

May 25, 2022

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

Dear Chair Khan,

Thank you for the opportunity to provide comments about the practices of pharmacy benefit managers (PBMs) and their impacts on patients, physicians, employers, pharmacies, and other participants in the healthcare system. Researchers at the USC Schaeffer Center for Health Policy & Economics have been studying the pharmaceutical distribution system since 2016; our comments about PBMs draw on that body of research.¹

EXECUTIVE SUMMARY

- PBMs play a central role in the economic system that distributes and pays for life-saving drugs in the United States. Unfortunately, evidence indicates they leverage their position to extract profits from other distribution system participants in ways that are detrimental to patients, payers, and the drug innovation system more broadly.
- In addition to their benefitting from a lack of transparency in the system, PBMs employ anticompetitive strategies and tactics that warrant investigation. These include gag clauses and copay clawbacks, rebate-driven formulary design, excessive prior authorization requirements, and vertical integration which are used to increase PBM profits at the expense of patients, taxpayers, and employers.
- Research on economic rents earned by different sectors of the distribution system indicates PBMs are earning excessive profits.
- PBMs are not delivering generic prescriptions to patients at the lowest possible cost. A 2020 study of cash prices at Costco for common generic prescriptions compared to Medicare costs found that Medicare overpaid on 43% of prescriptions in 2018, amounting to \$2.6 billion in overpayments that year.
- An FTC investigation of anticompetitive and harmful PBM business practices could help spur a more efficient and equitable pharmaceutical distribution system by: (1) increasing access to lifesaving medications for patients who need them, and (2) sharing economic surplus in a way that ensures both near-term affordability and ongoing healthcare innovation.

¹ The views expressed in this letter are those of the authors and do not necessarily reflect the views of the Schaeffer Center or the University of Southern California.

DETAILED COMMENTS

PBMs play a central role in the economic system that distributes and pays for life-saving drugs, a position that provides them with extraordinary information access and leverage among all system participants. As PBMs have merged with other distribution system participants over the last decade, the industry has become more vertically integrated—the top three PBMs are each part of a corporate structure that also includes an insurer, specialty pharmacy and healthcare provider.² The industry is also concentrated horizontally, with the top three PBMs accounting for 80% of the market. We believe that this vertical and horizontal consolidation threatens competition not only in the PBM market but also in the pharmacy and health plan markets. PBMs have leveraged their dominant information and network positions to extract profits from other distribution system participants in ways that are detrimental to patients, taxpayers, and employers, and more broadly to the drug innovation ecosystem.

Researchers at the USC Schaeffer Center for Health Policy & Economics have been studying the pharmaceutical distribution system since 2016. Below, we summarize key findings from that research, organized into two sections: 1) estimates of the economic rents earned by different sectors of the distribution system, and 2) analyses of commercial tactics employed to capture those rents. We also describe several concerning issues related to the business practices of PBMs and their affiliated companies in the pharmaceutical distribution system. We urge the FTC to open an investigation of anticompetitive and harmful PBM business practices, as a first step in bringing about a more efficient and equitable pharmaceutical distribution system that provides lifesaving medications to the patients who need them, and shares the economic surplus from doing so in a way that ensures both near-term affordability and ongoing healthcare innovation.

Economic Stakes: Rents Earned by Different Sectors in the Pharmaceutical Distribution System

Schaeffer researchers have produced several studies investigating which entities profit, and by how much, from their involvement in the system. An understanding of the economic and distributional consequences of PBMs' and other entities' involvement can provide a starting point for any FTC investigation of these entities and their activities.

Distribution of Rents for Retail Drugs

In one of the first investigations of the distribution of money flows through the retail drug distribution system, Sood, Shih, Van Nuys and Goldman (2017) combined data from the 2015 SEC filings of the largest publicly traded firms involved in pharmaceutical distribution (manufacturers, wholesalers, pharmacies, PBMs and insurers), to calculate average margins for each sector of the system.³ They estimate the share of money flows that each sector

² Drug Channels Institute (2022). "The Top Pharmacy Benefit Managers of 2021: The Big Get Even Bigger," <https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html>

