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Subcommittee on the Administrative State, Regulatory Reform, and Antitrust

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#### Introduction

Chairman Massie and Ranking Member Correa, thank you for inviting me to participate in this discussion of the role of Pharmacy Benefit Managers or PBMs. The cost of prescription drugs and the burden of those costs for individuals and families that need to be treated with prescription drugs involves the entire prescription drug supply chain. My testimony reflects my views and not those of any organizations with which I am affiliated. I will focus on four themes. First, I will touch on the original promise of PBMs. I will then discuss the market structure and the incentives facing PBMs. My third theme will be directed at steering of demand for products and delivery mechanisms by PBMs. Fourth and finally, I will offer some observations on the forces affecting the fortunes of retail pharmacies.

In considering these four themes, I arrive at several conclusions. At a high level, they are as follows.

- Undertaking efforts to improve competition and efficiency in PBM markets is sensible, but success in doing so will only contribute modestly to making prescription drugs more affordable.
- Much of the unhappiness with PBMs traces back to the dynamics in health insurance markets that have become increasingly vertically integrated. This development likely has resulted in less competition and regulatory avoidance conduct.
- Rebates on brand-name prescription drugs are frustratingly opaque and are in some cases subject to the exertion of market power. But they also create incentives for PBMs to work hard to get payers lower prices. As a result, they are common features of contracts between PBMs and payers.
- Consumers are increasingly exposed to significant out-of-pocket costs for prescription drugs. Some of this stems from the gap between list prices and net prices but also from the choices by payers and insurers to be increasingly reliant on cost-sharing in the forms of deductibles and coinsurance.
- Retail pharmacies face an array of challenging economic conditions threatening the survival of some of those operating in rural America. Yet much of what threatens these enterprises is not tied to PBMs.

My perspective is that of a health economist who has long studied markets for prescription drugs. In that role, I have at once a strong appreciation of the benefits that competition can bring to health care markets generally and the prescription drug market specifically. I also see many instances of market failures in health care markets that can benefit from interventions by various levels (local, state, federal) and agencies

<sup>&</sup>lt;sup>1</sup> The views I express in this testimony are my own and do not necessarily reflect the views of other Brookings staff members, officers, or Trustees of the Institution.

(regulatory and judicial) of government. My remarks today highlight market forces and incentives. Today's pharmaceutical markets and supply chains are very much creatures of public policy and so many of my observations will reflect the consequences of prior legislation, regulations, and litigation.

## **Background and Brief History**

Origins and Economic Rationale for PBMs

The PBM industry is located at the center of the pharmaceutical supply and distribution chain. PBMs offer specialty management services of prescription drug benefits to health insurers and employers. Key functions of PBMs include claims processing, negotiation of drug prices, generic substitution programs, the development of drug utilization management processes, the creation and management of networks of pharmacies, and the reimbursement of pharmacies for the prescription drug products they dispense to insured individuals.

PBMs became prominent in response to concerns about prescription drug prices stemming from a combination of factors. They include increasingly generous insurance coverage for prescription drugs (covering 26% of drug spending in 1980, increasing to nearly 85% in 2022²), product differentiation in drugs treating the same conditions (think SSRI antidepressants in the 1990s), and market exclusivity due to patent protection or Food and Drug Administration (FDA) market exclusivity provisions. The confluence of these market features made individual product demand unresponsive (inelastic) to relative prices, resulting in little competitive pressure on prices. PBMs offered a solution through formulary design, product placement decisions, and other administrative mechanisms. Those mechanisms were used by PBMs to make demand for specific drug products more responsive to prices (price-elastic) that, in turn, reduce the market power of prescription drug manufacturers. Thus, the ability of PBMs to "move market share" among competing products based on price was viewed as key to saving payers' money. PBMs also negotiated with pharmaceutical manufacturers over products that were the sole products in their class. The savings they realized tended to be smaller than in the case of differentiated competition with multiple suppliers.<sup>3</sup>

PBMs also serve a few functions that affect access, cost, and safety of care with prescription drugs. Those services are designed to control utilization and limit the potential misuse of drugs; control the payments to retail outlets; ensure that lowest price generic drugs are used when they are available; provide consumers with convenient dispensing arrangements; and management of high-cost drugs that frequently involve special handling.<sup>4</sup>

How do PBMs Make Money: Revenue Sources

For many of the functions noted here, PBMs charge insurers and employers a service fee.

