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

Office of Commissioner
Melissa Holyoak

Dissenting Statement of Commissioner Melissa Holyoak

In the Matter of the Pharmacy Benefit Managers Report
Matter Number P221200
July 9, 2024

Many Americans struggle to meet everyday household expenses. The costs of healthcare—including for prescription pharmaceuticals—are an important component of these expenses. For Americans with health insurance, there are legitimate concerns that Pharmacy Benefit Managers ("PBMs") may negatively impact the delivery of pharmacy benefits. These firms assemble pharmacy networks, develop drug formularies for their clients, negotiate with pharmaceutical companies for placement on formularies, and provide mail-order and specialty pharmacy services.[1] Concerning reports regarding PBM business practices suggest to me that the public needs a better understanding of the PBM business model—including a detailed review of their pricing decisions and effects on competition.[2] As pharmaceutical prices continue to rise, PBMs' practices warrant further study to better understand their role in healthcare markets. Indeed, in my role as Solicitor General of Utah, I was supportive of a law enforcement action against PBMs, where the facts and law warrant such action.[3]

Historically, the Federal Trade Commission has used its 6(b) authority[4] to study industries and issues, gather information, and issue reports that are "in the public interest."[5] These reports have provided Congress and the public with evidence-based, objective, and economically sound information that can shape the national debate on a wide range of important issues that affect consumers and competition.[6] The standard of these reports has been nothing

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[1] *See* FED. TRADE COMM'N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES (Aug. 2005), *available at* https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitrpt_0.pdf (hereinafter 2005 FTC PBM REPORT).

[2] Various media outlets have described concerns in the PBM industry. *See, e.g.*, Jared S. Hopkins, *Mail-Order Drugs Were Supposed to Keep Costs Down. It's Doing the Opposite*, WALL STREET J. (June 25, 2024), https://www.wsj.com/health/pharma/higher-drug-costs-mail-order-prescription-bf37886f?st=y96f7pnhj50hyp2&reflink=article_gmail_share; *Express Scripts Is Gouging Medicare and Seniors on Generic HIV Prevention Drug*, 12 CAPITOL FORUM 340 (June 25, 2024).

[3] *See* Utah Attorney General, *Division of Consumer Protection Sues Insulin Manufacturer* (Nov. 16, 2023) ("Though the cost of producing diabetes drugs has decreased over time, the lawsuit alleges manufacturers and PBMs worked together to inflate the reported price of these medications up to 1,000 percent over the last decade."), *available at* https://dcp.utah.gov/wp-content/uploads/2023/11/Insulin-Lawsuit-Press-Release-1.pdf.

[4] 15 U.S.C. § 46(b).

[5] 15 U.S.C. § 46(f).

[6] *See e.g.,* 2005 FTC PBM REPORT, *supra* note 1; FED. TRADE COMM'N, PATENT ASSERTION ENTITY ACTIVITY (Oct. 2016), *available at* https://www.ftc.gov/system/files/documents/reports/patent-assertion-entity-activity-ftc-

short of excellence. Indeed, when a Commission report reflects the historical excellence that the public has come to expect, it can generate significant public engagement and facilitate fruitful policy debates.

But today's Report fails to meet that rigorous standard.[7] To begin with, the Report was plagued by process irregularities and concerns over the substance—or lack thereof—of the original order.[8] In fact, the politicized nature of the process appears to have led to the departure of at least one senior leader at the Commission.[9] The concerns over process and substance turned out to be warranted. Rather than generate public engagement and fruitful policy discussion, the Report will only exacerbate ideological schisms and further degrade the legitimacy of the

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study/p131203_patent_assertion_entity_activity_an_ftc_study_0.pdf; FED. TRADE COMM'N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT (Aug. 2011), *available at* https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf.

[7] FED. TRADE COMM'N, PHARMACY BENEFIT MANAGERS: THE POWERFUL MIDDLEMEN INFLATING DRUG COSTS AND SQUEEZING MAIN STREET PHARMACIES, REPORT (July 8, 2024) (hereinafter 2024 REPORT). The Report also fails to meet the stated goals of the PBM Study when the Commission launched it. The press release explained that the study would "scrutinize the impact of vertically integrated pharmacy benefit managers on the access and affordability of prescription drugs." 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. Further, Commissioners Phillips and Wilson explained that they hoped the study would "allow the FTC to update the findings of the 2005 study, a task that will require resources and commitment to finishing the task." Concurring Statement of Commissioners Noah Joshua Phillips and Christine S. Wilson (June 7, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/P221200PhillipsWilsonPBMStatement.pdf (hereinafter Wilson & Phillips June 2022 Statement). As explained below, the Report, beyond conclusory statements, fails to offer any analysis on the affordability of prescription drugs and fails to make any efforts to update or even address the 2005 Report.