³ Sood, N., T. Shih, K. Van Nuys and D. Goldman (2017). "The Flow of Money Through the Pharmaceutical Distribution System." Schaeffer Center White Paper Series. <https://healthpolicy.usc.edu/research/flow-of-money-through-the-pharmaceutical-distribution-system/>

keeps, finding that distribution system intermediaries (wholesalers, pharmacies, PBMs and insurers) accounted for about 41% of all expenditures on retail pharmaceuticals. PBMs alone accounted for 5%. The findings differed markedly when brand and generic drug markets were considered separately. Reflecting manufacturers' patent-protected market power in brand markets, intermediaries accounted for 24% (PBMs alone accounting for 2%) in those markets, while in generic markets, intermediaries accounted for 64% of all expenditures (PBMs alone accounting for 7%).

The finding that PBMs and other intermediaries find generic markets especially profitable is a recurring theme in our work, and one that we believe deserves scrutiny. Generic markets are, in many ways, the lynchpin in our pharmaceutical innovation ecosystem. While they account for just 18% of drug expenditures, 90% of all prescriptions dispensed in 2020 were for generic drugs.⁴ When the Hatch-Waxman Act was passed in 1984, setting the terms for our current pharmaceutical innovation ecosystem, the promise of inexpensive generics in the future was the explicit “payback” mechanism used to justify expensive patent-protected drugs. As such, inefficiencies, rent capture and excessive profits in generic markets will have important and far-reaching impacts on both drug affordability today and drug innovation in the future. They should not be ignored simply because generics represent a small share of total drug expenditures.

Distribution of Rents for Insulin

Several states passed legislation after 2015 requiring PBMs and drug manufacturers to provide financial information about their operations related to insulin or diabetes drug markets, information previously unavailable at the drug or drug-class level. Using data from these and other sources, Van Nuys, Ribero, Ryan and Sood (2021) estimated the money flows to different entities from sales of 32 insulin products between 2014 and 2018.⁵ They find that while average total expenditures per 100mL of insulin grew just 3% over five years, the average net price (what manufacturers received after all rebates, fees and discounts) decreased by 31%. Juxtaposing the fact that total expenditures for consumers and taxpayers have remained flat while manufacturers are receiving lower net prices suggests that PBMs have been successful in negotiating steep price concessions from insulin manufacturers between 2014 and 2018, but they have not been passing those savings along to patients or taxpayers. Instead, the savings were captured by intermediaries in the distribution chain, including PBMs: out of every \$100 spent on insulin, intermediaries claimed \$31.29 in 2014, an amount that climbed to \$53.27—more than half—by 2018. PBMs' share alone grew 154.6%, from \$5.64 in 2014 to \$14.36 in 2018. PBM spokespeople frequently tout the important role PBMs play in negotiating lower prices from drug manufacturers, but those price discounts do not benefit patients or premium payers if they don't result in lower expenditures. Patients care about the total amount they spend per 100mL of insulin, not

⁴ IQVIA Institute for Human Data Science. (2021). The Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025. May. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-use-of-medicines-in-the-us/iqi-the-use-of-medicines-in-the-us-05-21-forweb.pdf?_=1638990422167.

⁵ Van Nuys, K., R. Ribero, M. Ryan and N. Sood (2021). “Estimation of the Share of Net Expenditures on Insulin Captured by US Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans From 2014 to 2018.” JAMA Health Forum. 2021;2(11):e213409. doi:10.1001/jamahealthforum.2021.3409.

whether their money is going to manufacturers or to other entities in the distribution system.

Evidence of Excess Returns

While the research described above estimates how much money intermediaries receive from their distribution activities, it does not evaluate whether these amounts are “excessive.” High returns may be justified if large risks are undertaken to make them; manufacturers’ high profit margins are often justified by the large risks involved in developing new drugs, most of which fail to make it to market.⁶ By contrast, PBMs’ contracts with health plans do not typically expose them to financial risk for drug spending, nor do they assume significant inventory risk; in the retail (non-mail-order, non-specialty) drug market, PBMs do not even take possession of the product.

To understand the risk-adjusted returns of distribution system intermediaries, Schaeffer researchers estimated the excess returns of publicly traded companies involved in drug manufacturing and distribution in the 2013-2018 period.⁷ Calculating excess returns as the difference between return on invested capital (ROIC) and the weighted average cost of capital (WACC), Sood and Mulligan (2021) find that both manufacturers and intermediaries had higher excess returns in 2013–2018 compared with the S&P 500.

