

May 25, 2022

The Honorable Lina Khan  
Chair  
Federal Trade Commission  
600 Pennsylvania Avenue, NW  
Washington, D.C. 20580

**Re: FTC-2022-0015, Comments in Support of 6(b) Study into Large Pharmaceutical Benefit Managers (PBM) Practices**

Dear Chairwoman Khan:

The undersigned unions, consumer groups and public interest organizations are concerned about the high cost of prescription drugs, escalating healthcare costs, and lack of meaningful patient choice.<sup>1</sup> These organizations work to rein in excessive drug prices and write to support the Federal Trade Commission's ("FTC") investigative authority under Section 6(b) of the FTC Act to issue orders to large vertically integrated pharmacy benefit managers ("PBMs") to study how the industry is harming patients. This study would give the FTC better insight into PBMs' drug pricing practices, anticompetitive behavior, rebate contracts with drug manufacturers, and onerous contracts with independent pharmacies.

An FTC study of PBM pricing practices, anticompetitive behavior and contractual relationships with drug manufacturers and pharmacies is long overdue. Patients are facing ever increasing prices of prescription drugs, which threatens patients' access to affordable medicines causing them to choose to stop or delay treatment because they cannot afford it.<sup>2</sup> Ensuring that patients can afford lifesaving and life-managing prescription drugs is critically important to public health because it will increase usage of necessary medications that help patients live longer and healthier lives.

The PBM industry has avoided antitrust scrutiny for far too long. As we describe more closely below, key points include the following:

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<sup>1</sup> The groups are American Federation of State, County and Municipal Employees, American Family Voices, Consumer Action, Consumer Federation of America, Doctors for America Public Interest Research Group, and Treatment Action Group. These comments are authored by David Balto, former Assistant Director for Policy in the FTC Bureau of Competition, and attorney advisor to Chairman Pitofsky, and Andre Barlow, a former Trial Attorney in the Healthcare Section of the Antitrust Division of the Justice Department.

<sup>2</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/>.

- The U.S. antitrust agencies have failed to protect consumers and patients as they have allowed PBMs to form a tight oligopoly and engage in conduct that has harmed patients' abilities to access affordable prescription drugs. The lack of antitrust enforcement 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>3</sup>
- Because lax antitrust enforcement allowed the three largest PBMs to become vertically integrated and form a tight oligopoly,<sup>4</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 profits have more than doubled and increased to \$28 billion annually.**<sup>5</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 to maximize rebates available from higher cost drugs.<sup>6</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>7</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>8</sup> from independent pharmacies who serve Medicare Part D participants.** Community pharmacies are crucial for patients in underserved low

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<sup>3</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>4</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>.

<sup>5</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>6</sup> Charlie Grant, *Hidden Profits in the Prescription Drug Supply Chain*, February 24, 2018, Wall Street Journal.

<sup>7</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>8</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>.

income and rural neighborhoods. These unfair and coercive tactics by PBMs result in inferior health care, less choice and higher costs.

For the PBM market to function properly for patients, employers, unions, and other stakeholders, we need greater antitrust and consumer protection enforcement. In these comments, we elaborate on the harms caused by the PBMs. And we conclude with some recommendations to the FTC on how to design its 6(b) study.

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

Ensuring that patients can afford lifesaving and life-managing prescription drugs is critically important to public health because better use of medicines has been shown to help patients live longer and healthier lives. Unreasonably high out-of-pocket costs for prescription drugs at the pharmacy counter threaten patient access to medicines, as some choose to stop or delay treatment because they cannot afford it.<sup>9</sup> Undoubtedly, rising prescription drug prices are a serious problem for patients.<sup>10</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>11</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>12</sup> Instead, consumers are facing ever-increasing cost sharing alongside growing profits from an industry that, at its core, serves as a middleman.

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>13</sup>

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<sup>9</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>10</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>11</sup> Fortune Rankings, <https://fortune.com/fortune500/2021/search/>.

