POLICY BRIEF

AMERICAN ECONOMIC LIBERTIES PROJECT

Why We Should Ban PBM Rebates

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I. INTRODUCTION

In December 2021, the House Committee on Oversight and Reform published a report on the rising cost of brand drugs.[2] The report showed a troubling dynamic in the market for glatiramer acetate, an essential medication used to treat relapsing multiple sclerosis. Despite the availability of cheaper generic alternatives starting in 2017, Teva Pharmaceuticals' brand version of the drug, Copaxone, retained a dominant market position and high list price. Research suggests both should have come down significantly, but Teva maintained its monopoly.[3] The evidence pointed to entities called pharmacy benefit managers (PBMs), which require rebates, sometimes characterized as kickbacks or quasi-bribes, from manufacturers so their drugs can get on their formularies. In exchange for rebates from Teva, the PBMs made Copaxone the only glatiramer acetate on their formularies and thus covered by certain insurance plans and dispensed by select drugstores. In other words, Teva and the PBMs leveraged the rebate system to prevent affordable generic drugs from gaining market share. This story shows something disturbing about pharmaceutical pricing in America.

1 The author would like to thank Matt Seiler from the National Community Pharmacists Association and Luke Slindee from Myers and Stauffer LC for comments and feedback on this report.

2 "Drug Pricing Investigation: Majority Staff Report," U.S. House of Representatives Committee on Oversight and Reform, December 2021, https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf.

3 "Exclusive Drug Dealing: Anticompetitive Practices in the Pharmaceutical Supply Chain," The Capitol Forum, May 2023, https://thecapitolforum.com/wp-content/uploads/2023/05/The-Capitol-Forum-Special-Report-Exclusive-Drug-Dealing.pdf.

The conventional wisdom about how pharmaceuticals are priced in the U.S. is that the PBM is supposed to hold down costs, and that rebates help do so.[4] Current policies for reform offer a variety of options for regulating PBMs and the rebates they require. But as revealed in the glatiramer acetate case and, as it turns out, in many others, PBMs' use of pharmaceutical rebates allows multiple players in the supply chain to financially benefit at the expense of patients. Rebates are not a mechanism to hold down costs but a weapon to raise them. They are the problem: kickbacks that distort pharmaceutical markets with conflicts of interest and price hikes. They should be banned, not reformed. Eliminating rebates would not only enable competition around list prices but align the interests of payers, PBMs, and patients to seek the lowest possible list price. Only PBMs and health plans benefit from the current system, while patients are left behind.

This brief lays out the broad impact of pharmaceutical rebates on drug affordability and access, the misperceptions and institutional barriers protecting them, and policy solutions to move forward. It begins by explaining what PBMs and rebates are and how they operate in pharmaceutical markets. It then lays out the arguments put forth by PBMs and other proponents in defense of rebates before explaining more holistically how they subvert normal competition and lead to higher prices. Next, it describes why agencies like the Congressional Budget Office (CBO) mistakenly report that rebates save the government money and surveys the current legislative proposals being debated. Lastly, this brief lists policy recommendations, particularly to abandon rebates and achieve drug manufacturer competition based on list price.

II. WHAT IS A PBM?

PBMs were originally created to process drug claims on behalf of health plans.[5] They now largely design drug benefits for health plans, bargain with them over the costs of these benefits, negotiate formulary placement and rebates with drug manufacturers, and establish reimbursement rates for pharmacies to dispense prescriptions. The top three PBMs — Caremark, Express Scripts, and Optum Rx — hold tremendous market power, together owning 80% of the PBM market.[6] They also are now integrated with some of the largest health insurers, as CVS Caremark is owned by Aetna, Express Scripts by Cigna, and Optum Rx by UnitedHealthcare.[7]

4 "Prescription Drug Rebates," Pharmaceutical Care Management Association, https://www.pcmanet.org/prescription-drug-rebates/.
5 Zach Freed, "The Pharmacy Benefit Mafia," American Economic Liberties Project, June 2022, http://www.economicliberties.us/wp-content/uploads/2022/06/2022-6-22-PBM-Quick-Take.pdf.
6 Id.
7 Id.

A core part of developing drug benefits involves designing formularies to have multiple tiers that a given drug may be placed on.[8] The tiers come with varying conditions determined by the PBM, such as how much a patient will have to pay out-of-pocket for a prescription at the pharmacy compared to their insurer. Because a patient wants to buy drugs covered by their insurance, formulary placement is a top priority for manufacturers, including what tier a PBM decides to place their drugs on. Formulary placement, therefore, is the core of rebate negotiations between PBMs and manufacturers. PBMs will include drugs in their formularies and put them on better tiers when their manufacturers promise bigger reductions in their list prices, which come in the form of post-sale rebates.

