

# **Testimony of David A. Balto**

**Hearing Before the United States Senate Committee  
on Commerce, Science, and Transportation:  
Subcommittee Consumer Protection, Product Safety,  
and Data Security entitled “Ensuring Fairness and  
Transparency in the Market for Prescription Drugs”**

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Good morning, Chair Blumenthal, Ranking Member Blackburn, and Members of the subcommittee: I thank you for giving me the opportunity to testify on the concerns and the need for regulation and accountability in the pharmacy benefit manager (“PBM”) market. My testimony documents the tremendous competitive and consumer protection problems in the PBM market and need for stronger antitrust enforcement, oversight, regulation, and federal legislation. For years PBMs have existed with scant regulation, and consumers have paid a heavy price in higher costs, less choice and inferior service. Congress and regulators need to reverse this permissive stance toward PBMs to lower prescription drug prices for patients.

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

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

My testimony makes the following points:

- PBMs are one of the least regulated sectors of the healthcare system and drug supply chain. There is almost no federal antitrust enforcement, oversight, or regulation. The lack of antitrust enforcement and regulation has created an environment in which PBMs are free to engage in anticompetitive, deceptive, and fraudulent behavior that harms patients, payors, employers, unions, and pharmacists and significantly increases drug costs.<sup>1</sup>
- Because lax antitrust enforcement allowed the three largest PBMs to become vertically integrated and form a tight oligopoly,<sup>2</sup> the PBM market lacks the essential elements for a competitive market: 1) choice, 2) transparency, and 3) a lack of conflicts of interest. PBMs leverage this lack of competition to further their own interests at the expense of patients, employers, and others in the system.
- The PBM rebate system turns competition on its head with PBMs seeking higher, not lower prices to maximize rebates and profits. **In the past decade, PBM**

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

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

**profits have increased to \$28 billion annually.**<sup>3</sup> PBMs are supposed to control costs, but because of the perverse incentives the rebate system creates, they frequently deny access to lower cost drugs including lower cost generics and biosimilars, to maximize rebates available from higher cost drugs.<sup>4</sup> That is why major consumer and patient groups and unions supported the past administration’s efforts to eliminate the antikickback safe harbor for PBM rebates.<sup>5</sup>

- Because of their market power and vertical integration these middlemen increasingly stifle competition from this country’s most accessible and trusted health care professionals – community pharmacies. PBMs create endless schemes to reduce reimbursement, claw back funds, restrict networks, and effectively force pharmacies to provide drugs below cost. **In 2020 alone, PBMs took \$9,535,197,775<sup>6</sup> from independent pharmacies who serve Medicare Part D participants.** Community pharmacies are crucial for consumers in underserved low income and rural neighborhoods. These unfair and coercive tactics by PBMs result in inferior health care, less choice and higher costs.
- The FTC has failed to protect consumers from unfair, deceptive and egregious conduct in this market. Thus, the Committee should consider amending the FTC Act to specify unfair acts or practices and unfair methods of competition that PBMs engage in that the FTC should address and provide a clear mandate for strong enforcement. Consumers should no longer be forced to pay billions for the schemes of these middlemen.

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

### **The PBM Market Is Broken**

Ensuring that patients can afford lifesaving and life-managing prescription drugs is critically important to public health because better use of medicines has been shown to help patients live longer and healthier lives. Unreasonably high out-of-pocket costs for prescription

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<sup>3</sup> PBM Accountability Project, *Understanding the Evolving Business and Revenue Models of PBMs*, 2021, [https://www.pbmacountability.org/\\_files/ugd/b11210\\_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true](https://www.pbmacountability.org/_files/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true)

<sup>4</sup> Charlie Grant, *Hidden Profits in the Prescription Drug Supply Chain*, February 24, 2018, Wall Street Journal.

<sup>5</sup> Comments of Consumer Action, Consumer Federation of America, Consumer Reports, NETWORK Lobby for Catholic Social Justice, and Public Research Interest Group PIRG in Support of Department of Health and Human Services Office of Inspector General’s (“HHS”) proposed new rules to eliminate the safe harbor for rebates in Medicare Part D plans, April 8, 2019, [https://docs.wixstatic.com/ugd/1859d0\\_c7d2ccf1d47d4f65a8965e9bbaed989d.pdf](https://docs.wixstatic.com/ugd/1859d0_c7d2ccf1d47d4f65a8965e9bbaed989d.pdf).

