $123.5 million in spread pricing annually.[149]

The Congressional Budget Office determined that a spread pricing ban in Medicaid programs would save federal taxpayers at least $1 billion over 10 years.[150] I introduced bipartisan legislation to stop this practice, H.R. 6101, the Drug Price Transparency in Medicaid Act of 2021.[151] This legislation would ban spread pricing tactics used by PBMs in Medicaid programs.[152] I have introduced this bill in previous Congresses as well,[153] but as of February 28, 2022 the legislation has still not passed Congress.

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[142] *Id.*

[143] *Id.*

[144] *Pharmacy Benefit Managers and Their Role in Drug Spending*, *supra* note 52.

[145] Rachel Garfield, Rachel Dolan & Elizabeth Williams, *Costs and Savings under Federal Policy Approaches to Address Medicaid Prescription Drug Spending*, KAISER FAM. FOUND. (June 22, 2021), https://www.kff.org/medicaid/issue-brief/costs-and-savings-under-federal-policy-approaches-to-address-medicaid-prescription-drug-spending/ [https://perma.cc/RQ47-3HX9].

[146] *See* Langreth, et al., *supra* note 137.

[147] *Id.*

[148] *See Spread Pricing 101*, *supra* note 140.

[149] *Id.*

[150] Garfield, et al., *supra* note 145.

[151] H.R. 6101, 117th Cong. (2021).

[152] *See id.*

[153] *NCPA Supports Bipartisan Bill to Ban PBM Spread Pricing Tactics; Pay Pharmacies Appropriately,* NAT'L CMTY. PHARMACISTS ASS'N (Dec. 1, 2021), https://ncpa.org/newsroom/news-releases/2021/12/01/ncpa-supports-bipartisan-bill-ban-pbm-spread-pricing-tactics-pay [https://perma.cc/DNB6-UA2A].

D. Patient Steering

PBMs also use a practice called patient steering to steer patients away from independent pharmacies in favor of pharmacies or mail-order programs the PBM directly owns.[154]

To illustrate, consider a patient in rural Kansas walking into their local pharmacy that they have been a customer of for decades. After their pharmacist fills the prescription, they may get a phone call from the PBM telling them that their drug costs could be less expensive if the PBM filled the patient's prescription at a big box drug store, like CVS, or a mail-order service the PBM runs. Or maybe the PBM informs the patient that their local pharmacy is no longer in-network, forcing them to take an extended drive to a larger town where the medication can be filled by an in-network pharmacy, or a pharmacy that is merged with the PBM.

This is patient steering and—make no mistake about it—it is harmful to patients.[155] Patient steering by PBMs requires patients to break pre-existing relationships with pharmacists with whom they are comfortable.[156] A survey conducted by the National Community Pharmacists Association found 79% of independent pharmacists say their patients' prescriptions were transferred to a different pharmacy by a PBM without the patients' consent.[157]

Although the short-term gain of a less expensive drug for the patient sounds beneficial, the long-term consequences are worse. As PBMs steer patients into pharmacies they own, independent pharmacies lose business, and the healthcare delivery system becomes more integrated and anti-competitive, driving higher drug costs and presenting opportunities for PBMs to take more profits.[158] Consumers should have the freedom to choose, especially when it comes to their healthcare.

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[154] *See* Letter from Ronna Hauser, Vice President, Pharmacy & Regul. Aff., Nat'l Comm. Pharmacists Ass'n, to Off. Sec'y, Fed. Trade Comm'n (Nov. 15, 2018), https://www.ftc.gov/system/files/documents/public_comments/2018/11/ftc-2018-0076-d-0018-162492.pdf [https://perma.cc/AR4W-JWBK].

[155] *See* CAL. PHARMACISTS ASS'N, SB 524 (SKINNER) – PBMS: PATIENT STEERING 1 (Aug. 2021), https://cpha.com/wp-content/uploads/2021/08/Patient-Steering-Fact-Sheet-_F.pdf [https://perma.cc/XTL2-UFXT].

[156] *See id.*

[157] Press Release, Nat'l Comm. Pharmacists Ass'n, Patient Steering a Massive Problem for Comm. Pharmacists, New Survey Shows (Sept. 17, 2020), https://ncpa.org/newsroom/news-releases/2020/09/17/patient-steering-massive-problem-community-pharmacists-new-survey [https://perma.cc/H7JS-D8WW].