Another source of revenue is the retention of rebates. PBMs are typically responsible for negotiating price concessions from manufacturers in the form of manufacturer rebates that are typically percentage reductions off list prices. Rebates are paid retrospectively based on the ability of a PBM to "move market share" and deliver extra volume to manufacturers. PBMs and payer contracts commonly allow PBMs to retain a portion

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<sup>&</sup>lt;sup>2</sup> Center for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group. (2024). National Health Expenditure Accounts, Historical Table 16. <a href="https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/historical">https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/historical</a>

<sup>&</sup>lt;sup>3</sup> Anderson-Cook, A., Maeda, J., & Nelson L. (2019). *Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid: An In-Depth Analysis, Working Paper 2019-02*. Congressional Budget Office. <a href="https://www.cbo.gov/publication/55011">www.cbo.gov/publication/55011</a>

<sup>&</sup>lt;sup>4</sup> For some early background see: Sroka C.J. (2000, November 29). *Pharmacy Benefit Managers*. (CRS Report No. RL30754). <a href="https://www.everycrsreport.com/reports/RL30754.html">https://www.everycrsreport.com/reports/RL30754.html</a>

of rebates. One estimate put the share of rebates retained by PBMs at 9% in 2016.<sup>5</sup> Other estimates suggest a figure of 13% in 2021.<sup>6</sup> Contracts that permit the retention of rebates create an incentive for PBMs to bargain hard to lower prices. Details about rebates have been closely guarded by PBMs as competitive secrets. That makes the net prices quite opaque. Yet, the Centers for Medicare and Medicaid Services (CMS) Actuary and a 2009 commentary by the Federal Trade Commission (FTC) noted that revealing net prices resulting from rebate negotiations would likely result in increases in net prices.<sup>7</sup>

PBMs also earn revenues through so-called Direct and Indirect Renumeration (DIR) fees. The term DIR in the context of PBM interactions with pharmacies refers to payment reconciliations and various other forms of payment (a much broader definition than that used in Part D of Medicare). . Some of the additional fees include "pay for play" network participation fees because network participation is associated with increased customer volume to pharmacies resulting in greater sales of both drugs and other consumer products. Pharmacies view the DIR fees as a claw back. This type of fee arrangement is sometimes known as "drip pricing" in that it occurs after an initial set of fees are established (drip pricing is commonly found in airline price structures). Because of the after-the-fact reconciliations and fee adjustments, pharmacies may be paid less than the insurer or employer pays the PBM. That "spread" creates a revenue source for the PBM that is referred to as "spread pricing." The mix of PBM revenues are frequent features of negotiated contracts between PBMs and their clients (insurers and employers).

A common result is that payers will have reduced fees in lieu of allowances for PBMs to retain rebates and engage in spread pricings.<sup>8</sup> Finally, the larger PBMs all own mail order and specialty pharmacies that are reputed to be the largest sources of PBM profits.

#### PBM Spending Impacts

Early in their development PBMs' use of formularies to negotiate lower payer prices through rebates was shown to realize significant savings for payers relative to a benefit managed by the insurer. One Government Accountability Office (GAO) study of the use of PBMs in the Federal Employees' Health Benefit Program showed savings for 14 brand-name drugs dispensed by retail pharmacies. The results showed savings of roughly 19% for the plans, while beneficiaries using those products experienced reduced out-of-pocket costs. More recently, in a series of studies, Feng showed savings associated with PBMs. In

https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored

<sup>&</sup>lt;sup>5</sup> Pew Charitable Trusts. (2019). *The Prescription Drug Landscape Explored*.

<sup>&</sup>lt;sup>6</sup> Drug Channels. (2022, August 9). *Texas Shows Us Where PBMs' Rebates Go*. https://www.drugchannels.net/2022/08/texas-shows-us-where-pbms-rebates-go.html

<sup>&</sup>lt;sup>7</sup> Centers for Medicare & Medicaid Services, Office of the Actuary. (2018, August 30). *Proposed Safe Harbor Regulation Impact*. www.regulations.gov/document?D=HHSIG-2019-0001-0004. A letter from the FTC to the New York State Legislature in 2009 makes a similar point about revelation of negotiated rebates, see: FTC NY Comment letter PBM leg.pdf. It is important to note that the FTC recently issued an opinion distancing itself from prior analyses and position with respect to PBMs.

<sup>&</sup>lt;sup>8</sup> National Association of Insurance Commissioners (NAIC). (2023, April 16). *Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation*. (NAIC White Paper Draft). <a href="https://content.naic.org/sites/default/files/inline-files/AphA%20Comments.pdf">https://content.naic.org/sites/default/files/inline-files/AphA%20Comments.pdf</a>

<sup>&</sup>lt;sup>9</sup> For an example of an early study of savings see: Motheral, B., & Fairman K.A. (2001). Effect of a three-tier prescription copay on pharmaceutical and other medical utilization. *Med Care*, 39(12):1293-304. <a href="https://doi.org/10.1097/00005650-200112000-00005">https://doi.org/10.1097/00005650-200112000-00005</a>

<sup>&</sup>lt;sup>10</sup> Available at: United States General Accounting Office (GAO). (2003, January). Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies. <a href="https://www.gao.gov/assets/gao-03-196.pdf">https://www.gao.gov/assets/gao-03-196.pdf</a>

a case study of statin drugs during the period 1996 to 2013, Feng and Maini reported savings of 28%.<sup>11</sup> In a more general analysis, Feng reported spending reductions associated with PBMs on the order of 15%.<sup>12</sup> Recent analyses also show some savings in (roughly 10%) out-of-pocket costs from preferred pharmacy networks.<sup>13</sup>

#### The PBM and its Market Context

The market structure within which PBMs operate has evolved over the past two decades. So too has the composition of brand-name prescription drug products on the market. The structure of cost-sharing for patients has changed along with changes in the insurance and PBM market segments. I discuss each of these below and how they can affect the conduct of PBMs in the marketplace. It appears that the changes in the market have been so significant that the FTC recently issued a statement distancing itself from earlier positions on the PBM industry. <sup>14</sup> In that statement they specifically cited changes in market structure and price determination as underpinning the Commission's altered position.