The researchers also calculated “adjusted ROIC,” in which research and development (R&D) costs are treated as investment expenses (capitalizing it over a useful life of 10 years rather than expensing it in the year in which it is incurred) since, like other investments, R&D expenditures on drug discovery eventually yield new commercial products that provide future returns for the firm. When excess returns calculated as the difference between *adjusted* ROIC and WACC are compared to those of the S&P 500, pharmaceutical manufacturers’ excess returns fall below those of the S&P 500 (1.7% vs. 3.6%), while those for biotech manufacturers (9.6%), wholesalers (8.1%), and insurers/PBM/retailers (5.9%) remain significantly above them. PBMs could not be disaggregated from the insurer/PBM/retailer category since so many of the companies in the sample were integrated across these parts of the distribution system. It is telling that the excess returns for the insurer/PBM/retailer sector increased over the study period, when both horizontal and vertical consolidation were also increasing. Broadly, these results suggest that the returns earned by companies in that category, including both standalone and integrated PBMs, cannot be justified by the risks they bear, and may instead reflect anticompetitive commercial tactics.

⁶ DiMasi, J.A. and H.G. Grabowski (2012) “R&D Costs and Returns to New Drug Development: A Review of the Evidence,” in *The Oxford Handbook of the Economics of the Biopharmaceutical Industry*, doi:10.1093/oxfordhb/9780199742998.001.0001

⁷ Sood, N., K. Mulligan and K. Zhong (2021). “Do Companies in the Pharmaceutical Supply Chain Earn Excess Returns?” *International Journal of Health Economics and Management*. 21:99–114 <https://doi.org/10.1007/s10754-020-09291-1>

Commercial Tactics: How Do Distribution Entities Profit?

PBMs and other distribution intermediaries use various commercial tactics to manage their businesses, some of which appear to leverage their unique market positions and information advantages to extract rents from patients and other players in the system. Many of these tactics have only been described through anecdote and example, but some have been subject to careful, peer-reviewed analysis. All would benefit from further investigation by the FTC.

Gag Clauses and Copay Clawbacks

In 2017, a PBM lobbyist testified before the Senate HELP Committee that PBMs did not support the practice of collecting patients' copay in excess of the cash price of the drug—so-called copay “clawbacks”—and that, if such practices happened, they were “outliers.”⁸ But, prior to a federal ban in 2018,⁹ many PBM-pharmacy contracts included “gag clauses” which facilitated the practice of clawbacks by prohibiting pharmacists from notifying customers when their copay exceeded the cash cost of their prescription. In a 2018 paper, Schaeffer researchers used data from a short-lived federal survey in 2013 (National Average Retail Price, or NARP) to compare patient copayments with the reimbursement pharmacies collected to settle the claims.¹⁰ Van Nuys, Joyce, Ribero and Goldman (2018) found that 23% of the prescriptions in a large sample of 2013 commercial pharmacy claims involved a patient copayment that exceeded the cost of the prescription to the PBM. When an overpayment occurred, it averaged \$7.69 per claim, which went to the PBM. Total overpayment in the sample studied amounted to \$135 million for the year, or about \$10.51 per member per year, similar to what Express Scripts reported its clients paid for metformin in 2016.¹¹

Consistent with other findings that generic markets are more profitable for intermediaries, overpayment was more common on generic than brand-drug claims (28% vs 6%), although the per-claim overpayment was lower (\$7.32 per generic claim vs. \$13.46 per branded claim). Many of the most common generic prescriptions involved overpayments on more than half of claims, including prednisone (50%), simvastatin (52%), amlodipine besylate (60%) and zolpidem tartrate (60%).¹² Although the 2018 legislation banning gag clauses likely curbed copay clawback activity, the fact that it was such a common practice, despite industry testimony that occurrences of clawbacks were outliers, illustrates the industry's eagerness to increase their profits at the expense of patients. It also illustrates the kind of behavior that lack of transparency in this industry has been facilitating, and the power of increased transparency: with only a very brief window of visibility into pharmacy

⁸ Testimony of Mark Merritt, CEO of PCMA, to Senate HELP Committee, October 17, 2017. (See exchange with Senator Susan Collins beginning at 1:15:55.)