When patients pick up their prescriptions at a pharmacy, the pharmacists charge them the amounts that PBMs say they owe, per the formulary tiering decisions, and bill health plans to cover any remaining costs.[9] The PBMs decide how much to reimburse the pharmacies and how much to charge the patients' health insurers for the sales. Months later, the drug manufacturers submit the agreed-upon rebates to the PBMs, which allegedly pass them along to the health insurers. Before doing so, PBMs take a cut as a fee for their services to the health insurers. This is a core part of their compensation, which creates a conflict of interest that will be discussed further in Section III.

III. WHAT ARE PHARMACEUTICAL REBATES?

Rebates are commonly known as marketing gimmicks in the consumer economy to increase sales.[10] At the most basic level, they are partial refunds given to customers after they purchase a product. Customers may buy multiple kitchen appliances from the same manufacturer, for example, knowing that the manufacturer is offering them a deal where it will send them a small refund afterwards. Rebates are prone to abuse, however. Like discounts, when shared widely with customers, they can allow sellers to artificially inflate their list prices and give customers the false impression that a percentage off reflects a cost saving, like when a department store always advertises 50%-off sales.[11] Rebates also give manufacturers significant leverage over buyers by withholding the rebates until the

8 Id.
9 PBMs also play an essential role when their insurance customers' members pick up their prescriptions at the pharmacy counter. First, they decide which drugstores are in network and whether they have to use so-called "specialty" pharmacies to buy certain kinds of medications. PBMs, again, are not neutral decision-makers over pharmacy networks. The top three operate some of the largest drug stores: Caremark is owned by CVS Pharmacy, while Express Scripts and Optum Rx run two of the biggest mail-order pharmacies.
10 See "What Is Rebate Marketing?," Incentive Insights, January 28, 2020, https://incentiveinsights.com/what-is-rebate-marketing/; Ian Floyd and Kate Monica, "Rebates vs discounts: Differences, examples, & more," Tremendous, September 28, 2023, https://www.tremendous.com/blog/consumer-rebates-vs-discounts/.
11 Kevin Brasler, "Manipulative Marketing Is Now The Norm," Consumers' Checkbook, November 2023, https://www.checkbook.org/washington-area/30-tricks-sellers-use-to-make-you-pay-up/.

buyers purchase, for example, a required number of products.[12] They can further serve to drive emerging or existing competitors that cannot afford them out of the market, thereby limiting customer choice.[13] Rebates have thus provoked scrutiny from competition regulators and experts alike.[14]

Rebates from drug manufacturers are a defining feature of U.S. pharmaceutical markets today. Congress introduced them in 1990 as a way to keep Medicaid spending under control, requiring drug manufacturers to enter rebate agreements with the Department of Health and Human Services in order to have their medications covered by the government program for low-income individuals.[15] Today, rebates have become so pervasive in government-backed and commercial health plans that the list prices of prescription drugs are widely understood to be meaningless reflections of the "real" prices of medications.[16] Rebates are given to PBMs as part of negotiations over formulary placement.[17]

It is difficult to quantify exactly how pervasive rebates are in the U.S. prescription drug market. In September, the Government Accountability Office (GAO), a congressional watchdog, issued a report giving some indication of their extent in sales covered partially or fully by Medicare Part D.[18] The report found that the private companies providing Part D coverage received $48.6 billion in rebates from drug manufacturers in 2021 alone, on $210.6 billion in gross expenditures for about 49 million beneficiaries.[19]

These rebates give PBMs and drug manufacturers a lever to control patients' access to certain drugs and, as seen with Teva's Copaxone, achieve monopoly positions against competitors. This is not surprising, given the fundamental nature of rebates, which are typically redeemable only when certain conditions are met. Even in consumer markets, customers may only receive rebates, for example, after buying a certain quantity of the