Market structure: Concentration and Vertical Integration

The main parties involved in the prescription drug market are prescription drug manufacturers, insurers, pharmacies (retail, mail order, and specialty), PBMs, and consumers. Historically each entity was owned and operated independently and there were varying levels of competition at each level, in some instances that took the form of price competition. Much has changed over the past several decades. In 2003, the top four PBMs accounted for about 68% of sales. <sup>15</sup> In 2022, the largest four PBMs accounted for 87% of sales. <sup>16</sup> The increased concentration over time is a product of both scale economies and horizontal mergers. <sup>17</sup> This structure indicates likely market power, giving large PBMs the upper hand in negotiations with some payers and pharmacies resulting in supra-competitive compensation and the ability to extract excess profits. It is also important to note that the entire prescription drug supply chain has become more concentrated. <sup>18</sup>

<sup>15</sup> Note that the entire supply chain has grown more concentrated include brand-name manufacturers, generic manufacturers, retail pharmacies, and wholesalers.

<sup>&</sup>lt;sup>11</sup> Feng J., & Maini L. (2024, March) Demand Inertia and the Hidden Impact of Pharmacy Benefit Managers. *Management Science*. <a href="https://doi.org/10.1287/mnsc.2021.03331">https://doi.org/10.1287/mnsc.2021.03331</a>

<sup>&</sup>lt;sup>12</sup> Feng, J. (2021). Pricing Intermediaries in Prescription Drug Markets: To Leverage or Replace? (Working Paper, University of Utah).

<sup>&</sup>lt;sup>13</sup> Starc, A., & Swanson A. (2021). Preferred Pharmacy Networks and Drug Costs. *American Economic Journal*, 13(3): 406-446. <a href="https://www.aeaweb.org/articles?id=10.1257/pol.20180489">https://www.aeaweb.org/articles?id=10.1257/pol.20180489</a>

<sup>&</sup>lt;sup>14</sup> Federal Trade Commission (FTC). (n.d.) Federal Trade Commission Statement Concerning Reliance on Prior PBM-Related Advocacy Statements and Reports that No Longer Reflect Current Market Realities. https://www.ftc.gov/system/files/ftc\_gov/pdf/CLEANPBMStatement7182023%28OPPFinalRevisionsnoon%29.pdf

<sup>&</sup>lt;sup>16</sup> Guardo J.R. (2023). Competition in Commercial PBM Markets and Vertical Integration of Health Insurers with PBMs: 2023 Update. American Medical Association. <a href="https://www.ama-assn.org/system/files/prp-pbm-shares-hhi.pdf">https://www.ama-assn.org/system/files/prp-pbm-shares-hhi.pdf</a>; Drug Channels. (2024, April 9). The Top Pharmacy Benefit Mangers of 2023: Market Share and Trends for the Biggest Companies—And What's Ahead. <a href="https://www.drugchannels.net/2024/04/the-top-pharmacy-benefit-managers-of.html">https://www.drugchannels.net/2024/04/the-top-pharmacy-benefit-managers-of.html</a>

<sup>&</sup>lt;sup>17</sup> Among the most notable horizontal mergers were Medco's acquisition of PAID (1985), Caremark's acquisition of Advance PCS (2004), and Express Scripts' acquisition of Medco (2012).

<sup>&</sup>lt;sup>18</sup> The analysis of market power in the PBM context has varied. Traditionally market concentration was a key indicator of market power. An alternative view was advanced by the FTC in its analysis of the Express Scripts-Medco merger (see Shelanski H., et al. (2012, December). *Economics at the FTC: Drug and PBM Mergers and Drip Pricing, Review of Industrial Organization*. Federal Trade Commission.

https://www.ftc.gov/sites/default/files/documents/reports/economics-ftc-drug-and-pbm-mergers-and-drip-pricing/shelanskietal\_rio2012.pdf. That view focused on the degree of competitive discipline that would exist from remaining competitors. More recently the FTC and others have again focused on concentration indicators.

The market has also moved rapidly towards vertical integration. Each of the top four PBMs is integrated with a major health insurer. These PBMs all own mail order and specialty pharmacies. Specifically, CVS Health owns Aetna, Caremark, and CVS retail pharmacies. Cigna owns Express Scripts. United Health Group owns United and Optum Rx. Humana owns Humana Pharmacy Solutions. This is new, as data from 2018 showed that vertically integrated PBMs accounted for about 50% of the market. Recent estimates indicate that about 70% of insured individuals obtain coverage from a vertically integrated firm that combines an insurer and a PBM. Lastly, several of these organizations have created so-called rebate aggregators, allegedly to negotiate and manage rebates.

