

Office of the Chair

UNITED STATES OF AMERICA Federal Trade Commission WASHINGTON, D.C. 20580

Statement of Chair Lina M. Khan Regarding the Policy Statement Concerning Reliance on Prior PBM-Related Advocacy Statements and Reports Commission File No. P230100

July 20, 2023

Today, the Federal Trade Commission ("FTC" or "Commission") is voting to warn the public not to rely on eleven older comments, reports, and studies by the FTC about pharmacy benefit managers ("PBMs"). We have taken this step because we believe that these previous FTC documents may not reflect the current reality of the marketplace with respect to PBMs.

PBMs are powerful intermediaries at the center of the U.S. prescription drug system. Through mergers, the three largest PBMs—CVS Health, Express Scripts and OptumRx—now control a large swathe of the marketplace. They have also vertically integrated such that each owns or is affiliated with health plans, specialty and mail order pharmacies, and health insurance providers. One—CVS—owns one of the nation's largest drug store chains. Consequently, PBMs today have substantial influence over multiple parts of the pharmaceutical supply chain.

In many instances, PBMs practically determine which medicines are prescribed to patients, which pharmacies patients can use, and the amount patients will pay at the pharmacy counter. As drug prices have soared and independent pharmacies have shuttered, scrutinizing the practices of PBMs is more critical than ever.

Shortly after I joined the Commission, we launched a public docket to gather input on unfair contractual clauses and another on the practices of PBMs. Across both we received over twenty-four thousand comments from pharmacies, doctors, and patients. Those who own competing pharmacies have shared that that PBMs impose unfair fees and clawbacks, impose byzantine contracts that often reimburse pharmacies less than their costs of acquisition, and steer patients to PBM-owned pharmacies. PBMs have also been accused of harming patients by extracting rebates and fees in exchange for refusing to cover generic and biosimilar drug products, ultimately raising the price that consumers pay for medicines. Additionally, doctors have shared that PBMs impose unnecessary and burdensome prior authorization and other administrative requirements.

These issues, and more, are currently the subject of the FTC's study of the PBM industry. Last year, the FTC ordered six of the largest PBMs to provide documents and data as part of an FTC inquiry into the impact of PBM practices on competing pharmacies, payers, doctors, and

patients.¹ More recently, we expanded that inquiry and sent similar orders to three group purchasing organizations affiliated with existing PBMs.²

Here are some of the things we have heard so far from the public. One patient told us that she was required by her health insurance carrier to go through the PBMs' specialty pharmacy, which significantly delayed medication she vitally needed to ensure she could have her baby. The PBMs requirements significantly slowed down her getting this vitally needed medication:

I was able to order that medication through my own pharmacy, but my insurance plan would not pay for the medication unless I got it from their specialty pharmacy. The doctor issued the order for the medication to the specialty pharmacy and the process for obtaining it was so complicated that I had to call multiple times a week to check on the medication status for 4 weeks until it was nearly past the time that I needed to begin the medication. I finally received the medication in the mail 2 days into my 16th week of pregnancy. If they had delayed any longer in shipping the medication I would have been past the window of administration and may have lost the pregnancy.³

Pharmacists report how PBMs' take-it-over-leave-it contracts are threatening their business. According to one, whose retail operation is in a rural area: "To keep up with the costs of PBM practices and the ever-increasing costs of prescription drugs while keeping the pharmacy doors open my mom, a pharmacist, was not able to pay her own wage for four months in 2019."⁴ He concluded:

If you don't accept these [take-it-or-leave-it] contracts, as an independent pharmacy, it means that you will go out of business. In rural areas, like my family's pharmacy, patients are represented by a few insurers (PBMs) that are in the area making you lose the majority of your patient base if you don't sign.

Another pharmacist highlighted PBMs onerous contracts, including "clawbacks," which he said had brought him "close to financial ruin." He told us, he has "had to cut back employee hours, limit services, and work more hours by myself than I ever have before."⁵

¹ See Press Release, Fed. Trade Comm'n, FTC Launches Inquiry Into Prescription Drug Middlemen Industry (June 7, 2022), <u>https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry</u>.