<https://www.help.senate.gov/hearings/watch?hearingid=46F406D9-5056-A066-60AF-6A032664F2FE>

⁹ “Trump Signs New Laws Aimed at Drug Costs and Battles Democrats on Medicare,” New York Times, October 10, 2018. <https://www.nytimes.com/2018/10/10/us/politics/trump-health-insurance-drug-costs.html>

¹⁰ Van Nuys, K., G. Joyce, R. Ribero and D. Goldman, “Frequency and Magnitude of Co-payments Exceeding Prescription Drug Costs,” JAMA. 2018; 319(10). doi:10.1001/jama.2018.0102

¹¹ Express Scripts. 2016 Drug Trend Report. Retrieved November 27, 2017 from: <http://lab.express-scripts.com/lab/drug-trend-report>

¹² Van Nuys, K., G. Joyce, R. Ribero and D. Goldman (2018). “Overpaying for Prescription Drugs: The Copay Clawback Phenomenon,” Schaeffer Center White Paper Series.

<https://healthpolicy.usc.edu/research/overpaying-for-prescription-drugs/>

reimbursements (the six months of NARP data), we were able to establish that this practice is not an outlier but relatively common, and being used to generate hidden revenue for PBMs, at patients' expense. If an FTC investigation were to lead to greater transparency and provide researchers with key data that are currently shrouded by questionable "trade secret" protections, more of this behavior could be readily revealed and addressed legislatively.

Manufacturer Rebates

The practice of using manufacturer rebates as a negotiating tool to gain preferred formulary placement for branded products has been extensively studied and debated in policy circles. Some third-party payers have begun to experiment with approaches to sharing rebates with patients at the pharmacy counter, although roll-out and take-up has been slow.^{13,14}

A simple example helps illustrate how rebates influence the dynamics in the market for pharmaceuticals and create upward pressure on list prices. Consider two manufacturers with branded drugs that are therapeutically similar who are each negotiating with a PBM for preferred formulary placement, and are willing to accept a net price, after rebates, of \$80. Manufacturer A sets a list price of \$100, and offers a 20% rebate, while Manufacturer B offers a list price of \$80 with no rebate. In both scenarios we assume that PBMs pass through 90% of rebates to health plans and earn a 10% spread on prescriptions filled. We also assume that wholesalers, pharmacies and health plans all earn 5% margins, and patients have a fixed \$20 copay.¹⁵

Figure 1 illustrates the money flows under the alternative pricing arrangements. Note that both manufacturers will keep the same amount (\$80), but total expenditures are higher under the rebate pricing offered by Manufacturer A; if the goal is to reduce system-wide expenditures without changing the financial incentives to innovate, the no-rebate pricing offered by Manufacturer B is the answer. But because every other distribution system entity keeps more under the rebate model pricing offered by Manufacturer A, there are strong incentives for the PBM to prefer Manufacturer A's drug on the formulary. Some manufacturers have shared anecdotes about offering to lower their list prices like Manufacturer B, only to be told by the PBM that if they do so, they will be passed over for another manufacturer offering higher list prices/higher rebates like Manufacturer A.