<sup>12</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/3272225-ftcs-inquiry-of-pbms-wont-lower-prescription-drug-costs/>

<sup>13</sup> “*Protecting Consumers and Promoting Health Insurance Competition*,” Testimony of David Balto, Before House

**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>14</sup> **Indeed, the three largest PBMs have a higher gross margin than any other players involved in the drug supply chain,<sup>15</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>16</sup>** It is hard to see what value these middlemen have added to our healthcare system in return for their skyrocketing profits.<sup>17</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, there was simply no pro-consumer reason to deny consumers the necessary information to receive drugs at a lower cost.<sup>18</sup> 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

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Judiciary Committee, Subcommittee on Courts and Competition Policy, October 8, 2009, at <http://www.dcantitrustlaw.com/assets/content/documents/CAP/protecting%20consumers.pdf>.

<sup>14</sup> CEA White Paper, *supra* note 4. The Top Pharmacy Managers of 2021, the big get even bigger, Drug Channels, April 2022, <https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html>. I expect the witness from PCMA will note that there are dozens of PBMs. But these firms are not competitors at least from the perspective of competition law and economic policy. Under the antitrust laws, a “competitor” in a relevant market is a firm that can constrain prices. *FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1078 (D.D.C. 1997) (“The pricing evidence indicates a low cross-elasticity of demand between consumable office products sold by Staples or Office Depot and those same products sold by other sellers of office supplies. This same evidence indicates that non-superstore sellers of office supplies are not able to effectively constrain the superstores prices, because a significant number of superstore customers do not turn to a non-superstore alternative when faced with higher prices in the one firm markets.”) None of these much smaller PBMs have either the incentive or ability to constrain the anticompetitive conduct of the three dominant PBMs.

<sup>15</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>16</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>17</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>18</sup> On October 10, 2018, President Donald Trump signed into law the “Know the Lowest Price Act of 2018” and the “Patients’ Right to Know Drug Prices Act of 2018”.

manufacturer rebates and the percentage of the rebate passed on to health plans and patients are secret.”<sup>19</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.

**Third, PBMs create and exploit numerous conflicts of interest.** PBM rebate schemes create a clear conflict between the PBM, the payor, and patients. Payors and patients prefer the lowest cost drug. But to maximize profits, PBMs often prefer the drug with the highest list price, which results in rebate schemes that sometimes prevent lower cost generics and biosimilars from receiving preferred access on their formularies over higher priced branded drugs.<sup>20</sup> This conflict of interest not only harms competition, but it also harms patients. Insured patients suffer because they either have high deductible plans where they pay the higher list price until they meet the deductible or must pay co-insurance or copays based off the higher list prices, and uninsured patients must simply pay the higher list.<sup>21</sup>

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 providers, pharmacies, and insurers? The fox is guarding the henhouse, and the FTC 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. According to a recent Senate Finance Committee Report, “PBMs have an incentive for manufacturers to keep list prices high, since the rebates, discounts, and fees PBMs negotiate are based on a percentage of a drug’s list price -- and PBMs may retain at least a portion of what

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<sup>19</sup> CEA White Paper *supra* note 4.

<sup>20</sup> Avalere. (July 20, 2021). “Some Part D Beneficiaries May Pay Full Price for Certain Generic Drugs.” <https://avalere.com/insights/some-part-dbeneficiaries-may-pay-full-price-for-certain-generic-drugs>. In some instances, generic drugs and biosimilars are covered on brand-drug formulary tiers in Medicare Part D instead of a generic, which causes patients to pay for the full cost of their medicine and after learning of this, patients will then purchase more expensive branded drugs because their copays will be less.

<sup>21</sup> Testimony of Robin Feldman, U.S. Senate Committee on Commerce, Science, & Transportation, Sub Committee on Consumer Protection, Product Safety, & Data Protection, “Ensuring Fairness & Transparency in the Market for Prescription Drugs, May 5, 2022, <https://www.commerce.senate.gov/services/files/37DB7CA0-F3FA-4D99-84C0-9C2697F913E3>.

they negotiate.”<sup>22</sup> PBMs have gone so far as to require additional payments in the event of any reduction in manufacturer list prices.<sup>23</sup>

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

PBMs often base formulary access decisions on the amount of the rebates, which encourages drug manufacturers to offer higher rebates to secure that preferred status. 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 efficacious medication is available.