12 See "A Question of Loyalty: How to analyse loyalty rebates and discounts," International Competition Network, accessed November 27, 2023, https://www.theantitrustattorney.com/files/2013/12/ICN-UCWG-webinar-9-December-Slides.pdf; "How Rebate Structure Affects Your Margin," e-bate, April 28, 2020, https://www.e-bate.io/blog/how-rebate-structure-affects-margin/#:~:text=Rebates%20are%20a%20powerful%20tool,and%20rebates%20are%20no%20exception; Rafi Mohammed, "When It's Wise to Offer Volume Discounts," Harvard Business Review, October 25, 2013.
13 "A Question of Loyalty," International Competition Network.
14 See "Fidelity Rebates and Competition," OECD Competition Committee Session, June 2016, https://www.oecd.org/daf/competition/fidelity-rebates.htm#:~:text=Firms%20use%20fidelity%20rebates%20to,as%20helping%20to%20achieve%20efficiencies; "Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower Cost Drug Products," Federal Trade Commission, June 16, 2022, https://www.ftc.gov/legal-library/browse/policy-statement-federal-trade-commission-rebates-fees-exchange-excluding-lower-cost-drug-products.
15 Rachel Dolan, "Understanding the Medicaid Prescription Drug Rebate Program," KFF, November 12, 2019, https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program/ (on the long-lasting use of drug rebates in the Medicaid program).
16 "Inside AWP: The arbitrary pricing benchmark used to pay for prescription drugs," 46brooklyn, November 8, 2018, https://www.46brooklyn.com/research/2018/11/7/visualizing-how-aint-whats-paid-awp-really-is.
17 "Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending," Government Accountability Office, September 2023, https://www.gao.gov/assets/gao-23-105270.pdf.
18 Id.
19 Id.

given product (minimum volume),[20] if they agree not to buy from a rival (exclusivity),[21] or if they also buy a different product by the same manufacturer (bundling).[22]

These practices are also common in pharmaceutical markets. For example, drug manufacturers often agree to send the PBM rebates only when it sells a certain quantity of its product to the PBM's health plans' members (minimum volume).[23] Drug manufacturers also sometimes agree to send the PBM rebates only if it is the sole product in its category to be listed on its tier, making any competitors more expensive by putting them on a worse tier (exclusivity).[24] Drug manufacturers will sometimes "bundle" their rebates as well, only providing them if the PBM gives preferential tiering to another, unrelated drug (bundling).[25] These strategies are often made possible by manufacturers' ability to withhold rebates until months after PBMs' health plans' members purchase their prescriptions. This power has led the Federal Trade Commission to scrutinize the legal implications of what many experts refer to as "rebate traps," whereby payers make decisions over what drugs to cover based on these financial incentives rather than adjusting naturally to, for example, new market entries of more affordable medications.[26]

IV. REBATES: THE LIES PBMS TELL

PBMs advance key myths to defend the rebate system. Each is discussed below, followed by the facts.

1. MYTH: REBATES MAKE DRUGS MORE AFFORDABLE AND ACCESSIBLE

PBMs say that rebates are discounts off manufacturers' list prices, thereby making drugs more affordable and accessible. Although PBMs keep a portion of the rebates for themselves, they tell the public that they pass the vast majority onto their health insurer clients. During a May 2023 hearing hosted by the Senate Health, Education, Labor, and Pensions (HELP) Committee, for example, the president of Caremark and CEO of Optum

20 "When It's Wise to Offer Volume Discounts."
21 "Fidelity Rebates and Competition."
22 "Manipulative Marketing Is Now The Norm."
23 Robin Feldman, "The devil in the tiers," Journal of Law and the Biosciences, January 2021, https://academic.oup.com/jlb/article/8/1/lsaa081/6103567; "Federal Trade Commission Report on Rebate Walls," Federal Trade Commission, May 2021, https://www.ftc.gov/reports/federal-trade-commission-report-rebate-walls.
24 Id.
25 Id.; Letter from Association for Accessible Medicines to Federal Trade Commission Chair Lina Khan, May 23, 2022, https://accessiblemeds.org/sites/default/files/2022-05/FTC-PBM-Business-Practices-05-20-2022_0_0.pdf.
26 "Federal Trade Commission Report on Rebate Walls."

Rx testified they pass at least 98% of rebates back to customers, while the president of Express Scripts testified the company passes on 95%.[27] The Optum Rx executive specifically told Congress that it saves insurers about $1,600 per person annually, a statistic it cited in 2019 congressional testimony and on its website as well.[28]

PBMs say that their insurance customers' members benefit from rebates as well. The leaders of the three major PBMs told the Senate HELP Committee in May 2023 that health insurers use these rebates to lower patient premiums and out-of-pocket costs.[29]

TRUTH: REBATES INFLATE DRUG PRICES

In truth, pharmaceutical rebates increase drug prices and patient spending.

Rebates inherently present a risk that manufacturers are hiking their list prices so significantly that the final net price is in fact higher than it would be otherwise, but there are further reasons why this is likely to occur in the PBM-run system. Mainly, because PBMs take a cut of rebates as fees, they naturally will prefer drugs that come with higher rebates, which tend to be those with higher list prices.[30] In other words, they are incentivized to give better formulary coverage to drugs like Teva's Copaxone, not necessarily those that deliver the lowest real, or post-rebate, prices, such as generic drugs. This encourages manufacturers to compete with one another by raising their list prices.[31] In other parts of the healthcare system, this arrangement would be recognized and prosecuted as a violation of the Anti-Kickback Statute (AKS). The Department of Health and Human Services' Office of Inspector General (HHS OIG), which Congress has authorized to make rules regarding safe harbors to the AKS, recently affirmed that manufacturer payments to PBMs under rebate agreements are not covered by an AKS safe harbor for discounts if they are not passed through to the final payer.[32] Nevertheless, violations of this rule are not enforced.