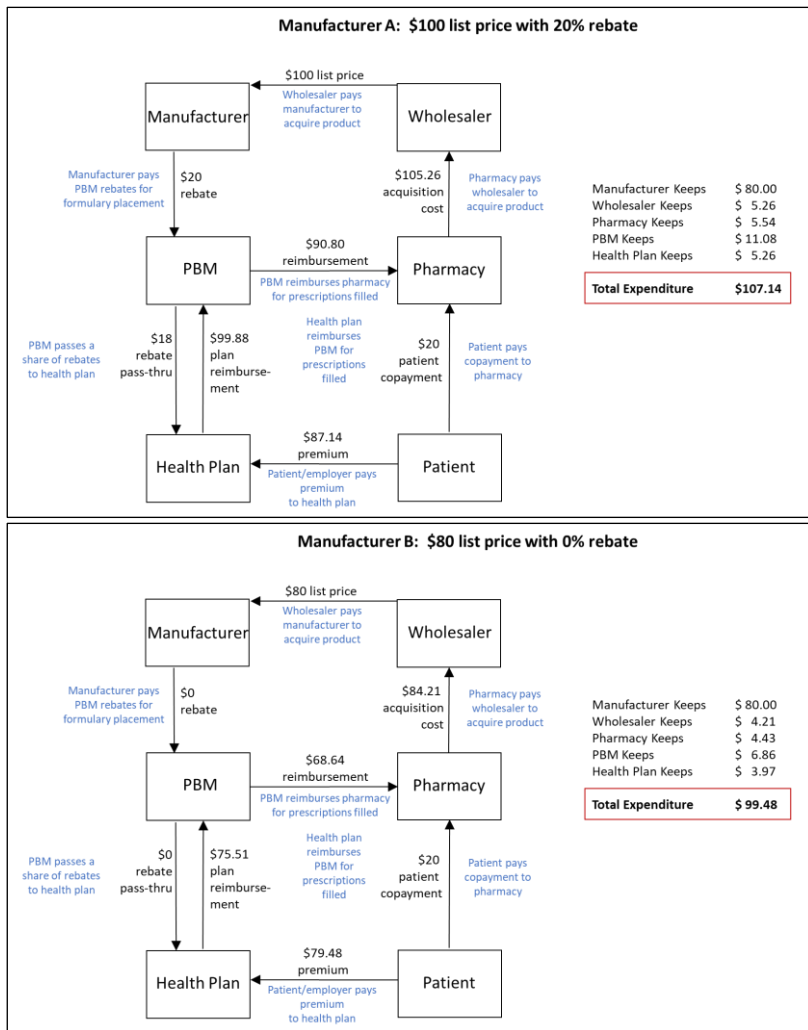
There is indirect empirical evidence to suggest that PBMs favor high list, high rebate drugs over drugs with a lower net cost, although it is hard to prove definitively without access to actual rebate data, not simply drug- or class-level average rebates. Buttorf, Xu and Joyce (2020) use the variation in generic dispensing rates within a therapeutic class across Part D

¹³ Lakdawalla, D., and M. Li (2021). "Association of Drug Rebates and Competition with Out-of-Pocket Coinsurance in Medicare Part D, 2014 to 2018," JAMA Network Open. 2021;4(5):e219030. doi:10.1001/jamanetworkopen.2021.9030

¹⁴ Fein AJ. Employers slowly warm to point-of-sale rebates—but must move faster for insulin. Drug Channels. Published 2019. Accessed May 17, 2022. <https://www.drugchannels.net/2019/09/employers-slowly-warm-to-point-of-sale.html>

¹⁵ The results also hold if patients face coinsurance calculated as a share of list price.

Figure 1



plans to infer this.¹⁶ They find lower generic utilization rates among firms operating as both a PBM and drug plan, specifically UnitedHealth, CVS, and Express Scripts. They also find evidence that some Part D plans place brand drugs in lower cost-sharing tiers than their generic equivalents, providing circumstantial evidence that rebates may play a role in influencing brand over generic use. In a study of Medicare Part D formularies in 2016, Socal, Bai and Anderson (2019) find that that 72% of those formularies placed at least 1 branded product in a lower cost-sharing tier than its generic product, and 30% of formularies adopted fewer utilization controls on the branded product for at least 1 drug.¹⁷

¹⁶ Buttorf, C., Y. Xu and G. Joyce (2020). "Variation in Generic Dispensing Rates in Medicare Part D," *Am J Manag Care*; 26(11): e355–e361. doi:10.37765/ajmc.2020.88530.

