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

Office of the Chair

February 13, 2024

The Honorable Charles E. Grassley
United States Senate
Washington, D.C. 20510

Dear Senator Grassley:

Thank you for your January 22, 2024, letter and your continued support of the Federal Trade Commission's (FTC) study of certain pharmacy benefit manager (PBM) industry practices. There is appropriately a high degree of public interest in this industry. The industry's practices and their effects remain opaque despite the central role PBMs play in deciding which drugs are prescribed to patients, which pharmacies patients can use, and how much patients ultimately pay at the pharmacy counter. Decisions by PBMs and their affiliates may have a significant impact on patients' ability to access and afford their prescription drugs.

This can have dire consequences for Americans, with nearly three in ten surveyed Americans reporting rationing or even skipping doses of their prescribed medicines due to high costs.[1] PBMs also have substantial influence over independent pharmacies, which have collectively voiced concern that PBMs impose contractual terms with these pharmacies that are confusing, unfair, arbitrary, and harmful to their businesses.

Given the importance of this industry and troubling reports about PBM practices, I share your sense of urgency regarding timely completion of the study and welcome this opportunity to provide you an interim progress update on our ongoing study of this industry.

As you know, in June 2022, the FTC issued Orders to PBMs pursuant to its 6(b) authority to study a range of PBM business practices that may affect drug affordability and access.[2] The Order requires the six largest PBMs—Caremark Rx, LLC; Express Scripts, Inc.; OptumRx, Inc.; Humana Pharmacy Solutions, Inc.; Prime Therapeutics LLC; and MedImpact Healthcare Systems, Inc.—to provide data and documents regarding certain business practices. This inquiry

[1] Ashley Kirzinger, et al, PUBLIC OPINION ON PRESCRIPTION DRUGS AND THEIR PRICES (2023), https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/; *see also*, Laryssa Mykyta & Robin A. Cohen, *Characteristics of Adults Aged 18–64 Who Did Not Take Medication as Prescribed to Reduce Costs: United States, 2021*, NAT'L CTR. FOR HEALTH STATISTICS (2023) at 5, doi:10.15620/cdc:127680 (research from the CDC found that 9.2 million adults in the U.S. are not taking their prescription drugs as prescribed, due to the high cost of medications).

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

builds on the more than 1,200 public comments[3] the Commission received in response to a request for information about PBMs that the agency issued on February 24, 2022.[4]

The PBM 6(b) inquiry seeks to examine several of the most common and serious complaints about PBMs. Our inquiry is aimed at shedding light on several business practices that have drawn public scrutiny in recent years, including: fees and clawbacks charged to unaffiliated pharmacies; methods to steer patients towards PBM-affiliated pharmacies; potentially unfair audits of independent pharmacies; complicated and opaque methods to determine pharmacy reimbursement; the prevalence of prior authorizations and other administrative restrictions; the use of specialty drug lists and surrounding specialty drug policies; and the impact of rebates and fees from drug manufacturers on formulary design and the costs of prescription drugs to payers and patients.

In May and June 2023, the FTC expanded its PBM study by issuing three additional compulsory orders to companies that perform rebate services for their affiliated PBMs.[5] These additional 6(b) Orders require the three group purchasing organizations (GPO) that are linked to the six largest PBMs—Zinc Health Services, LLC, Ascent Health Services, LLC, and Emisar Pharma Services LLC —to produce documents. These GPOs, also called rebate aggregators, negotiate rebates with drug manufacturers on behalf of the PBMs and hold the contracts that govern those rebates. Zinc was founded in 2020 and operates as the GPO for CVS Caremark. Ascent was founded in 2019 and operates as the GPO for Express Scripts, Prime Therapeutics, Envolve Pharmacy Solutions, and Humana Pharmacy Solutions. Emisar, like Zinc and Ascent, negotiates rebates with drug manufacturers. Emisar negotiates rebates on behalf of OptumRx and, like OptumRx, is a subsidiary of UnitedHealth Group.

Although our compulsory orders were issued in June 2022, and May and June 2023, to date no company has turned over sufficient documents and data to be in full compliance with those orders. FTC staff continues to push the PBM/GPOs to finalize their production of documents and data required by the Orders as quickly as possible. The respondents have proceeded with varying levels of speed in their productions and compliance with the Orders. We expect to have all the materials very soon. If, however, some of the companies fail to fully comply with the orders or engage in any actionable delaying tactics, the FTC can take them to court to compel compliance.