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27 David Joyner, "The Need to Make Insulin Affordable for All Americans," Senate Health, Education, Labor, and Pensions Committee, May 2023, https://www.help.senate.gov/imo/media/doc/Statement%20of%20David%20Joyner_050823_FINAL1.pdf; Heather Cianfrocco, "The Need to Make Insulin Affordable for All Americans," Senate Health, Education, Labor, and Pensions Committee, May 2023 https://www.help.senate.gov/imo/media/doc/Cianfrocco%20Written%20Testimony%20HELP%20Committee%20_Final.pdf; Adam Kautzner, "The Need to Make Insulin Affordable for All Americans," Senate Health, Education, Labor, and Pensions Committee, May 2023, https://www.help.senate.gov/imo/media/doc/Kautzner%20Express%20Scripts%20HELP%20Hearing%20Testimony%2005102023.pdf.

28 Heather Cianfrocco, "The Need to Make Insulin Affordable for All Americans"; John M. Prince, "Drug Pricing in America: A Prescription for Change," Senate Finance Committee, April 19, 2019, https://www.finance.senate.gov/download/04092019-prince-testimony; "Optum Rx Differentiated Pharmacy Benefit Solutions," UnitedHealth Group, accessed November 27, 2023, https://www.unitedhealthgroup.com/ns/optum-rx/differentiated-pharmacy-benefit-solutions.html.

29 David Joyner, "The Need to Make Insulin Affordable for All Americans"; Heather Cianfrocco, "The Need to Make Insulin Affordable for All Americans"; Adam Kautzner, "The Need to Make Insulin Affordable for All Americans."

30 "The Pharmacy Benefit Mafia."

31 Id.

32 "General Questions Regarding Certain Fraud and Abuse Authorities," Department of Health and Human Services Office of Inspector General, accessed November 27, 2023, https://oig.hhs.gov/faqs/general-questions-regarding-certain-fraud-and-abuse-authorities/.

TRUTH: PBMS DO NOT PASS ON SAVINGS FROM REBATES

Accordingly, research indicates that PBMs do not pass as much of the rebates they receive through to health insurers as they publicly indicate.[33] Mandatory rebate disclosure reports in Texas, for example, show that PBMs actually kept 13% of payments from manufacturers in 2021 and anywhere from 9% to 13% between 2016 and 2021.[34] In addition, according to a September 2023 report by Nephron Research, PBM compensation from rebates and other kickbacks doubled from $3.8 billion in 2018 to $7.6 billion in 2022.[35] Any payment that PBMs keep, whether derived from rebates, list price-based fees, or group purchasing organization (GPO) fees, is a cost that could be used to offset premiums or out-of-pocket expenses for patients.

Crucially, pharmaceutical rebates force patients to pay more than their fair share for a drug. It is important to note that patients' out-of-pocket obligations are not calculated based on the net price after the rebate is accounted for, but on the artificially high list price.[36] For example, a patient in the deductible phase of her insurance agreement may have to pay a full $100 list price of her medication, even though her plan sponsor received a $30 rebate that made the actual price $70. A patient in the cost-sharing phase required to contribute 40% has to pay $40 for the same drug, ultimately a much higher percentage of the net price than she realizes. There are even cases when the rebate is so large that the patient is paying more at the pharmacy counter than the net price to her insurer.[37]

TRUTH: REBATES RESTRICT PATIENT ACCESS TO DRUGS

PBMs also restrict the choice of drugs that patients have, often excluding or discouraging the use of lower-priced generic medications, such as the cheaper version of Teva's Copaxone. This may occur because the more affordable new entrants can simply not afford the rebates and thus cannot pay to get on a PBM's formulary. PBMs also exclude through the use of minimum volume, exclusive tiering, or bundling rebate agreements with drug

33 Some of the payments that PBMs receive from drug manufacturers appear to be routed through their group purchasing organization (GPO) businesses. The major PBMs have established GPOs in recent years to negotiate with drug manufacturers on their behalf, creating an additional layer of opacity in the system. See Deborah Abrams Kaplan, "PBMs are Creating GPOs, and Stirring Debate as to Why," Managed Healthcare Executive, July 2022, https://www.managedhealthcareexecutive.com/view/pbms-are-creating-gpos-and-stirring-debate-as-to-why.