¹⁷ Socal MP, Bai G, Anderson GF. Favorable formulary placement of branded drugs in Medicare prescription drug plans when generics are available. *JAMA Intern Med.* 2019;179(6):832-3. doi:10.1001/jamainternmed.2018.7824

Other recent Schaeffer research has demonstrated the broader impact of these dynamics. Lakdawalla and Li (2021) find that the most competitive drug classes feature the fastest growth in list prices, with list prices growing 11.1% annually for off-patent drugs with multiple molecules in the same class, compared to 10.8% for on-patent drugs in single-molecule classes and 9.3% for on-patent drugs in multi-molecule classes.¹⁸

The dynamics illustrated here, driven by the perverse incentives of PBMs and other distribution system players to prefer higher rebates and higher list prices, underlie increasing list price trends over the last 10 years.¹⁹ In 2020, Schaeffer researchers used data from SSR Inc. on list prices and estimated net prices to explore the relationship between list prices and estimated rebates. Sood, Ribero, Ryan, and Van Nuys (2020) found that, for every \$1 increase in estimated rebates, list prices increased \$1.17 between 2015 and 2018.²⁰ This relationship persisted after controlling for time trends, and was not explained by the mandatory Medicaid rebates imposed on drugs whose list prices increased faster than inflation. Other researchers have documented similar findings.^{21,22,23} In late 2021, the Department of Health and Human Services issued a final Part D rebate rule to counter this effect by passing manufacturer rebates through to patients at the point of sale, but its implementation has been delayed until 2026.

PBMs have deflected blame for these rebate practices by pointing out that they pass through most of the rebates they collect to health plans, who may then use them to keep premiums low for beneficiaries.²⁴ But the ultimate result of such practices is to decrease the effective generosity of insurance by reducing premiums but increasing OOP costs—effectively, this transfers resources from sick people to healthy premium-paying beneficiaries.²⁵ This is the opposite of insurance, which is intended to pool funds from a large, mostly healthy group of beneficiaries and use it to defray the costs of those who experience the misfortune of falling ill.

The recent FDA approval of the first interchangeable insulin biosimilar, an insulin glargine injection from Viatris and Biocon Biologics that is interchangeable with Lantus, provides an

¹⁸ Op. cit. Lakdawalla and Li, p.6.

¹⁹ IQVIA Institute (2022). “The Use of Medicines in the U.S. 2022: Usage and Spending Trends and Outlook to 2026.”

²⁰ Sood, N., R. Ribero, M. Ryan and K. Van Nuys (2020). “The association between drug rebates and list prices,” Schaeffer Center white paper series. <https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/>

²¹ Hernandez, I., A. San-Juan-Rodriguez, C. B. Good, and W. Gellad (2020). “Changes in List Prices, Net Prices, and Discounts for Branded Drugs in the US, 2007-2018,” *JAMA*. 2020;323(9):854-862. doi:10.1001/jama.2020.1012

²² Op. cit. Lakdawalla and Li, p.6.

²³ Kakani, P., M. Chernew and A. Chandra (2020). “Rebates in the Pharmaceutical Industry: Evidence from Medicines Sold in Retail Pharmacies in the U.S.,” NBER working paper 26846. doi: 10.3386/w26846

²⁴ Sweeney, E., “CVS, Express Scripts provide a rare moment of transparency on rebate profits,” *Fierce Healthcare* August 10, 2018. <https://www.fiercehealthcare.com/payer/cvs-caremark-express-scripts-pbm-pass-through-cigna-merger>

²⁵ Op. cit. Lakdawalla and Li, p.6.

instructive example of these rebate dynamics.²⁶ Viatris simultaneously launched two versions of the drug—a branded product (Semglee), and an authorized but unbranded version (Glargine). Both are interchangeable with the originator Lantus product. Compared to the list price of Lantus, the list price of the branded Semglee is 5% lower, while the list price of unbranded Glargine is 65% lower. Although net price to the manufacturer after rebates is not observed, there is good reason to believe they are similar, meaning the branded Semglee product is offering substantially larger rebates than the unbranded version. Express Scripts issued a press release announcing that they would prefer the biosimilar on their largest formulary, covering 28 million lives, in 2022 and would exclude the originator Lantus product.²⁷ But the preferred product Express Scripts chose was the high list price branded biosimilar, Semglee, with larger rebates. The low list price/low rebate, unbranded product was excluded from the formulary.

Beyond rebates, PBM contracts frequently calculate other fees received from manufacturers as a share of a drug's list, not net, price. Such arrangements tie PBM revenues directly to list prices, giving them a strong financial incentive to prefer products with higher list prices, and creating pressure on manufacturers to increase list prices.