<u>Vertical integration incentives</u>: There are a variety of incentives that drive the trend towards vertical integration of parts of the prescription drug supply chain. Some potentially lead to improved efficiency in supply chain management, while others have possible anti-competitive impacts or serve to avoid regulatory provisions enacted by the government.

Among the impulses for integration that may improve efficiency and health outcomes is the promise of improved alignment of medical and pharmaceutical care delivery thereby realizing synergies beneficial to the health of insured individuals. Another benefit is reduced costs associated with "double marginalization" that results from a multi-layered supply chain. That is the traditional efficiency gain associated with vertical integration that is also present in this case. Relatedly, it has been argued that redundancies in functions would be reduced with vertical integration.<sup>20</sup>

Vertical integration along the supply chain also offers opportunities to engage in practices that serve to avoid the impact of regulatory rules. One example is the Medical Loss Ratio (MLR) regulation that aims to limit profits in insurance. In the Medicare Advantage program, the MLR requires Medicare Advantage plans to spend 85% of their premium dollar on services and quality improvement efforts. However, in a vertically integrated supply chain, an insurer and a PBM that are owned by the same parent entity can disguise profits as costs to avoid the MLR requirements. That is, the payments to the PBM from the related insurer are counted as a cost to the insurer but they serve to generate profits for the parent company. So, by charging the insurer higher fees, the PBM can move profits to the parent company out of the reach of the MLR regulation.<sup>21</sup>

Another concern related to vertical integration involves potential anti-competitive effects. A vertically integrated firm that links an insurer and a PBM can potentially raise a rival's costs by increasing fees charged or reducing rebates to rival nonintegrated insurers.<sup>22</sup> Such anti-competitive effects might be constrained in markets where there is a great deal of competition among PBMs. However, in a highly concentrated PBM market, the opportunities to find an alternative PBM are more limited. An extreme version of that phenomenon is the opportunity to impede competitors from using key goods and services thereby foreclosing markets. This might occur with access to pharmacy services (retail or specialty).

<sup>20</sup> Orzag P., & Rekhi R. (2020, April 15). The Economic Case for Vertical Integration in Health Care. *NEJM Catalyst*, 1(3). <a href="https://doi.org/10.1056/CAT.20.0119">https://doi.org/10.1056/CAT.20.0119</a>

plans/; and Frank R.G., & Milhaupt, C. (2023). Medicare Advantage spending, medical loss rations, and related businesses. An initial investigation. *Brookings Institution*. <a href="https://www.brookings.edu/articles/medicare-advantage-spending-medical-loss-ratios-and-related-businesses-an-initial-investigation/">https://www.brookings.edu/articles/medicare-advantage-spending-medical-loss-ratios-and-related-businesses-an-initial-investigation/</a>.

<sup>&</sup>lt;sup>19</sup> Op. cit. see Guardo Note 15.

<sup>&</sup>lt;sup>21</sup> For more complete discussion of this issue see: Frank, R.G., & Milhaupt, C. (2022). Profits, medical loss rations, and the ownership structure of Medicare Advantage plans. *Brookings Institution*. https://www.brookings.edu/articles/profits-medical-loss-ratios-and-the-ownership-structure-of-medicare-advantage-

<sup>&</sup>lt;sup>22</sup> U.S. Department of Health and Human Services, Office of Inspector General. (n.d.) *Audit of Vertically Integrated Medicare Part D Sponsors*. <a href="https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000849.asp">https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000849.asp</a>

Insurers also may choose to sell their PBM and health insurance services to employers as a package or bundle that would impede competition from insurers without a PBM.

Finally, vertical integration may facilitate health insurer pursuit of existing incentives to enroll healthier people in their plans, because people who use high-cost drugs disproportionately also use other medical care. Thus, PBMs can design formularies and utilization management protocols in ways that would discourage sicker people from enrolling in the vertically integrated plan. This is a long-standing source of market failure in health insurance markets.

The empirical evidence on the potential impacts of vertical integration of PBMs, insurers, and pharmacies are very limited. Two of the FTC Commissioners made such an observation in response to the recently released FTC Interim Report, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs*.<sup>23</sup> MedPAC analyzed rebates in the context of the Medicare Part D drug benefit and found that vertically integrated plans obtained larger rebates than nonintegrated PBMs.<sup>24</sup> Yet at the same time MedPAC observed that for vertically integrated entities that included insurers, PBMs, and (specialty) pharmacies for "a limited number of drugs" (six categories), net prices were more likely to be higher than those at non-integrated pharmacies.<sup>25</sup>