34 Adam Fein, "Texas Shows Us Where PBMs' Rebates Go," Drug Channels, August 9, 2022, https://www.drugchannels.net/2022/08/texas-shows-us-where-pbms-rebates-go.html.

35 Eric Percher, "Trends in Profitability and Compensation of PBMs and PBM Contracting Entities," Nephron Research, September 18, 2023, https://nephronresearch.com/trends-in-profitability-and-compensation-of-pbms-and-pbm-contracting-entities/. Within that increase, payments to PBMs generated by their GPOs specifically grew from nearly zero in 2018 to more than $1.7 billion in 2022, demonstrating the increasing reliance on GPOs.

36 Kai Yeung, Stacie Dusetzina, and Anirban Basu, "Association of Branded Prescription Drug Rebate Size and Patient Out-of-Pocket Costs in a Nationally Representative Sample, 2007-2018," JAMA Network, June 14, 2021, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780950.

37 Tara Hayes, Shinobu Suzuki, and Rachel Schmidt, "Analysis of Part D data on drug rebates and discounts," Medicare Payment Advisory Commission, September 30, 2022, https://www.medpac.gov/wp-content/uploads/2021/10/DIR-Slides-MedPAC-29-Sept-2022.pdf.

manufacturers. Under these deals, manufacturers get to withhold the rebates until the given conditions are met.

To illustrate, consider the asthma inhaler market. PBMs commonly force patients to use the brand inhaler drug Symbicort by simply refusing to include the generic version budesonide/formoterol on their formularies. Symbicort costs over $150 per month more than budesonide.[38] Such formulary decisions may be better for the PBM, as Symbicort manufacturer AstraZeneca may offer a large rebate, part of which the PBM gets to keep as compensation. However, it can be disastrous for patients, who have to pay unnecessarily high out-of-pocket costs, particularly when they are in the deductible phase and are thus responsible for paying the entire costs of their medications.

There is empirical evidence to back this up. According to a 2021 study by UC Hastings law professor Robin Feldman, PBMs have increasingly pushed generic drugs off formulary tiers with better insurance coverage.[39] Between 2010 and 2017, the percentage of generics on the tier with the best coverage decreased from 73% to 28%.[40] Feldman noted that rebates are distorting the economics here, such that patients are discouraged from buying lower-priced drugs of similar, if not equal, value to the brand ones.[41]

A 2022 whistleblower lawsuit against CVS Caremark provided further evidence of rebates as the distortionary factor. The complaint, filed by a former employee, alleges that in exchange for rebates, CVS Caremark would agree not to substitute expensive brand name drugs with more affordable generic medications on its formularies.[42] Meanwhile, in a 2023 research study, the Association for Accessible Medicines, a trade group representing generic drug manufacturers, found that both Medicare Part D and commercial health plans have consistently delayed covering generic drugs when they enter the market.[43]

2. MYTH: REBATES GIVE PBMS LEVERAGE OVER MANUFACTURERS

When PBMs and drug manufacturers come to the negotiating table to bargain over drug prices and formulary placement, rebates are what they fight over. PBMs say that drug manufacturers are forced to bid larger and larger rebates to secure a better position on the PBM formulary for their products compared to their rivals', reducing drugs' net prices

38 Letter from National Community Pharmacists Association to Federal Trade Commission Chair Lina Khan, May 23, 2022, https://ncpa.org/sites/default/files/2022-05/5.23.2022-NCPAcommentFTCPBMsolicitation.pdf.
39 "The devil in the tiers."
40 Id.
41 Id.
42 *United States of America ex rel. v. CVS Health Corporation,* E.D. Pennsylvania, https://www.statnews.com/wp-content/uploads/2022/06/CVS-Miller-whistleblower-lawsuit.pdf.
43 "Middlemen Increasingly Block Patient Access to New Generics," Association for Accessible Medicines, January 2023, https://accessiblemeds.org/sites/default/files/2023-01/AAM-Middlemen-Block-Patient-Access-New-Generics-2023.pdf.

as they do.[44] PBMs keep these rebates confidential, saying they amount to trade secrets — a cover that legal experts have questioned.[45] Because manufacturers do not know how much of a rebate their competitors are offering to obtain preferential insurance coverage, PBMs argue that drug manufacturers are compelled to submit even larger rebates than they would in an open market.[46] They add that this secrecy may also prevent drug manufacturers from colluding on price.[47]

The Pharmaceutical Care Management Association, a trade group representing PBMs, laid out this theory in a complaint filed against a Trump administration rule that would have mandated the use of upfront discounts, rather than retroactive rebates. "The retrospective rebate system preserves confidentiality … [which] in turn, allows PBMs to bargain from a position of strength to reduce drug prices. … In effect, the public availability of pricing information allows tacit collusion between manufacturers, who would find it more difficult to set prices below their competitors' prices without detection."[48]

TRUTH: PBMS HAVE SUFFICIENT LEVERAGE WITHOUT REBATES

PBMs already have great leverage over drug manufacturers as a result of their sheer size. The top three PBMs own 80% of the market, and this high level of concentration means that they can leverage the possibility of drug manufacturers losing out on their health plans' patients to push for lower list prices.[49] They do not need rebates to secure reductions.