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[3] *See* Regulations.gov, Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers, FTC-2022-0015 (Feb. 24, 2022), https://www.regulations.gov/docket/FTC-2022-0015. The FTC received 24,100 comments on the Federal Register docket. However, most consist of mass mail campaigns, duplicates, or unrelated comments that are not required to be posted online.

[4] Press Release, Fed. Trade Comm'n, FTC Requests Public Comments on the Impact of Pharmacy Benefit Managers' Practices (Feb. 24, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/02/ftc-requests-public-comments-impact-pharmacy-benefit-managers-practices.

[5] Press Release, Fed. Trade Comm'n, FTC Deepens Inquiry into Prescription Drug Middlemen (May 17, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/05/ftc-deepens-inquiry-prescription-drug-middlemen; Press Release, Fed. Trade Comm'n, FTC Further Expands Inquiry into Prescription Drug Middlemen Industry Practices (June 8, 2023), Launches Inquiry Into Prescription Drug Middlemen Industry (June 7, 2022), https://www.ftc.gov/news-events/news/press-releases/2023/06/ftc-further-expands-inquiry-prescription-drug-middlemen-industry-practices.

Even as FTC staff continues to press the companies to turn over the required documents and data, the team has simultaneously been diligently working through the information and data that we have received, much of it only recently. This includes sifting through, reviewing, and analyzing the millions of documents and several terabytes of data that have been produced to date—a significant and complex undertaking.

This 6(b) inquiry remains one of my top priorities, and I view it as a crucial part of scrutinizing business practices across the pharmaceutical supply chain that can raise drug prices and limit access for patients and that may contribute to the shuttering of independent pharmacies across the country. I share your view that this is a time-sensitive matter of paramount importance, and that we should provide the public and policymakers with as much information about what we are learning and insight about possible competitive harms as quickly as possible. I have asked FTC staff to prioritize doing so to the maximum extent possible, so that dilatory tactics by companies do not prevent us from sharing what we learn in the course of the 6(b) study as quickly as we can. And to be clear: if we find evidence of illegal practices—be it unfair methods of competition or unfair or deceptive practices—I will prioritize bringing the Commission's full authorities to bear.

Separately, I wanted to take the opportunity to ask for your support for two measures essential for a vigorous FTC that can fully protect Americans from unlawful business practices: (1) providing the Commission with the funding necessary for us to fulfill our vital mission; and (2) restoring the Commission's full authority to return money to victimized consumers.[6]

Demands on the Commission continue to grow and strain the agency's resources and capacity as the FTC conducts more 6(b) studies and our merger review and litigation have become more complex, involving cases against some of the most well-resourced companies in the world. While Congress has charged the Commission with a critical mission, our resources have failed to keep pace. We currently employ fewer staffers than we did in the early 1980s, even though our nation's GDP has increased six-fold over the same period, and the Commission has been forced to make difficult decisions about prioritizing investigations. Additional resources would better equip the Commission to fully pursue its mandate and continue the vital work of promoting competition throughout the economy, including in healthcare markets. I look forward to working with Congress to ensure that the Commission has the resources and tools it needs to vigorously protect Americans from unlawful business practices throughout the economy.

With respect to remedies, the Commission's loss of its ability to obtain monetary relief under Section 13(b) has already had a profound effect on consumers and honest businesses: by conservative estimates, this court decision has caused consumers to already lose out on more than $1.5 billion of relief that the agency previously could have obtained under Section 13(b), and the losses increase with each passing day.[7]

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[6] In April 2021 the Supreme Court held that Section 13(b) of the FTC Act does not authorize federal courts to require defendants to pay refunds to harmed consumers or give up the unjust gains they earned from breaking the law. *AMG Capital Mgmt., LLC. v. FTC*, 141 S. Ct. 1341 (2021).

[7] Statement of Commissioner Rebecca Kelly Slaughter Joined by Chair Lina M. Khan Regarding Section 13(b) of the FTC Act (Apr. 28, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Statement%20of%20Comm%27r%20Slaughter%20Joined%20by%20Chair%20Khan%20Regarding%20Section%2013%28b%29%20of%20the%20FTC%20Act_April%202022.pdf.

Thank you again for your letter and continued leadership on this important issue. If you or your staff have any questions, please don't hesitate to contact Jeanne Bumpus, the Director of the FTC's Office of Congressional Relations, at (202) 326-2195.

Sincerely,

Lina Khan

Lina M. Khan
Chair, Federal Trade Commission