Earlier I noted the potential for improved incentives to coordinate care in the interest of whole person health may lead integrated plans to offer more efficient health care. <sup>26</sup> In 2012, the Congressional Budget Office (CBO) outlined the synergy benefits of managing the prescription drugs and medical care together. <sup>27</sup> There is little direct evidence on the impact of synergies from PBM-insurer integration. One recent study of vertical integration between PBMs and insurers in the context of Medicare Part D standing Prescription Drug Plans or PDPs found an association between elevated premiums and insurers that owned PBMs. <sup>28</sup> That analysis does not allow for key synergies that have been proposed stemming from integrated management of both the medical and pharmaceutical benefits. In addition, the "natural experiment" studied is a horizontal change in market structure (a merger of PBMs). That means that one cannot easily make inferences about vertical integration impacts. As a result, the authors note that the estimated relationship may not offer causal or generalizable results on vertical integration. Finally, even though there is some support to suggest that integrated plans design coverage to take advantage of synergies, there is

<sup>&</sup>lt;sup>23</sup> The report can be accessed at: Federal Trade Commission (FTC). (2024, July). *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*.

https://www.ftc.gov/system/files/ftc\_gov/pdf/pharmacy-benefit-managers-staff-report.pdf. Commissioner Holyoak dissented due to her concerns about evidence. Her statement is available at: Holyoak, M. (2024, July 9). *Dissenting Statement of Commissioner Melissa Holyoak*. Federal Trade Commission.

https://www.ftc.gov/system/files/ftc\_gov/pdf/Holyoak-Statement-Pharmacy-Benefit-Managers-Report.pdf. In addition, Commissioner Ferguson in a concurring statement raised concerns about available evidence. His statement is available at: Ferguson, A. N. (2024, July 9). Concurring Statement of Commissioner Andrew N. Ferguson. Federal Trade Commission. <a href="https://www.ftc.gov/system/files/ftc\_gov/pdf/Ferguson-Statement-Pharmacy-Benefit-Managers-Report.pdf">https://www.ftc.gov/system/files/ftc\_gov/pdf/Ferguson-Statement-Pharmacy-Benefit-Managers-Report.pdf</a>

<sup>&</sup>lt;sup>24</sup> Medicare Payment Advisory Commission (MedPAC). (2023, June). Chapter 2: Assessing postsale rebates for prescription drugs in Medicare Part D. In *Report to the Congress: Medicare and the health care delivery system*. <a href="https://www.medpac.gov/wp-content/uploads/2023/06/Jun23\_MedPAC\_Report\_To\_Congress\_SEC.pdf">https://www.medpac.gov/wp-content/uploads/2023/06/Jun23\_MedPAC\_Report\_To\_Congress\_SEC.pdf</a>

<sup>&</sup>lt;sup>26</sup> Lavetti, K., & Simon, K. (2018). Strategic Formulary Design in Medicare Part D Plans. *American Economic Journal*, Economic policy, 10(3), 154–192. <a href="https://doi.org/10.1257/pol.20160248">https://doi.org/10.1257/pol.20160248</a>

<sup>&</sup>lt;sup>27</sup> Congressional Budget Office. (2012, November 29) Offsetting effects of prescription drug use on Medicare's spending for medical services. https://www.cbo.gov/publication/43741

spending for medical services. <a href="https://www.cbo.gov/publication/43741">https://www.cbo.gov/publication/43741</a>
<sup>28</sup> Gray, C., Alpert, A., & Sood, N. (2023). Disadvantaging rivals: Vertical Integration in the pharmaceutical market. SSRN. <a href="https://papers.ssrn.com/sol3/papers.cfm?abstract">https://papers.ssrn.com/sol3/papers.cfm?abstract</a> id=4533250

accompanying evidence to suggest that they also design their benefits and management structure to discourage enrollment by high-cost enrollees.<sup>29</sup>

While the systematic evidence is quite limited there are some observations that can be made about vertical integration and PBMs. The pass through of rebates, spreads, and discounts to insurers has been attenuated by the fact that such a large segment of the PBM market is now integrated with health insurers. Vertical integration has created new opportunities for anticompetitive conduct in the form of raising rival costs and local market foreclosures. Finally, the vertical structure serves to facilitate "gaming" of regulations such as the MLR.

### Other Changes in the Market Environment

The composition of brand-name products offered has been shifting rapidly. Biological products have been accounting for a growing share of prescription drug spending in the U.S. In 2023, biological drugs accounted for about 51% of prescription drug spending and specialty drugs made up 54% of spending.<sup>30</sup> The corresponding shares for 2018 were 42% and 49% respectively. These drugs typically are distributed and managed quite differently than small molecule, oral solid products. This in part explains the growing role of specialty pharmacies.

The benefit design in insurance coverage of prescription drugs has also evolved in recent years. IQVIA reports that in 2013 54% of cost-sharing was in the form of co-payments that are not based on list prices. In contrast, by 2017 that figure had declined to 44% indicating greater exposure to list prices. The trend in exposing patients to greater cost-sharing appears to have continued past 2017, where co-payments as a share of cost-sharing fell to roughly 40% in 2021. Therefore health insurance designs for prescription drugs have been changed in ways that leave consumers more exposed to list prices. The net effect of such changes on consumer out-of-pocket costs depend on the health plan choices of employers and consumers. There is strong evidence suggesting that consumers commonly have difficulties in making choices among complex insurance designs that may result in failures to make plan choices that avoid overly high levels of cost-sharing. There is some evidence that supports an association between higher rebates and greater out-of-pocket costs.