[8] The Commission attempted to launch this study in February of 2022 but failed to obtain the necessary votes over the objections of Commissioners Phillips and Wilson, who explained the highly unusual situation:

> In February, the Chair moved a vote on a 6(b) study that was neither comprehensive nor rigorous, and that failed even to examine the topic the agency announced on its website at that time—the competitive impact of PBM contracting practices. It omitted a number of matters raised by proponents of issuing the study, including the impact upon consumers. The study was hastily prepared. Unbeknownst to us at the time, it was modified minutes before it was circulated for a vote. We opposed issuing that study.

Wilson & Phillips June 2022 Statement, *supra* note 7 at 1-2. Further, as Commissioner Phillips explained at the time:

> In the past, I have insisted that 6B studies approach questions comprehensively, rigorously and oppose them when they fail that test. If we hope to use our 6B authority to still study the competitive impact of PBM practices, we have to scope a study that can inform the public about whether and how those practices might impact out of pocket drug costs for consumers. I don't have a basis at this point to believe that the proposed 6B study does that, so I'm going to vote, no.

Remarks of Commissioner Noah Joshua Phillips at Feb. 17, 2022 Open Commission Meeting, Transcript pp. 30-32, https://www.ftc.gov/system/files/ftc_gov/pdf/FTC%20Transcript%20February%2017%2C%202022%20Open%20Commission%20Meeting.pdf. Months later, after Commissioner Bedoya joined the Commission, this current (and heavily modified) study was approved by a unanimous Commission.

[9] It has been reported that the Director of the Bureau of Economics, Marta Wosinska, resigned abruptly the day before the failed vote in February of 2022. Leah Nylen, *FTC's Top Economist Resigned Amid Dispute Over Pharma Study*, POLITICO (Feb. 25, 2022), https://www.politico.com/news/2022/02/25/ftcs-top-economist-resigned-amid-dispute-over-pharma-study-00011878.

Commission. And most importantly, the Report leaves us without a better understanding of the competition concerns surrounding PBMs or how consumers are impacted by PBM practices. I therefore dissent.

To find the benchmark for a high-quality Commission report, the Commission's 2005 report on the PBM industry is a good example.[10] The report, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* ("2005 Report"), was issued by a unanimous Commission[11] and reflects the type of rigor that the public expects from the Commission. The 2005 Report is thorough, objective, relies on empirics and economics, and avoids hyperbolic language.[12] To be sure, as the cost of prescription drugs continues to rise, it is legitimate to ask whether the empirical conclusions of the 2005 Report reflect the current state of our nation's healthcare markets. Indeed, when authorizing the related order for this report, Commissioners Phillips and Wilson hoped today's Report would "allow the FTC to update the findings of the 2005 study."[13] Despite this hope, the Report does not directly engage with the economic findings and conclusions of the 2005 Report and provides no explanation for contradictions between the reports.[14]

Instead, the Commission's method for engaging with the objective findings in the 2005 Report was to add a warning label to the 2005 Report on the Commission's website that says it is "for reference purposes only and should not be assumed to reflect current market conditions."[15] This branding was the result of a Commission statement in July 2023—after the departures of Commissioners Phillips and Wilson—that "discourages reliance on these advocacy letters and

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[10] 2005 FTC PBM REPORT, *supra* note 1.

[11] Press Release, Fed. Trade Comm'n, *FTC Issues Report on PBM Ownership of Mail-Order Pharmacies* (Sep. 6, 2005), https://www.ftc.gov/news-events/news/press-releases/2005/09/ftc-issues-report-pbm-ownership-mail-order-pharmacies ("The Commission vote to issue the report was 4-0.").

[12] *See generally,* 2024 REPORT, *supra* note 7. As far as unsupported hyperbolic language, the Report employs this tactic in the title ("Powerful Middlemen" and "Squeezing Main Street Pharmacies") and then continues throughout. *See, e.g.*, 2024 REPORT, *supra* note 7, at 1 ("wield enormous power" with "dire circumstances"); *id.* at 3 ("dominant PBMs can often exercise significant control"); *id.* at 4 ("proliferation of complex and opaque contract terms"); *id.* at 6 ("enormous healthcare conglomerates that can exercise vast control over huge swaths of the healthcare sector"); *id.* at 48 ("outsized bargaining leverage"); *id.* at 14 ("little choice but to interact with the large, dominant PBMs.").