<sup>6</sup> Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, CMS 4192-F, <https://public-inspection.federalregister.gov/2022-09375.pdf>.

drugs at the pharmacy counter threaten patient access to medicines, as some choose to stop or delay treatment because they cannot afford it.<sup>7</sup>

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

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

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

**First, there is a lack of choice.** The PBM industry is a tight oligopoly, which results in reduced consumer choice. According to the Council of Economic Advisors (CEA), three PBMs - CVS Caremark, Optum Rx, and Express Scripts - control over 80% of the market, “which allows them to exercise undue market power against manufacturers and against health plans and beneficiaries.”<sup>12</sup> **Indeed, the three largest PBMs have a higher gross margin than any other**

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

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

<sup>9</sup> Fortune Rankings, <https://fortune.com/fortune500/2021/search/>.

<sup>10</sup> J.C. Scott, *FTC's Inquiry of PBMs Won't Lower Prescription Drug Costs*, The Hill, April 18, 2022, <https://thehill.com/blogs/congress-blog/327225-ftcs-inquiry-of-pbms-wont-lower-prescription-drug-costs/>

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

<sup>12</sup> CEA White Paper, *supra* note 2. The Top Pharmacy Managers of 2021, the big get even bigger, Drug Channels, April 2022, <https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html>. I expect the witness from PCMA will note that there are dozens of PBMs. But these firms are not competitors at least from the

players involved in the drug supply chain,<sup>13</sup> and in recent years, more of the increase in spending on brand medicines has gone to payers, including PBMs and health plans, than to drug manufacturers.<sup>14</sup> PBM profits have more than doubled in the past decade. It is hard to see what value these middlemen have added to our healthcare system in return for the skyrocketing profits.<sup>15</sup>

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

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

Legislation requiring transparency or imposing a fiduciary duty might be one solution. Yet PBMs regularly fight against any such legislative proposals. For example, the PBMs fought

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perspective of competition law and economic policy. Under the antitrust laws, a “competitor” in a relevant market is a firm that can constrain prices. *FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1078 (D.D.C. 1997) (“The pricing evidence indicates a low cross-elasticity of demand between consumable office products sold by Staples or Office Depot and those same products sold by other sellers of office supplies. This same evidence indicates that non-superstore sellers of office supplies are not able to effectively constrain the superstores prices, because a significant number of superstore customers do not turn to a non-superstore alternative when faced with higher prices in the one firm markets.”) None of these much smaller PBMs have either the incentive or ability to constrain the anticompetitive conduct of the three dominant PBMs.

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

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

<sup>15</sup> PBM Accountability Project, *Understanding the Evolving Business and Revenue Models of PBMs*, 2021, [https://www.pbmaccountability.org/files/ugd/b11210\\_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true](https://www.pbmaccountability.org/files/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true)

<sup>16</sup> CEA White Paper *supra* note 2.

against a 2014 Department of Labor consideration of transparency even though the proposal was supported by HR Policy Association, the AFL-CIO and Consumers Union.<sup>17</sup>

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

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

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

The most significant conflict that leads to escalating drug costs involves PBMs' incentives to maximize the rebates paid by manufacturers to get preferred access on their drug formularies. PBMs were formed to act as honest brokers to negotiate with drug manufacturers for lower prices for payors, but when PBMs share in the rebates that they negotiate, it creates an incentive for them to want higher, not lower, list prices. According to a recent Senate Finance Committee Report, "PBMs have an incentive for manufacturers to keep list prices high, since the rebates, discounts, and fees PBMs negotiate are based on a percentage of a drug's list price --