Rebate Interest

Another potential issue related to the practice of collecting rebates is that the PBM will collect the rebates when the manufacturer pays them, but generally pass the rebates through to health plans on a quarterly schedule. It is unclear whether the PBM pays interest on any rebate dollars held until the quarterly disbursement, or whether they keep the interest earned. We would recommend that any future FTC study clarify whether this represents another hidden PBM revenue source, or whether PBMs should pay interest on rebates collected but not yet passed through to their health plan clients.

Prior Authorization

Prior authorization requirements (PA) are commonly used by PBMs to manage drug utilization and steer patients away from certain medications. Under PA, a patient's physician must submit documentation to the PBM about a patient's clinical history before coverage will be provided for a specific drug. Physicians generally object to the practice, arguing that it is "overused, costly, inefficient, opaque and responsible for patient care delays."²⁸ These delays result in real clinical harms—in one study of severe asthma and urticaria patients, PA added an average of three weeks to the wait time to fill prescriptions for needed biologic medications; during that period, 47% of asthma patients experienced an exacerbation that

²⁶ Details are taken from A. Fein (2021). "Why PBMs and Payers Are Embracing Insulin Biosimilars with Higher Prices—And What That Means for Humira," Drug Channels blog November 9, 2021. <https://www.drugchannels.net/2021/11/why-pbms-and-payers-are-embracing.html>

²⁷ Express Scripts press release, 10/20/2021. "Express Scripts Will Unlock \$20 Million in Savings for Clients in 2022 by Preferring the First Interchangeable Insulin Biosimilar," at <https://www.prnewswire.com/news-releases/express-scripts-will-unlock-20-million-in-savings-for-clients-in-2022-by-preferring-the-first-interchangeable-insulin-biosimilar-301404121.html>

²⁸ American Medical Association statement on prior authorization, at <https://www.ama-assn.org/practice-management/sustainability/prior-authorization>

required treatment with prednisone.²⁹ And in a forthcoming study of Medicare beneficiaries with incident atrial fibrillation, Zhou et al. (2022) find that restricting access to novel anticoagulants (NOACs) through PA or step therapy requirements or excluding them from coverage reduced patients' probability of filling a first prescription within 30 days of atrial fibrillation incidence by 9.1 percentage points among new NOAC users. Lower use and delayed initiation of NOACs were associated with elevated risks of stroke and bleeding, consistent with data from clinical trials and other observational studies.³⁰

The number of drugs subject to PA has increased significantly over the last decade.³¹ In 2021, more than one in four drugs on Medicare plan formularies were subject to PA.³² PBMs argue that requiring authorization allows them to control drug costs by putting patients on less expensive therapies than those initially prescribed by their physicians. But with more than 80% of PA requests eventually approved and with many established generic drugs with no lower-cost alternatives now subject to the practice,³³ cost savings may not be the only explanation for the rise in the use of PA. In fact, PA requests are also a source of revenue for PBMs, who charge their health plan clients a prior authorization fee for every PA request processed. As such, the PBM earns revenues from PA reviews while at the same time choosing how many and which drugs on their formulary require PA. This conflict of interest merits further scrutiny.

Anticompetitive Incentives in Vertically Integrated Markets

With the recent wave of vertical consolidation in pharmaceutical distribution markets, the three largest PBMs all belong to conglomerates that include both health insurers and specialty pharmacies (OptumRx/United Healthcare/Briova; CVS Caremark/Aetna/CVS Specialty; Express Scripts/Cigna/Accredo); the CVS Health conglomerate also includes the largest retail pharmacy chain, CVS pharmacy. These vertically integrated organizational structures facilitate and create incentives for PBMs to extend their market power into adjacent markets. For example, a PBM in the same ownership group as a health plan might offer less attractive rebate pass-through terms to unaffiliated health plans compared to those provided to plans affiliated with their insurance company in an effort to strengthen their competitive position in the insurance market. A vertically integrated PBM might offer more attractive reimbursement to their affiliated pharmacies than to other pharmacies to foreclose rival competition in pharmacy markets.³⁴

²⁹ Dudiak, G., J. Popyack, C. Grimm, S. Tyson, J. Solic, F. T. Ishmael (2021). "Prior Authorization Delays Biologic Initiation and is Associated with a Risk of Asthma Exacerbations," *Allergy & Asthma Proceedings* 2021. 42(1);65-71.