² Press Release, Fed. Trade Comm'n, FTC Deepens Inquiry into Prescription Drug Middlemen (May 17, 2023), <u>https://www.ftc.gov/news-events/news/press-releases/2023/05/ftc-deepens-inquiry-prescription-drug-middlemen;</u> Press Release, Fed. Trade Comm'n, FTC Further Expands Inquiry into Prescription Drug Middlemen Industry Practices (Jun. 8, 2023), <u>https://www.ftc.gov/news-events/news/press-releases/2023/06/ftc-further-expands-inquiry-prescription-drug-middlemen-industry-prescription-drug</u>

³ Comment Submitted by Heidi Romero, Solicitation for Public Comments on the Impact of Prescription Benefit Managers' Business Practices, *Regulations.gov* (May 25, 2022), <u>https://www.regulations.gov/comment/FTC-2022-0015-0819</u>.

⁴ Comment Submitted by Anonymous, Solicitation for Public Comments on the Impact of Prescription Benefit Managers' Business Practices, *Regulations.gov* (Apr. 25, 2022), <u>https://www.regulations.gov/comment/FTC-2022-0015-0626</u>.

⁵ Comment Submitted by Plymouth Park Pharmacy Inc., Solicitation for Public Comments on the Impact of Prescription Benefit Managers' Business Practices, *Regulations.gov* (May 9, 2022), https://www.regulations.gov/comment/FTC-2022-0015-0778.

Over the past 25 years, there have been repeated efforts at the state level to check the power of PBMs. For example, state regulators have sought to mandate that PBMs disclose to state regulators and health insurers details of their financial arrangements with drug makers. However, when New York State Assemblyman Richard Gottfried sought to introduce such legislation in New York, he found himself dealing with opposition not only from the PBM industry but also from the FTC.⁶ In advocacies sent to state legislators—such as an April 8, 2004 letter sent to Rhode Island legislators and one sent to New York officials in 2009—the FTC argued that imposing transparency requirements "could lead to higher prices."⁷ These advocacies had a meaningful impact in derailing such legislation. Indeed, then-New York Governor Cuomo cited the FTC's position as one of the reasons he vetoed the legislation.⁸

In the past, the FTC was concerned that mandated disclosure requirements between PBMs and payors (such as larger employers) and healthcare plans—as proposed in state legislative initiatives—could encourage price coordination and collusion. However, given the trends toward extensive consolidation by PBMs and extensive vertical integration by these PBMs into the entire drug supply and payment chain, employers and other payers in this marketplace appear to have been placed at a severe information disadvantage. In such a situation, it may be appropriate for policymakers to require that PBMs provide accurate and timely information for buyers.

The FTC is now pursuing an inquiry into the PBM industry, one that is designed to capture and detail the current realities on the ground in this complex marketplace. While we finalize our market study, we urge the public not to continue to cite or rely on these outdated comments, reports, and studies.

It is important that the FTC's work reflect current market dynamics. I am pleased that the FTC is alerting the public to the risks of relying of earlier work based on outdated market conditions and assumptions.

⁶ Stacy Mitchell & Zach Freed, *How the FTC Protected the Market Power of Pharmacy Benefit Managers*, PROMARKET (Feb. 19, 2021), <u>https://www.promarket.org/2021/02/19/ftc-market-power-pharmacy-benefit-</u>

<u>managers/</u> (noting the FTC "had taken a stance against state legislation like his that sought to rein in the PBMs"). ⁷ Letter from Todd J. Zywicki, Director, Office of Policy Planning, Fed. Trade Comm'n, et al. to Patrick C. Lynch, Attorney General, State of Rhode Island, and Juan M. Pichardo, Deputy Majority Leader, Senate, State of Rhode Island (Apr. 9, 2004), <u>https://www ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-commenthon.patrick-c.lynch-and-hon.juan-m.pichardo-concerning-competitive-effects-ri-general-assembly-bills-containingpharmaceutical-freedom/ribills.pdf.</u>

⁸ Stacy Mitchell & Zach Freed, *supra* note 6. It should be noted that, since 2021, ten states have passed some type of PBM transparency legislation. Compilation of State Pharmacy Benefit Manager Business Practice Laws, Nat'l Assn. of Ins. Comm'rs (Mar. 2022),

https://content.naic.org/sites/default/files/call_materials/Compilation%20of%20State%20PBM%20Business%20Pra ctice%20Laws%203.2022.pdf. More recently, other states, such as Florida, have taken similar action. News Service of Florida, *Florida Gov. DeSantis Signs Bill to Increase Transparency for Prescription Drug Costs*, NBC Miami (May 3, 2023), https://www.nbcmiami.com/news/local/florida-gov-desantis-signs-bill-to-increase-transparency-forprescription-drug-costs/3027175/.