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<sup>17</sup>PCMA Testimony to the ERISA Advisory Council, William J. Kilberg, June 19, 2014 <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/about-us/erisa-advisory-council/2014-pbm-compensation-and-fee-disclosure-kilberg-06-19.pdf>; Consumers Union Testimony, June 12, 2014, <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/about-us/erisa-advisory-council/2014-pbm-compensation-and-fee-disclosure-quincy-06-19.pdf>. I expect that Professor Graithwaite will suggest that that PBM transparency may be harmful because it may lead to collusion. I firmly disagree with that suggestion. First even Professor Graithwaite seems to admit the PBM market may not be competitive. TESTIMONY OF CRAIG L. GARTHWAITE, Ph.D., Before the House Committee on Education and Labor Subcommittee on Health, Employment, Labor, and Pensions On "Making Health Care More Affordable: Lowering Drug Prices and Increasing Transparency," September 26, 2019, at 21, <https://edlabor.house.gov/imo/media/doc/GarthwaiteTestimony0926191.pdf>. Second, although there may be a theoretical argument that excessive transparency can lead to collusion, I think that is rather unlikely in this market. It assumes that buyers will disclose the precise amount of rebates to rival manufacturers. I represent payors and based on my experience I doubt that would occur. Moreover, in my 15 years as an antitrust enforcer including working as the FTC Policy Director, I cannot recall a single case where transparency led to the type of collusion the Professor suggests.

and PBMs may retain at least a portion of what they negotiate.”<sup>18</sup> PBMs have gone so far as to require additional payments in the event of any reduction in manufacturer list prices.<sup>19</sup>

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

PBMs base formulary access decisions on the amount of the rebates, which encourages drug manufacturers to focus on offering higher rebates to secure that preferred status. Focusing on rebates gives PBMs incentives to put higher-cost drugs on their formularies, because the rebates are based on a percentage of a drug’s list price. In essence, PBMs are making decisions on inclusion of a drug based not on clinical research or evidence-based efficacy and safety, but on which manufacturer offers a higher rebate payment. In pursuit of higher rebates, PBMs routinely deny access to formularies, change drug formularies, or require prior authorization for drugs that may be best for a patient’s condition, even in cases where a more affordable medication is available. For example, a PBM often excludes a lower priced generic or biosimilar because the higher priced branded drug offers higher rebates.

As important as cost is the adverse impact on patient health. PBM rebate schemes interfere with doctor-patient relationships, and harm patients’ health when they cannot get the drugs they need. PBMs may exclude new innovative drugs that may be less expensive and more effective, in favor of higher rebates.<sup>20</sup> On many occasions PBMs may require patients to go through cumbersome and health-threatening step therapy programs in order to secure the more efficacious drug. As Robin Feldman, a professor at UC Hastings College of Law, puts it, “the system contains odd and perverse incentives, with the result that higher-priced drugs can receive more favorable health-plan coverage, channeling patients toward more expensive drugs.”<sup>21</sup> Uninsured patients face higher prices and insured patients pay higher coinsurance or pre-deductible out-of-pocket costs when list prices rise.<sup>22</sup>

### **PBMs use Their Market Dominance to Harm Community Pharmacies.**

As detailed below, PBMs engage in a long list of egregious, unfair and abusive practices that harm community pharmacies. Community pharmacies simply have no reasonable bargaining power with PBMs who extend contracts on a “take it or leave it” basis. You simply have to look no further than pharmacy direct and indirect remuneration fees. As noted above, the PBMs pulled in over \$9 billion dollars in these fees in 2022 alone. The foundation for these fees

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

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

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

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

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

are the inflated price points that were established by PBMs themselves. The fact that these fees skyrocketed from practically nothing to over \$9 billion demonstrates the PBMs market dominance. They reap additional fees beyond the \$9 billion by way of inflated coinsurance payments by seniors. There is simply no pro-consumer reason to inflate Medicare Part D beneficiaries' coinsurance costs at the point of sale. Never have seniors received a rebate from PBMs for overpayment of their coinsurance.