Moreover, the secrecy that accompanies rebates creates a number of risks. First, because health insurers do not know real drug prices, PBMs can more easily take money that would have gone to insurers or final patients without their knowledge.

Second, and more generally, claims that secrecy incentivizes manufacturers to offer larger price concessions contradict the dynamics that govern nearly every other industry. Put

44 "The Role of Pharmacy Benefit Managers in Prescription Drug Markets, Part II: Not What the Doctor Ordered," Hearing Before U.S. House of Representatives Committee on Oversight and Accountability, Testimony of Pharmaceutical Care Management Association President Juan Carlos Scott, September 19, 2023, https://oversight.house.gov/wp-content/uploads/2023/09/PCMA-Oversight-Written-Testimony-Scott.pdf.
45 Robin Feldman and Charles Graves, "Naked Price and Pharmaceutical Trade Secret Overreach," 22 Yale J.L. & Tech. 61, 2020, https://repository.uclawsf.edu/cgi/viewcontent.cgi?article=2771&context=faculty_scholarship.
46 *Pharmaceutical Care Management Association v. U.S. Department of Health and Human Services*, U.S. District Court, District of Columbia, 17, 2021, https://www.pcmanet.org/wp-content/uploads/2021/01/PCMA-Complaint-US-District-Court-for-the-District-of-Columbia.pdf.
47 Id. at 5.
48 Id. Note: The complaint refers to letters the Federal Trade Commission (FTC) previously wrote warning that public disclosures of pricing information could result in collusion. The FTC has since withdrawn these letters, given changing market conditions. See "FTC Votes to Issue Statement Withdrawing Prior Pharmacy Benefit Manager Advocacy," Federal Trade Commission, July 20, 2023, https://www.ftc.gov/news-events/news/press-releases/2023/07/ftc-votes-issue-statement-withdrawing-prior-pharmacy-benefit-manager-advocacy.
49 "The Pharmacy Benefit Mafia."

simply, in order to attract more customers, sellers are pressured to lower their prices when they know their competitors' prices for similar products. Moreover, contrary to the supposed benefit that confidentiality helps to prevent price-fixing, legislators have found that drug manufacturers do engage in such predatory behavior under the current system.

The 2021 report by the House Committee on Oversight and Reform, for example, found that makers of insulin and arthritis treatments were nonetheless engaging in shadow pricing, in which sellers raise prices in lockstep.[50] Among the multiple instances of this conduct, the report showed that between 2013 and 2021, AbbVie and Amgen, the makers of rival blockbuster arthritis medications Humira and Enbrel, increased their prices in lockstep increments, from about $25,000 for an annual course of treatment to more than $70,000.[51]

V. MORE MYTHS: REBATES AND BUDGET SCORING

Despite these harms, rebates have been given the benefit of the doubt when their effects on federal budgets and spending are evaluated. During the Trump administration, the Department of HHS OIG finalized a rule[52] that would have developed a new pricing model. It would have effectively eliminated retroactive rebates and forced drug manufacturers to instead issue discounts when patients buy medications at the pharmacy counter.[53] Under this rule, PBMs would instead need to negotiate discounts that would be given to patients at point of sale, at the pharmacy counter, rather than retroactive rebates as they currently do. While this model may not fix some of the problems laid out in this paper, such as exclusive tiering and obscure prices, it would potentially eliminate the quantity- or market share-based rebates that this paper critiques, and patients would directly benefit.

Both the HHS Office of the Actuary and Congressional Budget Office (CBO), however, cast doubt on the benefits of doing so. They released reports in 2018 and 2019, respectively, which found that mandating upfront discounts, rather than post-sale rebates, would increase government spending by $177 billion and Medicare premiums by $56 billion over

50 "Drug Pricing Investigation: Majority Staff Report."
51 Id.
52 The Inflation Reduction Act of 2022 delayed implementation of this rule until 2032. See Juliette Cubanski, Tricia Neuman, and Meredith Freed, "Explaining the Prescription Drug Provisions in the Inflation Reduction Act, KFF, January 24, 2023, https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/.
53 "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," Department of Health and Human Services, Federal Register, November 30, 2020, https://www.federalregister.gov/documents/2020/11/30/2020-25841/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals.