[158] Elizabeth Seeley & Surya Singh, *Competition, Consolidation, and Evolution in the Pharmacy Market*, COMMONWEALTH FUND (Aug. 12, 2021) https://www.commonwealthfund.org/publications/issue-briefs/2021/aug/competition-consolidation-evolution-pharmacy-market [https://perma.cc/32B4-JHRL].

IV. Potential Policy Solutions

Significant change addressing PBMs' predatory practices has proven to be difficult.

The Trump administration recognized the harmful impacts of PBMs, and, in February 2019, CMS issued a notice of proposed rulemaking to reduce out-of-pocket spending for beneficiaries at the pharmacy and other points-of-care.[159] This proposed rule would have forced PBMs to transfer rebates to the customer at the pharmacy counter, and DIR fees would have to be assessed at the point of sale instead of months after the medication is dispensed.[160]

This proposal would have ensured patients' out-of-pocket costs were reduced because the PBMs would no longer be able to take the drug manufacturer rebates for themselves—saving patients up to 30% of what they spend on drugs.[161] Assessing DIR fees at the point of sale would allow independently owned pharmacies to plan ahead for these fees and remodel their business to account for them.[162]

The Trump administration issued a final rule in November 2020, but the rule excluded any DIR fee reform and opted only to force rebates to patients at the point of sale.[163] The rule was set to take effect on January 1, 2022.[164] The PCMA sued the Trump administration, arguing the rule would lead to higher insurance premiums in Medicare Part D.[165] On January 30, 2021, the

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[159] *See* Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 84 Fed. Reg. 3240 (proposed Feb. 6, 2019) (to be codified at 42 C.F.R. pt. 1001), https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals [https://perma.cc/8WKR-UNNG].

[160] *See id*.

[161] *See* Jeff Lagasse, *Updated: Trump-Era Rebate Rule for Medicare Part D on Hold Until 2023*, Healthcare Fin. (Feb. 1, 2021), https://www.healthcarefinancenews.com/news/biden-administration-puts-hold-trump-era-rebate-rule-medicare-part-d [https://perma.cc/SPJ5-K263].

[162] *See* T. Joseph Mattingly II & Ge Bai, *Reforming Pharmacy Direct and Indirect Remuneration in the Medicare Part D Program*, Health Affs. (July 19, 2021), https://www.healthaffairs.org/do/10.1377/forefront.20210714.70749/full/ [https://perma.cc/BBJ5-YW9W].

[163] 42 C.F.R. § 1001 (2020); *see* Press Release, U.S. Dep't of Health & Human Servs., HHS Finalizes Rule to Bring Drug Discounts Directly to Seniors at the Pharmacy Counter (Nov. 20, 2020), https://www.hhs.gov/about/news/2020/11/20/hhs-finalizes-rule-bring-drug-discounts-directly-seniors-pharmacy-counter.html [https://perma.cc/LS3Q-PB48].

[164] Thomas Sullivan, *PBM Rebate Rule Effective Date Postponed*, Pol'y & Med., https://www.policymed.com/2021/02/pbm-rebate-rule-effective-date-postponed.html [https://perma.cc/V6BB-D5B5] (last updated Feb. 14, 2021).

[165] *See Pharm. Care Mgmt. Ass'n v. U.S. Dep't of Health & Human Servs.*, 21 Civ. 21-95 (JDB) (D.D.C. Mar. 15, 2021).

United States District Court for the District of Columbia issued an order postponing the rule's enactment until January 1, 2023.[166]

In a win for PBMs, the Biden administration further delayed the rule's implementation after a court order staying litigation on the rule until HHS is able to review it.[167] Congress then passed a legislative delay of the rule until 2026 as a "pay-for" to finance the infrastructure bill signed into law by President Biden on November 15, 2021.[168] The legislative delay was projected by the Congressional Budget Office to save the federal government $49 billion in premium increases if the rule took effect.[169]

As previously discussed, members of Congress have also introduced legislation to stop these PBM practices, notably the Pharmacy DIR Reform to Reduce Senior Drug Costs Act[170] and the Drug Price Transparency in Medicaid Act of 2021.[171]

State action has also taken place to stop PBMs. On December 10, 2020, the Supreme Court ruled 8-0 in *Rutledge v. Pharmaceutical Care Management Association (PCMA)*[172] that an Arkansas law ("Act 900") does not preempt federal Employee Retirement Income Security Act of 1974 ("ERISA") laws.[173] Act 900 regulates reimbursements to pharmacies by PBMs for the cost of prescription drugs.[174] Under Act 900, PBMs are required to raise reimbursement rates for drugs if they are below the pharmacy's wholesale acquisition cost.[175] This would prohibit PBMs from reimbursing pharmacies less than what it cost for them to purchase the drug.[176]

The *Rutledge* case will likely serve as a model for other states to enact laws aimed at stopping PBMs' practices. It was a big win for all pharmacists, and the ruling opens the door for states to take additional action against PBMs, not just stopping low reimbursement rates.