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

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

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

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

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

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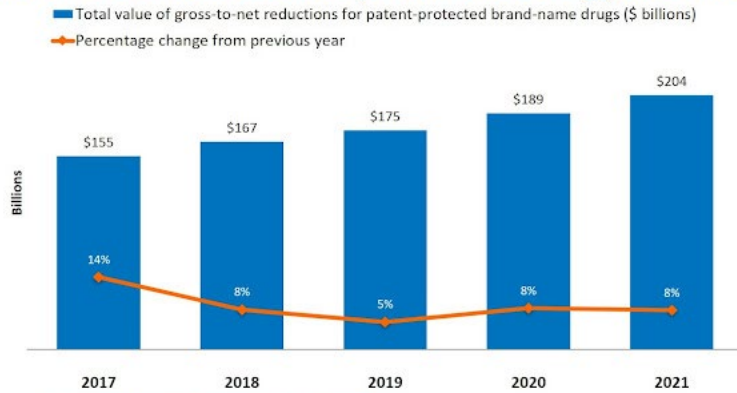
<sup>23</sup> Stacey Mitchell and Zach Freed, *How the FTC Protected the Market Power of Pharmacy Benefit Managers*, February 19, 2021, Pro Market, <https://www.promarket.org/2021/02/19/ftc-market-power-pharmacy-benefit-managers/>.

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



The PBMs did secure the market power that the antitrust laws are meant to protect against. Rather than use that market power to effectively lower drug prices they used it to massively increase rebates and rebate schemes. As the following two charts demonstrate, PBMs have taken a majority of any reductions in pharmaceutical drug costs in the form of rebates and fees over the past five years and they are pocketing an increasing portion in profits.

### Total Value of Pharmaceutical Manufacturers' Gross-to-Net Reductions for Patent-Protected, Brand-Name Drugs, 2017 to 2021

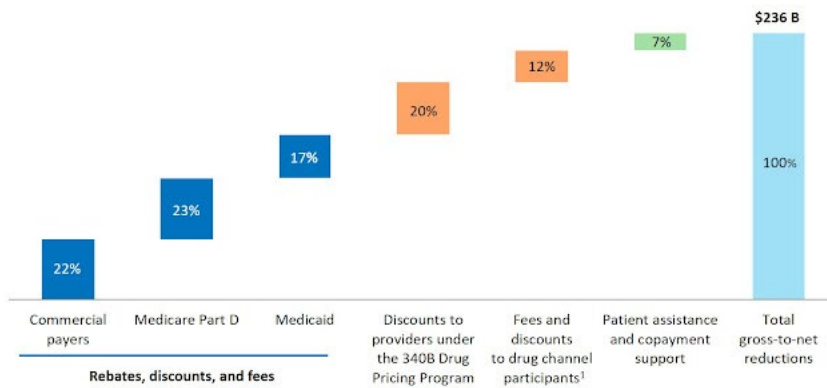


Source: *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Exhibit 168. Gross-to-net reductions include the total value of rebates, off-invoice discounts, copy assistance, price concessions, and such other reductions as distribution fees, product returns, the 340B Drug Pricing Program, and more. Includes value for patent-protected brand-name drugs that do not face generic competition. Figures have been updated and restated to reflect new disclosures and updates to underlying data sources.

Published on Drug Channels ([www.DrugChannels.net](http://www.DrugChannels.net)) on March 22, 2022.



### Total Value of Pharmaceutical Manufacturers' Gross-to-Net Reductions for Brand-Name Drugs, by Source, 2021



<sup>1</sup> Payments by manufacturers include: administrative fees to PBMs; fees and discounts to pharmacies and wholesalers; and all other off-invoice discounts and rebates.

Source: *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Exhibit 169. Percentage figures show each category's share of total gross-to-net reductions. Includes gross-to-net value for all brand-name drugs. See text for details. Total may not sum due to rounding.

Published on Drug Channels ([www.DrugChannels.net](http://www.DrugChannels.net)) on March 22, 2022.



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

Contrast the FTC decision to “hope” creating mega-middlemen would benefit consumers with the DOJ decision five years later to block the Aetna-Humana and Cigna-Anthem mergers.

The insurance companies presented many of the same arguments as ESI-Medco – there were lots of competitors, there was little risk of monopsony power because healthcare providers could protect themselves, and the mergers were needed to lower healthcare costs. But the DOJ saw that approving the mergers were a poor bargain for consumers and properly challenged them. Consumers and providers today benefit from competition between the four firms.<sup>25</sup>

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

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

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

The lack of enforcement has harmed pharmacies, and this has a direct impact on consumers. I know as a consumer advocate that consumers place tremendous value on their access to community pharmacies. Community pharmacists are consistently ranked as our most trusted health care professionals. And community pharmacies are often the most accessible form of health care services in underserved rural or inner-city markets. Community pharmacies

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<sup>25</sup> Unfortunately, the DOJ allowed CVS to acquire Aetna, Inc. and Cigna, Inc. to acquire Express Scripts, Inc. in 2019.