10 years.[54] These reports helped pressure Congress, through the 2022 Inflation Reduction Act, to postpone the rule's implementation until 2032.[55] They also continue to spread concerns today about the risks of dismantling the PBM rebate system, which is why it's important to interrogate their underlying assumptions.

The HHS Actuary and CBO reports assumed that the drug manufacturers would offer smaller decreases from the list price if they did not have purchase quantities guaranteed.[56] They estimated that drug manufacturers would withhold about 15% of the price reduction they would otherwise give. This, they argued, would increase government spending and patient premiums.[57]

However, it is crucial to emphasize that this 15% figure does not appear to have derived from any particular quantitative analysis but is merely an assumption. Furthermore, implicit in the HHS Actuary's and CBO's analyses is the notion that guaranteed market share for brand drug manufacturers would result in lower prices than introducing competition with generic medications. This assumption overlooks the drastic difference in prices between the two categories and the benefits that derive from an influx of competition with generic drugs.

It is also crucial to emphasize that the CBO report in particular is not free from conflicts of interest. The office relies on a group of outside healthcare advisers to inform its analyses. Representatives of the PBM industry tend to fill these positions. According to its website, CBO's health adviser panel currently includes current and former senior executives at Cigna and UnitedHealth Group, owners of top-three PBMs Express Scripts and Optum Rx, respectively.[58] The website states that CBO "hosts periodic meetings of the advisers and solicits their views between meetings," but the precise content of this communication is not released to the public.[59]

54 "Proposed Safe Harbor Regulation," Centers for Medicare & Medicaid Services Office of the Actuary, August 30, 2018, https://aspe.hhs.gov/sites/default/files/private/pdf/260591/OACTProposedSafeHarborRegulationImpacts.pdf; "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," Congressional Budget Office, May 2019, https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf.
55 Juliette Cubanski, Tricia Neuman, and Meredith Freed, "Explaining the Prescription Drug Provisions in the Inflation Reduction Act," Kaiser Family Foundation, January 24, 2023, https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/.
56 "Proposed Safe Harbor Regulation"; "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."
57 Id.
58 "Panels of Advisers," Congressional Budget Office, accessed December 1, 2023, https://www.cbo.gov/about/panels-advisers; "Lewis Sandy," LinkedIn, accessed December 1, 2023, https://www.linkedin.com/in/lewsandy/.
59 "Panels of Advisers."

VI. CURRENT REFORM EFFORTS

Congress is currently debating a variety of bipartisan bills to crack down on the various troublesome practices of PBMs. Some of these do not have to do with rebates. Sens. Maria Cantwell (D-Wash.) and Chuck Grassley (R-Iowa), for example, have a bill to prohibit PBMs from charging health plans more than they reimburse pharmacies for a prescription.[60]

One bill in particular directly targets poor incentives in the PBM rebate system but does not upend the model. Sens. Ron Wyden (D-Ore.) and Mike Crapo (R-Ida.) introduced the Modernizing and Ensuring PBM Accountability Act to reform the PBM compensation model that incentivizes the preferential coverage of higher-priced drugs.[61] Specifically, it bans PBMs from receiving any payments connected to the utilization of drugs, apart from "bona fide service fees," or flat dollar amounts.[62]

The bill states, however, that rebates and other price concessions are not in violation of the legislation so long as PBMs pass them entirely through to the plan sponsor.[63] In other words, it leaves the retroactive rebate system intact, meaning that drug manufacturers would, in theory, still be able to withhold price reductions until they achieve a certain volume in sales. It may appear, however, that PBMs would no longer be likely to guarantee certain market shares to drug manufacturers if they are not financially incentivized to give exclusive or better coverage to a particular medication.

In addition to the high level of PBM consolidation already discussed, which can give drug manufacturers assurances, this suggestion notably overlooks a key dynamic of the PBM market today: The insurers that own PBMs have the same incentives as the PBMs. They prefer drugs with higher prices and rebates because they can keep the rebates for themselves and pass on costs to the government and patients in the form of artificially deflated premiums.[64] In other words, PBMs will continue to have an interest in awarding exclusive formulary deals to steer patients to more expensive medications rather than affordable generics.

60 Denise Myshko, "Senators seek PBM transparency in reintroduced bill," Medical Economics, February 3, 2023, https://www.medicaleconomics.com/view/senators-seek-pbm-transparency-in-reintroduced-bill.
61 "Wyden and Crapo Introduce Finance Committee PBM Bill," U.S. Senate Committee on Finance, September 28, 2023, https://www.finance.senate.gov/chairmans-news/wyden-and-crapo-introduce-finance-committee-pbm-bill.
62 Id.
63 Id.
64 "PBM Reform Has Not Raised Costs For Patients and Payers," National Community Pharmacists Association, accessed December 8, 2023, https://ncpa.org/sites/default/files/2022-03/pbm-regulations-one-pager.pdf.