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[166] *See* Order, *Pharm. Care Mgmt. Ass'n v. U.S. Dep't of Health & Human Servs.*, 21 Civ. 21-95 (JDB), at 1 (D.D.C. Jan. 30, 2021).

[167] *See* Order, *Pharm. Care Mgmt. Ass'n v. U.S. Dep't of Health & Human Servs.*, 21 Civ. 21-95 (JDB), at 1 (D.D.C. Mar. 15, 2021); *see also* Jacquie Lee & Ian Lopez, *HHS Delays Trump-Era Drug Rebate Rule to 2023 After Court Order*, BLOOMBERG (Mar. 18, 2021), https://news.bloomberglaw.com/pharma-and-life-sciences/biden-delays-drug-rebate-rule-that-gao-says-violates-review-law-1 [https://perma.cc/533Z-UU8U].

[168] Infrastructure Investment and Jobs Act, Pub. L. No. 117-58, 135 Stat. 429 (2021).

[169] CONG. BUDGET OFF., INCORPORATING THE EFFECTS OF THE PROPOSED RULE ON SAFE HARBORS FOR PHARMACEUTICAL REBATES IN CBO'S BUDGET PROJECTIONS—SUPPLEMENTAL MATERIAL FOR UPDATED BUDGET PROJECTIONS: 2019 TO 2029 (2019), https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf [https://perma.cc/Q54Q-587P].

[170] S. 1909, 117th Cong. (2021).

[171] H.R. 6101, 117th Cong. (2021).

[172] 598 U.S. __ (2020).

[173] *See* Kimberly J. Donovan & Michele Noble, *Supreme Court Rules That Arkansas Act 900, Affecting the Prices That PBMs Pay to Pharmacies, Is Not Preempted Under ERISA*, NAT'L L. REV. (Dec. 11, 2020), https://www.natlawreview.com/article/supreme-court-rules-arkansas-act-900-affecting-prices-pbms-pay-to-pharmacies-not [https://perma.cc/DM85-TH22].

[174] *PBM Reimbursement*, ARK. PHARMACISTS ASS'N, https://www.arrx.org/reimbursement [https://perma.cc/D2X5-N6YF].

[175] *Id.*

[176] *Id.*

V. Advocacy

Thomas Jefferson famously said, "[t]he purpose of government is to enable the people of a nation to live in safety and happiness. Government exists for the interests of the governed, not for the governors."[177]

Politicians need to know how you feel about specific policies. We serve our constituents at their pleasure, from local government and state legislatures, all the way to Congress and the White House. We are elected by you, the people. It is your responsibility to hold us accountable for our actions and votes as legislators.

Every American is paying higher drug costs. That is no secret. I have revealed how PBMs steal profits from patients, pharmacists, drug makers, and other entities in the chain. You can do something with this knowledge. If there is an issue you care about, like drug pricing, go talk to your representative. Let them know how it is impacting your family and your community. Personal stories make significant impacts in Washington, D.C.

VI. Conclusion

Members of Congress, and legislators across the country, have a tall order to fill. Lowering the cost of prescription drugs and addressing the role that PBMs play in setting those costs are not overly partisan issues. These are issues Democrats and Republicans all over the country and in Congress agree must be addressed. The PBM lobby is powerful and influential, but they are not untouchable. We know how to fix this mess. We know how to bring immediate relief to American wallets. But we, collectively, must have the courage to fight back against PBMs and enact significant reforms to stop their predatory practices.

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[177] *Thomas Jefferson on Politics & Government Section 5: The Sovereignty of the People*, Fam. Guardian Fellowship, https://famguardian.org/Subjects/Politics/ThomasJefferson/jeff0300.htm [https://perma.cc/E8UD-H42F].