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

<sup>27</sup> See Commissioner Brill’s Letter to the ERISA Advisory Council, August 19, 2014, available at [https://www.ftc.gov/system/files/documents/public\\_statements/579031/140819erisaletter.pdf](https://www.ftc.gov/system/files/documents/public_statements/579031/140819erisaletter.pdf).

provide essential advice and health care monitoring especially for patients taking specialty drugs. Yet despite receiving hundreds of complaints from community pharmacies for the egregious and deceptive actions by PBMs, the FTC has never brought an enforcement action. Not even one.

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

Moreover, PBMs have engaged in a variety of practices that fundamentally can be defined as theft from the pharmacies, ultimately to the detriment of patients. For example, in 2018, the Ohio State Auditor audited its Medicaid Prescription Drug Program and found that the difference between what independent pharmacies are paid and what PBMs report back to the plans, commonly referred to as the “spread,” had been growing. However, this growth in savings failed to translate into lower costs for the state.<sup>30</sup> The Auditor further described that the spreads, which resulted in reimbursement cuts to local providers, actually turned into PBM profits.<sup>31</sup> The Ohio Pharmacist Association explained that “[b]eing that PBMs also own their own pharmacies, this essentially amounts to one pharmacy company reaching into the pockets of competitors, pulling out cash, and putting it right into their own. Regardless of the intent, this warped incentive has absolutely no place in a fair, competitive marketplace.”<sup>32</sup> Again, the FTC has failed to act despite numerous examples of this type of behavior.

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

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

<sup>29</sup> *Id.*

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

<sup>31</sup> *Id.*

<sup>32</sup> Ohio Pharmacist Association Press Release, *Ohio Auditor releases stunning Medicaid PBM audit report*, [https://www.ohiopharmacists.org/aws/OPA/pt/sd/news\\_article/184063/PARENT/layout\\_interior\\_details/false](https://www.ohiopharmacists.org/aws/OPA/pt/sd/news_article/184063/PARENT/layout_interior_details/false).

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

pharmacies.<sup>34</sup> Or the PBMs may engage in egregious auditing practices to harm rival pharmacies.

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

And, when state legislatures try to pass basic reform laws to protect independent pharmacies and consumers from predatory practices of PBMs, the PBMs, without fail, bring lawsuits to challenge such statutes based on ERISA (the Employee Retirement Income Security Act of 1974) pre-emption. Recently, such PBM reform passed by the State of Arkansas, which guaranteed that Arkansas pharmacists would be reimbursed by PBMs for the dispensing of drugs at least the amount of their wholesale cost, was challenged by the PCMA. This lawsuit culminated in a unanimous decision by the U.S. Supreme Court that such PBM reform legislation aimed at protecting independent pharmacies in the wake of PBM oppression is not pre-empted by ERISA. *See Rutledge v. PCMA*, 141 Sp. Ct. 474 (2020). While consumers hold out hope that such state protections could open a fair playing field for pharmacies, PBMs have

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

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

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

<sup>37</sup> *See*, Stacy Mitchell, *Small Pharmacies Beat Big Chains at Delivering Vaccines. Don’t Look So Shocked*, Washington Post, February 5, 2021, [https://www.washingtonpost.com/outlook/small-pharmacies-beat-big-chains-at-delivering-vaccines-dont-look-so-shocked/2021/02/05/6bb307ec-671b-11eb-886d-5264d4ceb46d\\_story.html](https://www.washingtonpost.com/outlook/small-pharmacies-beat-big-chains-at-delivering-vaccines-dont-look-so-shocked/2021/02/05/6bb307ec-671b-11eb-886d-5264d4ceb46d_story.html).

found ways to circumvent such laws resulting in more invasive pharmacy audits, network exclusions and increased pharmacy terminations.

### **Legislative Action to Prevent PBM Abuse**

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

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

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

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

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

### **Concluding Thoughts**

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

Fraud, deception, anticompetitive conduct, higher prices, and reduced choice harms payors, including the government and taxpayers, and, most importantly, patients, who rely on access to lifesaving and life-managing prescription drugs.

I look forward to answering any questions.