VII. RECOMMENDATIONS

To lower drug prices, the federal government must eliminate rebates and discounts altogether. The U.S. should migrate to a model in which drug manufacturers compete for better formulary placement by simply lowering their list prices. According to UC Hastings law professor Robin Feldman, "Although there is no silver bullet, and all approaches have challenges, basing tiering on list price is a remarkably streamlined approach for cutting through a wide swath of perverse incentives and manipulations."[65]

The federal government has a number of ways to foster a model of competition based on list price:

1. APPLY THE ANTI-KICKBACK STATUTE TO PHARMACEUTICAL REBATES

The Anti-Kickback Statute is a law designed to prevent financial incentives — such as payments from drug manufacturers that seek to encourage PBMs to give better insurance coverage to their medications — from influencing healthcare decision-making. PBMs argue they have an exemption from the Anti-Kickback Statute under the congressionally authorized safe harbor for discounts.[66]

Congress can pursue the following steps:

i. Pass legislation stating that pharmaceutical rebates do not fall under any exemption to the Anti-Kickback Statute. Such legislation should mention that fees from drug manufacturers to PBMs, even when not labeled as rebates, are in violation.

ii. Pass legislation clarifying that payments from drug manufacturers to PBM-owned GPOs do not qualify for the GPO safe harbor from the Anti-Kickback Statute.

65 "The devil in the tiers."
66 *Pharmaceutical Care Management Association v. U.S. Department of Health and Human Services.*

The executive branch can take the following actions:

i. HHS OIG can issue a rule declaring that all fees from drug manufacturers to PBMs and health insurers are ineligible for safe harbor protection under the Anti-Kickback Statute.

ii. HHS OIG can issue a rule banning PBM-owned GPOs from qualifying for the GPO safe harbor to the Anti-Kickback Statute that Congress enacted in the 1980s.

iii. HHS OIG can pursue litigation now against PBMs to the degree they keep rebates and do not pass them along to health insurers. According to the HHS OIG website, any "payment retained by a PBM—even if characterized as a 'rebate'—is a service or administrative fee that would not be eligible for protection under the discount safe harbor." The agency does warn, however, that remuneration kept by PBMs may be protected by other safe harbors, which would require an assessment.[67]

2. ENFORCE THE ROBINSON-PATMAN ACT

The 1936 Robinson-Patman Act states it is unlawful, "either directly or indirectly, to discriminate in price between different purchasers of commodities of like grade and quality."[68] Originally designed for the retail sector, the law was meant to ensure that smaller resellers, such as independent grocery stores, could compete fairly with giant chain stores. The federal government has not enforced this law in decades.

However, it is arguably illegal under this act when drug manufacturers give varying rebate sizes, resulting in different net prices, to different customers. One relevant provision of the law, Section 2(d), also bans payments to a buyer/reseller for marketing and other services in connection with the resale, "unless such payment or consideration is available on proportionally equal terms to all other customers competing in the distribution of such products or commodities."[69]

The federal government should examine its enforcement authority to bring Robinson-Patman cases against drug manufacturers for discriminatory pricing.

67 "General Questions Regarding Certain Fraud and Abuse Authorities."
68 15 U.S. Code § 13(a).
69 15 U.S. Code § 13(d).

3. ALTER HHS ACTUARY/CBO ASSUMPTIONS

As Congress pursues legislative reforms, it is crucial that agencies like the HHS Actuary and CBO make estimates about the impact on patient and federal spending based on a comprehensive understanding of the exclusionary conduct of the large PBMs and do so in a transparent way. More specifically, they should account for how today's volume-based retroactive rebate agreements function to drive out competition, which can result in higher prices.

The agencies should also consider how PBMs and drug manufacturers will change their negotiating tactics under a bargaining model that bases formulary decisions on list prices. This would inherently mean the introduction of more competition than currently exists, as more brand and generic drug manufacturers would have the opportunity to gain preferential coverage for their treatments. With more competition, manufacturers will face downward pressure on their list prices. This affects spending by not only the federal government but patients as well. The aggregate effect on both parties should be accounted for. Further, the agencies should publish their methodologies and assumptions for calculating spending estimates.

It is also essential that the HHS Actuary and CBO are not influenced by biased parties connected to the PBM industry. Advisory board members should reflect the interests of patients and independent medical experts, without conflicts of interest.

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