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>24</sup> On many occasions PBMs may require patients to go through cumbersome and health-threatening step therapy programs 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>25</sup> Uninsured patients face higher prices and insured patients pay higher coinsurance or pre-deductible out-of-pocket costs when list prices rise.<sup>26</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 (“DIR”) fees. DIR was a term advanced by the Centers for Medicare and Medicaid Services (“CMS”) used to ensure that Medicare Part D sponsors and PBMs accurately report rebates and other “price concessions” from manufacturers or other third parties which could not be reasonably determined at the point-of-sale. Because the government is the ultimate payor of prescription drugs under Medicare Part

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<sup>22</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/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf).

<sup>23</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>. Error! Hyperlink reference not valid.

<sup>24</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>25</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>26</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.

D prescription drug plans, it wants to know exactly how much Part D and Medicare Advantage drugs cost the plans so the government does not reimburse them too much. In practice, however, the PBMs have used this concept to claw back fees from pharmacies. The problem with that is that total costs of DIR fees on pharmacies may not be known until more than a year after a medication has been dispensed, as some PBM contracts create the *potential* for a partial or total refund of DIR fees. Ultimately, many prescriptions may be filled for less than even the acquisition cost of the drugs after accounting for DIR Fees. When a pharmacy is paid unreasonably low amounts and in extreme circumstances below the acquisition cost of a drug, it is a financially untenable position. No pharmacy would sign on to this agreement unless it had no choice. The foundation for these fees are the inflated price points and unattainable performance that were established by PBMs. The fact that these fees skyrocketed from practically nothing to over \$9 billion demonstrates the PBMs market dominance over pharmacies.

### **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.** Past leadership at 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. The FTC knew that PBMs “gagged” pharmacists from telling consumers of lower-priced alternatives, yet the FTC 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>27</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>28</sup> The Commission suggested that there were ten competitors in the market, yet by this point its list

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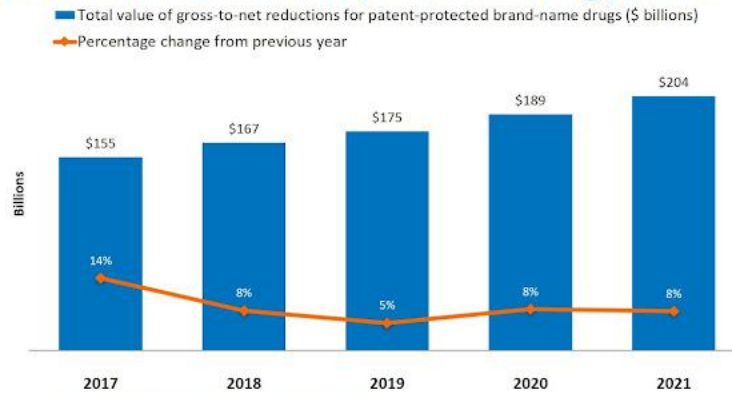
<sup>27</sup> Stacey Mitchell and Zach Freed, *How the FTC Protected the Market Power of Pharmacy Benefit Managers*, February 19, 2021, Pro Market, <https://www.promarket.org/2021/02/19/ftc-market-power-pharmacy-benefit-managers/>.

<sup>28</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).

looks more like a list of fossils -- a record of firms that have since been acquired or exited the market. The Commission also suggested the concerns of pharmacies were unfounded because they “negotiate” contracts with PBMs, but no one with any business sense would suggest those are anything more than take it or leave it arrangements. The merging parties suggested that the country needed the merger so the merged firm could force down drug prices. The FTC bought into this Faustian bargain, but the real result was skyrocketing prescription drug prices, rebates, and massive profit increases.

The PBMs secured 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 along with health plans have taken a majority of any reductions in pharmaceutical drug costs in the form of rebates and fees over the past five years.