#### **Steering**

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<sup>&</sup>lt;sup>29</sup> See Lavetti and Simon Note 25.

<sup>&</sup>lt;sup>30</sup> IQVIA. (2024, May). *The Use of Medicines in the U.S. 2024: Usage and Spending Trends, and Outlook to 2028*. <a href="https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-use-of-medicines-in-the-us-2024/the-use-of-medicines-in-the-us-2024-usage-and-spending-trends-and-outlook-to-2028.pdf">https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-use-of-medicines-in-the-us-2024/the-use-of-medicines-in-the-us-2024-usage-and-spending-trends-and-outlook-to-2028.pdf</a>.

<sup>&</sup>lt;sup>31</sup> Devane, K., Harris, K., & Kelly, K. (2018, May 18). *Patient affordability part one: The Implications of Changing Benefit Designs and High-Cost Sharing*. IQVIA. <a href="https://www.iqvia.com/locations/united-states/library/case-studies/patient-affordability-part-one">https://www.iqvia.com/locations/united-states/library/case-studies/patient-affordability-part-one</a>

<sup>&</sup>lt;sup>32</sup> PhRMA Org. (2022, November 14) *Deductibles and coinsurance drive high out-of-pocket costs for commercially insured patients taking Brand Medicines*. Pg. 5. <a href="https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/G-I/IQVIA-Report-High-OOP-for-Brand-Medicines\_November-2022\_v2.pdf#page=5">https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PhRMA-Refresh/Report-PDFs/G-I/IQVIA-Report-High-OOP-for-Brand-Medicines\_November-2022\_v2.pdf#page=5">https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhR

<sup>&</sup>lt;sup>34</sup> Abaluck, J., & Gruber, J. (2011). Choice inconsistencies among the elderly: Evidence from plan choice in the medicare part D program. *American Economic Review*, *101*(4), 1180–1210. <a href="https://doi.org/10.1257/aer.101.4.1180">https://doi.org/10.1257/aer.101.4.1180</a> Yeung, K., Dusetzina, S. B., & Basu, A. (2021). Association of branded prescription drug rebate size and patient out-of-pocket costs in a nationally representative sample, 2007-2018. *JAMA Network Open*, 4(6). <a href="https://doi.org/10.1001/jamanetworkopen.2021.13393">https://doi.org/10.1001/jamanetworkopen.2021.13393</a>

Earlier we noted how vertical integration may facilitate anti-competitive actions or strategies to avoid regulatory constraints. Here we address the incentives related to permitting PBMs to retain parts of rebates and price spreads. It is frequently claimed that paying PBMs through rebates and price spread retention creates incentives for PBMs to steer patients to higher list price drugs.

In assessing the incentives and claims about PBM conduct, several points are important. In the discussion of vertical integration, we noted that for 70% of the market, the insurer and the PBM are a single entity. The list-net price gap can lead patients to pay higher prices than the insurer or PBM does when the benefit design consists of deductibles and coinsurance.<sup>36</sup> A GAO study of Part D prices found that PBM pursuit of high rebates frequently leads to patients paying elevated out-of-pocket prices that are higher than the net price paid by the PBM and higher than the lowest out-of-pocket cost drug in a class.<sup>37</sup> In the extreme case, out-of-pocket prices can exceed to cost of goods sold to the pharmacy. Data presented earlier suggests that the changes in health insurance benefit designs for prescription drugs have contributed to many harms experienced by consumers.

Next, I examine the proposition that insurers and employers pay more because PBM fees are in part paid for through the retention of rebates and price spreads. To substantiate those claims, one needs to compare net prices for the high list price drugs and those with lower list prices. The evidence is limited but data from Medicare Part D suggests that Medicare benefits from lower net prices for highly rebated drugs relative to competitor products with lower list prices. Making similar comparisons in the larger context of commercial coverage is difficult because net prices are closely guarded secrets by PBMs.

Since the retention of rebates and price spreads is frequently part of a negotiated arrangement between insurers and other payers with PBMs, reducing the ability to retain rebates and price spreads would likely result in increased administrative fees. That might result in some attenuation in list price growth but would also reduce the incentive for PBMs to drive hard bargains. So, there is a trade-off between regulating how fees are set and the potential to limit PBM profits against incentives for cost control and supply of "extra services."

Spread pricing is mostly focused on generic drugs. This is because pharmacies have the most bargaining power with generic manufacturers in competitive markets. Generic drugs in this sense are commodities. This is what enables spread pricing. This applies to all pharmacies. Retail, mail order, and specialty pharmacies are all in positions to negotiate low prices with manufacturers and then charge insurers a price above the negotiated cost of goods sold. Vertical integration often makes the PBM the conduit of the price paid to the pharmacy. Yet non-integrated pharmacies, especially chain retail pharmacies, also have market power in price negotiations with generic drug manufacturers.

