PATIENTS FOR AFFORDABLE DRUGS NOW™

Patients For Affordable Drugs Now Comments In Response to the Federal Trade Commission's "Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers"

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Introduction

Patients For Affordable Drugs Now is pleased to offer these comments in response to the Federal Trade Commission's "Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers."

Patients For Affordable Drugs Now is the only national patient organization focused exclusively on policies to lower drug prices. We are bipartisan and independent. We don't accept funding from any organizations that profit from the development or distribution of prescription drugs.

Today, pharmacy benefit managers (PBMs) administer prescription drug benefits for more than 266 million Americans, or 80% of the population. While drug prices are set by manufacturers, there is ample evidence that indicates the profit-driven and secretive practices of PBMs play a major role in the cost of and access to drugs for our patient community. In order to better understand PBMs' impact on patients — and to guide future government and industry reforms — we urge the Federal Trade Commission to conduct a study of PBMs.

PBMs Are Shrouded In Secrecy

PBMs are supposed to act as intermediaries, leveraging the buying power of insurers, employers, and government purchasers in order to capture savings, which at the end of the day are supposed to accrue to the benefit of patients and consumers. But because the business practices of PBMs are shrouded in secrecy, policymakers and the public are left in the dark about the amount of savings actually passed on to payers and patients through lower premiums and out-of-pocket costs. While PBMs claim to be utilizing their bargaining power on behalf of patients, they are simultaneously fighting to ensure their rebate practices stay hidden from view. As a result, a patient cannot know if the preferred drug on the formulary is placed there because it is the best, most cost-effective option or because it is the one for which the PBM received a substantial rebate. Without further transparency and accountability, PBM decision-making and its impact on patients will remain a mystery.

Are Patients Actually Paying More For Some Drugs Because Of Rebate Practices?

Because larger rebates can be exchanged for more favorable formulary placement, PBM rebate practices may in fact incentivize drug companies to raise list prices in order to be able to provide deep enough rebates to gain and maintain placement. This ongoing cycle demonstrates how rebate practices can contribute to ever-increasing list prices.

Pay-for-position rebate practices also lead to higher costs for patients. A PBM may receive a substantial rebate from a brand-name drug company in exchange for placing that brand-name drug — instead of a less expensive generic option — in a preferred tier. Because patient cost-sharing is most often based on the full, non-discounted price of the drug, this structure exposes insured patients to higher costs even though an equally effective, more affordable option may exist. The impact on uninsured patients is even more severe because they must pay the entire, rebate-inflated list price without the benefit of insurance coverage to absorb some of the costs. The relationship between rebates and higher out-of-pocket costs has been substantiated in academic research.

PBM Practices May Be Used To Block Competition

Our drug pricing system is designed around the expectation that the market entry of generic and biosimilar drugs will generate competition and promote affordability. Unfortunately, PBM practices may make it difficult or impossible for generic and biosimilar drugs to gain uptake in the market. Current incentives in the negotiations between drugmakers and PBMs leave contracts vulnerable to gaming.

For example, as part of drug manufacturer Teva's effort to delay generic competition for its blockbuster multiple sclerosis drug Copaxone, the company developed a higher concentration version of the drug and began efforts to switch patients to this dosage before the existing dosage faced generic competition. The House Committee on Oversight and Reform uncovered documents that show that Teva pressured PBMs "by tying contractual rebates on [the previously marketed concentration] to adding [the newly developed concentration] to their formularies." The participating PBM conceded, seeking the sizable rebates in question. Teva's efforts to impede generic competition resulted in considerable costs to our health system and kept affordable alternatives out of reach for patients. In addition, in 2017, Pfizer filed a lawsuit accusing Johnson & Johnson of offering PBMs larger rebates to incentivize them to place its blockbuster rheumatoid arthritis drug Remicade in a favorable formulary position instead of Pfizer's new biosimilar competitor, Inflectra. Both examples illustrate instances in which drug companies worked in tandem with PBMs to hinder market penetration of more affordable generic and biosimilar medications.

PBMs Put Shareholders First, Not Patients

PBMs have become some of the most profitable players in the health care sector. In 2021, PBMs handled more than $422 billion of gross drug revenues in the United States. The profitability of PBMs has risen in recent years as a result of vertical mergers between PBMs, insurance companies, and pharmacies. Almost 90% of those gross revenues in 2021 moved through the "Big Three" alone — CVS, Express Scripts, and OptumRx. The gross profit of PBMs grew 12% between 2017 and 2019, increasing from $25 billion to $28 billion. Because they are profit-driven entities with a duty to shareholders but without a fiduciary responsibility to beneficiaries, additional transparency could clarify whether their practices best serve patients or shareholders. We believe U.S. law and policy should be amended to give PBMs a fiduciary responsibility to beneficiaries, requiring them to put beneficiary health and financial interests first.

Lack Of Competition Leads To Profits Over Patients

Concentration in the PBM industry is yet another factor that appears to contribute to a drug pricing system where profits come before patients. Because three large PBMs have a stranglehold on the market, these companies have a disproportionate impact on what medications patients have access to. For example, at the end of last year, CVS Caremark announced that it would no longer cover the blockbuster anticoagulant Eliquis in 2022 and would instead cover only warfarin and Xarelto. This decision had enormous implications for patients since CVS Caremark has the largest market share (34%) of any PBM. As a result, many patients were forced to switch products in order to remain on a covered drug. For some medications — especially biologics — a forced switch can carry with it significant health and safety implications for the patient. Patient choice can be further limited by PBMs, like CVS Caremark, that own retail pharmacies and may be directing or requiring beneficiaries to fill prescriptions with their retail affiliates.

Recent mergers have also made the lines between PBMs and insurance companies increasingly difficult to distinguish. This trend creates conflicting incentives stemming from the fact that PBMs are typically more profitable than insurance companies. Insurers, which are typically motivated by cost-containment, may pivot to direct patients to treatments with higher rebates instead of acting in the best health and financial interests of their beneficiaries. This dynamic could exacerbate all the aforementioned effects that PBMs have on patients and their costs.

Conclusion

PBMs were created with the stated purpose of negotiating on behalf of patients. Today, PBMs handle more than $420 billion and cover more than 266 million lives. Nevertheless, their work is shrouded in secrecy, so their practices remain unclear and their effects on patients are at best uncertain — and at worst deleterious. The Federal Trade Commission should investigate PBMs in order to reveal the practices and effects of these large and growing entities. Such an investigation could be critical for identifying problem areas and an important step in building a foundation for policymakers to utilize as they seek to develop appropriate legislative solutions to ensure PBMs can best serve consumers.