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

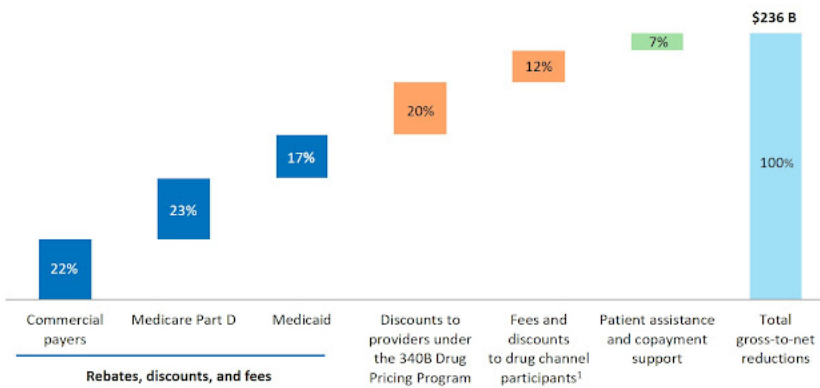


Source: *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Exhibit 168. Gross-to-net reductions include the total value of rebates, off-invoice discounts, copy assistance, price concessions, and such other reductions as distribution fees, product returns, the 340B Drug Pricing 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



1. 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*, Exhibits 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, the manufacturers have provided approximately \$141 billion in rebates and discounts to PBMs and plans, however, because of the lack of competition, transparency and the conflicts of interest in the system, it is unclear how these rebates benefit patients.

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 one example of how the FTC failed to address PBM misconduct. When states recognized the rampant consumer protection concerns and proposed legislation 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>29</sup> For example, in the past, the FTC 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>30</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 previous 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 and continue to call for change.

The lack of enforcement has harmed pharmacies, and this has a direct impact on patients. Patients place tremendous value on their access to community pharmacies. Community pharmacists are consistently ranked as our most trusted health care professionals. And community pharmacies are often the most accessible form of health care services in underserved rural or inner-city markets. Community pharmacies provide essential advice and health care monitoring especially for patients taking specialty drugs. Yet despite receiving hundreds of complaints from community pharmacies for the egregious and deceptive actions by PBMs, the FTC has never brought a single enforcement action.

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<sup>29</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>30</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).

Just one example of egregious non-enforcement involves the numerous allegations that large PBMs are engaging in predatory pricing activities using retroactive DIR and related fees. PBMs typically utilize DIR fees in networks which they represent as measuring a pharmacy's performance. 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>31</sup> In fact, PBM claw backs of pharmacy revenue have been increasing each year, causing significant financial strain on these small businesses.<sup>32</sup> The FTC, however, has not prevented PBMs from engaging in these predatory acts.

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>33</sup> The Auditor further described that the spreads, which resulted in reimbursement cuts to local providers, actually turned into PBM profits.<sup>34</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>35</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>36</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 pharmacies.<sup>37</sup> Or the PBMs may engage in egregious auditing practices to harm rival pharmacies.

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<sup>31</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>32</sup> *Id.*

<sup>33</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>34</sup> *Id.*

<sup>35</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>36</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/>.

<sup>37</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

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>38</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>39</sup> This is a significant problem for these vulnerable patients because many times their community pharmacists are the most accessible providers that they have.<sup>40</sup> 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.

### **Recommendations to the FTC in Designing its 6(b) Study**

In designing its 6(b) study, the FTC needs to take a broad approach, including qualitative evidence (as opposed to a narrow focus on market shares, for example), while keeping impact on patients front and center. We strongly encourage the following key steps:

**First, the FTC needs to determine the impact of PBM practices on actual consumers, not just payors.** Actual consumers are the patients. To this end, the study should account for patient cost, choice, convenience, and service. It is critical for the FTC to consider how PBM conduct harms patients.

**Second, the study should not simply rely on market shares to determine a PBM’s market power** as market power can be demonstrated by the PBM’s ability to engage in anticompetitive conduct such as imposing gag clauses; depressing pharmacist reimbursement rates to uncompetitive levels; and offering “take it or leave it” contracts with onerous terms that generate profits for themselves.

**Third, the study should evaluate how PBMs have the power to steer patients to affiliated services and simply exclude independent pharmacies from their networks altogether, limiting patient access and choice.** Indeed, after CVS and Caremark merged in

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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>38</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>39</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>40</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).

2007, there were allegations that CVS Caremark, the PBM arm, used its PBM business to steer patients to CVS retail pharmacies over independent pharmacies.<sup>41</sup> In some cases, CVS simply excludes independent pharmacies from its network if they do not comply with its rules and onerous contract provisions. Now that all three PBMs are integrated with their own health insurer and pharmacies, the FTC needs to examine whether they can steer patients to other affiliated services.