Steering and the Economic Status of Retail Pharmacies

Steering has also been associated with the disadvantaging of independent pharmacies. Such steering has been connected by some to the decline in the availability of independent pharmacies in rural America and the greater potential for pharmacy deserts. Independent pharmacies face a variety of economic forces that exert pressure on their revenues and ability to survive in the marketplace. These include competition from mail order pharmacies, smaller scale, less robust purchasing arrangements than chain pharmacies, and

<sup>&</sup>lt;sup>36</sup> As discussed earlier this requires that coinsurance and deductibles are fixed, that is consumers do not switch to avoid what they view as excessive cost-sharing.

<sup>&</sup>lt;sup>37</sup> U.S GAO. (2023, September 5) *Medicare part D: CMS should monitor effects of rebates on plan formularies and beneficiary spending*. https://www.gao.gov/assets/gao-23-105270.pdf.

pricing pressures. Steering directed by PBMs clearly affects the degree of competition from mail order pharmacies and the level of dispensing fees. The use of "drip pricing" in the form of so-called DIR adjustments post-transaction has been cited by the FTC and others as creating special difficulties for independent retail pharmacies.<sup>38</sup>

Despite the claims, the available evidence on the role of PBMs in affecting the fortunes of independent retail pharmacies is not clear. Specifically, independent pharmacy supply has declined in rural areas relative to chain pharmacies but has increased more than chains in metropolitan areas.<sup>39</sup> PBMs manage pharmacy benefits in both types of markets. Thus, the attribution of such changes in the fortunes of independent pharmacies is hard to establish. An analysis of the state of rural pharmacies in the U.S. reports that about 50% of rural pharmacies are independently owned and operated. That research shows that rural independent pharmacies declined 16.1% from 2003 to 2021; while rural chain pharmacies grew 4.6%. During the same time, independent pharmacies grew 28% in metropolitan areas compared to 10.5% for chain pharmacies. Data on gross margins for prescriptions dispensed by independent pharmacies shows that they have remained steady between 20.8% and 21.1% from 2016 through 2020.<sup>40</sup>

In considering the role of PBMs and other economic forces in affecting the supply of independent pharmacies one must acknowledge that there are some important scale differences between various types of retail pharmacies that are likely to affect the efficiency of pharmacy services. The average chain drug store dispenses about 138,000 prescriptions per year. Grocery store pharmacies dispense an average of about 91,000 prescriptions per year, while independent pharmacies dispense about 48,000 on average. <sup>41</sup> These differences likely create cost advantages for the larger chain stores. Finally, the purchasing power of chains has been estimated to result in margin advantages of 2% to 6%. This data makes sorting out the net impact of PBM policies on the financial status of independent pharmacies challenging.

Beyond the uncertain role of PBMs in the economic status of retail pharmacies is the fact that retail pharmacies like the rest of the supply chain have become more concentrated and as a result often have market power. Keeping the exertion of that market power in check serves to benefit payers and consumers alike.<sup>42</sup>

## A Comment on Profitability of PBMs and Prescription Drug Affordability

The profits of PBMs (and in turn their parent companies) have been pointed to as being an important part of the prescription drug affordability problem. Estimates of operating margins of the largest PBMs have in recent years ranged from 4% to 6%. Those estimates include the PBM services, specialty pharmacy and

 $\underline{https://www.ftc.gov/system/files/ftc\_gov/pdf/pharmacy-benefit-managers-staff-report.pdf}$ 

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<sup>&</sup>lt;sup>38</sup> See FTC report: Federal Trade Commission. (2024, July 9). *Pharmacy benefit managers: The powerful middlemen inflating drug costs and squeezing Main Street pharmacies*.

<sup>&</sup>lt;sup>39</sup> Lazaro, E., Ullrich, F., & Mueller, K. J. (2022, August). Update on Rural Independently Owned Pharmacy Closures in the United States, 2003-2021. *Rural Health Research & Policy Center, University of Iowa*. <a href="https://iro.uiowa.edu/esploro/outputs/report/Update-on-Rural-Independently-Owned-Pharmacy/9984388646502771">https://iro.uiowa.edu/esploro/outputs/report/Update-on-Rural-Independently-Owned-Pharmacy/9984388646502771</a>

<sup>&</sup>lt;sup>40</sup> Fein, A. J. (2022, February 15). Five things to know about the state of Independent Pharmacy Economics. Drug Channels. <a href="https://www.drugchannels.net/2022/02/five-things-to-know-about-state-of.html">https://www.drugchannels.net/2022/02/five-things-to-know-about-state-of.html</a>

<sup>&</sup>lt;sup>41</sup> Ladsariya, A., McLeod, A., Sahni, N., Tevelow, B., & Noh, G. (2023, March 17). Meeting changing consumer needs: The US retail pharmacy of the future. *McKinsey* &