³⁰ Zhou, et al. (2022). "Formulary Restrictions and Stroke Risk in Patients With Atrial Fibrillation," *American Journal of Managed Care*, forthcoming.

³¹ Resneck, J. (2020) "Refocusing Medication Prior Authorization on Its Intended Purpose," *JAMA* 2020. 323(8);703-704.

³² MedPAC July 2021 Data Book: Healthcare Spending and the Medicare Program. https://www.medpac.gov/wp-content/uploads/2021/10/July2021_MedPAC_DataBook_Sec10_SEC.pdf

³³ B. Barnett "Who's Choosing Americans' Medications — Doctors or Insurers? The Bane of Prior Authorization." *Stat News*, January 1, 2021. <https://www.statnews.com/2021/01/01/prior-authorization-whos-choosing-americans-medications-doctors-or-insurers/>

³⁴ Sood, N. (2018) "Potential Effects of the Proposed CVS Acquisition of Aetna on Competition and Consumer Welfare." Expert witness report for evidentiary hearing in CVS-Aetna merger; U.S. District Court for the District

Lack of Information on Prices, Fees, Discounts, Rebates and Rents

An overarching issue confounding all outside research seeking to understand the economics of PBM commercial practices is the lack of information about true transaction prices. Researchers must rely on publicly available data such as wholesale acquisition costs, plan reimbursements and patient copayments from pharmacy claims, but we lack information on rebates, discounts, fees and spreads that materially impact the economics of the system at each step. As a result, research to estimate the rents going to PBMs and other distribution system intermediaries must triangulate among a host of public sources, and generally only broad averages over all drugs as a group can be estimated. We are only rarely able to estimate drug- or even drug-class-level results. This makes it very difficult to determine who is profiting by how much in the system. The argument that prices, discounts, fees, etc. must be kept secret because they are “proprietary information” creates the opacity that ensures PBMs can hide from scrutiny by outside researchers. A key benefit of an FTC investigation would be the commission’s ability to subpoena pricing and other transaction information so that it can be determined, definitively, where the money is going in the pharmaceutical distribution system.

Conclusion

PBMs’ unique position in the pharmaceutical distribution system gives them unparalleled access to information and leverage that can be used to wring profits from manufacturers and other distribution system participants. While they *could* pass these savings along to patients, taxpayers, and employers, they could also use them to increase their own profits. Evidence suggests that they are doing the latter in insulin markets, but data limitations—underpinned by obfuscating practices such as gag clauses, confidentiality clauses, trade secret provisions, and vertical integration—prevent outsiders from discovering how widespread or intensive these practices are. And although PBM representatives have testified under oath that abusive practices such as copay clawbacks are “outliers,” a glimpse into retail practices using a brief window of average reimbursement data (NARP) demonstrates that these abusive practices were not outliers at all, but present on nearly one in four claims in 2013.

These issues might be less concerning if we believed our current system of pharmaceutical distribution and reimbursement—centered on and orchestrated by PBMs—was working efficiently by getting drugs to patients at the lowest possible costs. But it is not. In a recent study comparing the cash prices at Costco for common generic prescriptions to their costs to the Medicare system, Trish, Gascue, Ribero et al. (2020) found that Medicare overpaid on 43% of prescriptions in 2018.³⁵ If Medicare plans had simply paid the Costco cash price for 184 of the most common generic drugs, the system would have saved \$2.6 billion that year. This *de facto* evidence that the current distribution system is failing to provide pharmaceuticals efficiently suggests that an investigation by the FTC into PBM business

of Columbia. <https://www.insurance.ca.gov/01-consumers/110-health/60-resources/upload/Sood-AMA-finalv3.pdf>

³⁵ Trish, E., L. Gascue, R. Ribero, K. Van Nuys and G. Joyce (2021). “Comparison of Spending on Common Generic Drugs by Medicare vs Costco Members.” *JAMA Intern Med.* 2021;181(10):1414–1416. doi:10.1001/jamainternmed.2021.3366

practices and their potential anti-competitive effects is much needed. We strongly encourage the FTC to undertake this study, and would be happy to offer any assistance we can provide in that effort.

Thank you again for the opportunity to provide our input on this important question.

Sincerely,

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