**Fourth, the FTC needs to study PBMs' rebate contracts with manufacturers.** PBMs have a great deal of control in the construction of formularies for payors and manufacturers pay rebates for preferred position on the formularies. Not only does this practice lead to higher prices, but some branded drugs, generics, and biosimilars are being excluded from formularies, which results in patients not being able to obtain more affordable and efficacious drugs that they need.

**Fifth, a broad study is necessary to capture allegations of widespread fraudulent and deceptive practices.** PBMs are reducing reimbursements to independent pharmacies so much that independent pharmacies dispense prescription drugs to consumers below the independent pharmacies' cost of the prescription drug. In fact, PBM clawbacks of pharmacy revenue have been increasing year after year causing significant financial strain on these small businesses.<sup>42</sup> The FTC should explore whether vertically integrated PBMs reimburse their own pharmacies at the same level as they reimburse independent pharmacies. Further, it should examine whether there are any other differences in how vertically integrated PBMs treat their own pharmacies versus independent pharmacies. For example, do they all follow the same standards and rules to be part of the pharmacy network?

**Sixth, the study should examine whether PBMs' use of firewalls protect independent pharmacies' patient data.** The study should evaluate allegations of how vertically integrated PBMs such as CVS obtain competitively sensitive information of non-CVS pharmacies including the identity of their customers and prescribers, the drugs prescribed, the cost of the drugs, the amount of the drugs acquired, the drug acquisition cost, and the reimbursement amount.<sup>43</sup> Non-CVS pharmacists believe that Caremark shares its patient data with CVS's pharmacy arm and uses the information to steer customers toward CVS's pharmacies. While CVS claims that it has firewalls that protect this information, no one is monitoring whether CVS is following its self-imposed firewall.

**Finally, as part of the study, the FTC needs to conduct a retrospective of the Express Scripts/Medco merger,** which the FTC cleared in 2012.<sup>44</sup> Since then, concentration levels in the PBM industry have increased. Moreover, the FTC's Express Scripts/Medco merger

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<sup>41</sup> Reed Abelson and Natasha Singer, *Pressure Grows to Unwind CVS Merger*, Henderson Times News, April 14, 2011, <https://amp.blueridgenow.com/amp/28267825007>.

<sup>42</sup> *Id.*

<sup>43</sup> Catherine Candisky, Darrel Rowland, and Marty Schladen, *Pharmacies, consumers question CVS*, Columbia Dispatch, April 15, 2018, <https://www.dispatch.com/story/news/politics/2018/04/15/pharmacies-consumers-question-cvs-actions/12688660007/>.

<sup>44</sup> Press Release, Fed. Trade Comm'n, *FTC Closes Eight-Month Investigation of Express Scripts, Inc.'s Proposed Acquisition of Pharmacy Benefits Manager Medco Health Solutions, Inc.*, Apr. 2, 2012, <https://www.ftc.gov/news-events/press-releases/2012/04/ftc-closes-eight-month-investigation-express-scripts-incs>.

review did not focus on the issue of the competitive effects of different PBM plan designs, or the competitive effects of state law requirements that mandate either transparent plan designs or the inclusion of proposals with transparent plan designs as a component of PBM bids to plan sponsors. The FTC needs to evaluate the competitive impact of different plans designs considering the significant changes in the PBM market and state laws.

### **Concluding Thoughts**

In conclusion, the FTC should vote to issue a 6(b) study of PBMs' anticompetitive practices and contracts with pharmaceutical manufacturers as well as affiliated and independent pharmacies. The vertically integrated PBMs play significant role in driving up prices and lessening competition among pharmacies and drug manufacturers. The FTC should issue orders to large PBMs to study the competitive impact of contractual provisions, reimbursement adjustments, and other practices affecting drug prices, including those that may disadvantage independent or specialty pharmacies. The study should be broad in scope to capture the different ways that large PBMs are harming competition and, most importantly, patients, who are the ultimate consumers.

Thank you for considering our comments. If you have any questions regarding these comments, please contact David Balto at (202) 577-5424.

Sincerely,

American Federation of State, County and Municipal Employees  
American Family Voices  
Consumer Action  
Consumer Federation of America  
Doctors for America  
Public Interest Research Group  
Treatment Action Group