 $<sup>\</sup>frac{Company.\ https://www.mckinsey.com/\sim/media/mckinsey/industries/healthcare\%20systems\%20and\%20services/our\%20insights/meeting\%20changing\%20consumer\%20needs\%20the\%20us\%20retail\%20pharmacy\%20of\%20the\%20future/meeting-changing-consumer-needs-the-us-retail-pharmacy-of-the-future-f.pdf$ 

<sup>&</sup>lt;sup>42</sup> See Starc and Swanson Note 12

mail order earnings.<sup>43</sup> The PBM trade association or Pharmaceutical Care Management Association (PCMA) commissioned a study by Visante that included a larger number of PBMs and excluded mail order and specialty pharmacy earnings. They reported accounting for 6% of the drug dollar and 2% due to profit.<sup>44</sup> Since much of what is counted as revenues for the PBM are pass throughs of payments made by insurers and employers, PBM profits only make up a small portion of the nation's prescription drug spending. As my colleagues and I have previously stated, PBMs may nevertheless be exercising market power and regulatory avoidance strategies to gain excess returns and reduce market efficiency.

#### Take Aways

Addressing the ills associated with PBMs noted here are well worth addressing, but it is important to recognize that successfully remedying those ills would have only a modest impact on the affordability of prescription drugs in the U.S. There are however meaningful benefits to individuals, public programs, and other payers from improving the competitive environment within which PBMs operate. In considering policy actions it is important to recognize that many of the troubling features of how the prescription drug supply chain is managed today are related to new and existing market dynamics in health insurance. Key among the changes is vertical integration alongside increased PBM concentration. The avoidance of regulation related to margins in health insurance like the MLR coupled with the ownership of related businesses by insurers and their parent companies, potential distortions in formulary and drug benefit designs motivated by insurer selection incentives, and the changing shape of cost-sharing arrangements, all have their origins in markets for health insurance.

A great deal of discontent has focused on rebates. Yet rebates are common features of negotiated contracts. And while it is important to be attentive to the exertion of market power in those negotiations, the incentives to drive hard bargains on behalf of payers created by rebates should be recognized. The lack of transparency associated with rebates is frustrating, yet private negotiations can also yield benefits to premium payers, taxpayers, and patients. Finding the right level and type of transparency to enhance the bargaining power of smaller purchasers where complex PBM contracts serve to disadvantage them while retaining the ability to get the best deals would improve matters but is very challenging to implement. One focal point might be the composition of products and utilization patterns offered under competing PBM contracts.<sup>45</sup>

The harms to patients are directly related to the cost-sharing arrangements in the insurance design. Self-insured employer health plans and health insurers each have a great deal of say about those arrangements. Reduced reliance on deductibles and coinsurance can go a long way toward mitigating the harms to patients associated with rebates.

Finally, the recent FTC report highlighted potential harms to retail pharmacies. There are important policy concerns about the appearance of pharmacy deserts, especially in rural America. It is also clear that independent pharmacies are what stand in the way of rural areas experiencing a larger number of pharmacy deserts. Pharmacy deserts disproportionately affect lower-income, non-white, and older adult populations.<sup>46</sup>

<sup>&</sup>lt;sup>43</sup> See Fiedler M., Adler L., Frank R.G (2023, September 7). A brief look at current debates about pharmacy benefit managers. *Brookings Institution*. <a href="https://www.brookings.edu/articles/a-brief-look-at-current-debates-about-pharmacy-benefit-managers/">https://www.brookings.edu/articles/a-brief-look-at-current-debates-about-pharmacy-benefit-managers/</a> (4.0%+); author's calculation from CVS, Cigna, and United Health Group end of year 2023 10K filings (4.0%-5.1%), and 2018 Express Scripts filings (5.8%).

<sup>&</sup>lt;sup>44</sup> Visante. (2023, January). *The return on investment (ROI) on PBM Services*. <a href="https://www.pcmanet.org/wp-content/uploads/2023/01/The-Return-on-Investment-ROI-on-PBM-Services-January-2023.pdf">https://www.pcmanet.org/wp-content/uploads/2023/01/The-Return-on-Investment-ROI-on-PBM-Services-January-2023.pdf</a>

<sup>&</sup>lt;sup>45</sup> For a more extended discussion of this see: Fielder, Adler, Frank op cit. Note 42.

<sup>&</sup>lt;sup>46</sup> Constantin J., Ullrich, F., & Mueller, K. J. (2022, August). Rural and Urban Pharmacy Presence—Pharmacy Deserts. *Center for Rural Health Policy Analysis, University of Iowa*. https://iro.uiowa.edu/esploro/outputs/report/Rural-and-Urban-Pharmacy-Presence/9984388644902771

There are, however, significant economic forces threatening the supply of independent pharmacies in rural America that are not the result of PBM conduct. There is little reason to believe that PBMs are the main economic force creating these risks. Moreover, there is market power in the supply chain, including in retail pharmacies. Consumers and payers benefit from institutions that constrain the exertion of that market power.