[13] Concurring Statement of Commissioners Noah Joshua Phillips and Christine S. Wilson (June 7, 2022).

[14] The only reference to the 2005 Report is in a string cite of a footnote for background information. 2024 REPORT, *supra* note 7, at 5 n.13. As for some of the contradictions, see *infra* note 17. The Report also ignores other past Commission findings related to PBMs. For example, at the conclusion of the Commission's investigation into the acquisition of Medco by Express Scripts, the Commission explained:

> Our investigation revealed a competitive market for PBM services characterized by numerous, vigorous competitors who are expanding and winning business from traditional market leaders. The acquisition of Medco by Express Scripts will likely not change these dynamics: the merging parties are not particularly close competitors, the market today is not conducive to coordinated interaction, and there is little risk of the merged company exercising monopsony power.

Statement of the Federal Trade Commission Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc. (Apr. 2, 2012), https://www.ftc.gov/sites/default/files/documents/public_statements/statement-commission-concerning-proposed-acquisition-medco-health-solutions-express-scripts-inc./120402expressmedcostatement.pdf. Again, the competitive conditions may have changed since 2012, but the Report fails to address these Commission findings or explain why, beyond broad assertions of increased verticality and concentration, circumstances are different today.

[15] 2005 FTC PBM REPORT, *supra* note 1, at Cover Page.

Commission reports [including the 2005 Report] until its current PBM study is complete and earlier materials can be reevaluated in light of current market conditions."[16] But the warning label was placed on the 2005 Report *prior* to FTC staff conducting any new market analysis. Assuming conclusions without analysis should not be Commission practice.

Setting these highly irregular events aside, to assert that market conditions have changed is one thing—but to ignore the 2005 Report without conducting a new empirical analysis of market conditions or explaining why the findings, conclusions, and empirical work no longer apply is a different matter entirely. Among other critical conclusions, the Report does not address the seemingly contradictory conclusions in the 2005 Report that PBMs, including vertically owned PBMs, generated cost savings for consumers.[17] In fact, the Report does not present any empirical evidence to rebut the 2005 Report's findings. Chair Khan's statement fails to identify any scholarship or empirical evidence to support overturning and otherwise ignoring the 2005 Report.[18] Instead, she cobbles together structural observations that in her apparent view dispenses with the need to conduct comprehensive and empirical analysis of the PBM market. I disagree. Additionally, we should resist calls to overturn staff's work—regardless of how powerful those calls may be—without unimpeachable evidence that the work is no longer consistent with empirical reality.[19]

Beyond failing to address the 2005 Report, the Report fails to meet the standards of economic rigor expected of Commission reports more generally. The Report provides no analysis of the competitive environment in which PBMs operate or how it has changed in the intervening years since 2005. Nor does it explain how competition among PBMs—even vertically integrated ones—mitigates or exacerbates the role PBMs play in the healthcare markets. Plan sponsors, for example, are sophisticated parties themselves, and evaluating the dynamics between them and PBMs is critical to understanding market realities. Put differently, it is impossible to evaluate the PBMs' conduct in isolation from that of other market participants.

Perhaps most troubling is the Report's failure to examine how PBM practices affect consumer prices. I previously supported law enforcement action against PBMs because I found that, in certain situations, PBMs' conduct had the effect of raising the costs of life-saving prescription drugs for patients. However, the Report does not provide any empirical evidence as

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[16] Fed. Trade Comm'n Statement Concerning Reliance on Prior PBM-Related Advocacy Statements and Reports That No Longer Reflect Current Market Realities at 6 (Jul. 20, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/CLEANPBMStatement7182023%28OPPFinalRevisionsnoon%29.pdf (hereinafter "Statement on Prior PBM-Related Advocacy").

[17] 2005 FTC PBM REPORT at vi ("For large PBMs, average total prices at owned mail-order pharmacies typically were lower than at mail-order pharmacies not owned by the large PBMs."); *id.* at vii ("Retailer-owned PBMs charged lower total average prices for generic and MSB drugs, but not for SSB drugs, at their owned mail-order pharmacies compared to not-owned mail-order pharmacies."); *id.* ("For a common basket of drugs dispensed in December 2003 with the same-sized prescriptions, retail prices typically were higher than mail prices at both large PBMs and retailer-owned PBMs.").

[18] Chair Khan's statement alludes to "research" but cites only articles in the popular press (*e.g.*, New York Times and Wall Street Journal).

[19] If the FTC conducts the type of analysis I am calling for today, then there would be no need to put any so-called warning label on the relevant past report. The new report would speak for itself, explaining how and why things have changed and leave the public with a proper understanding of market realities.

to the state of competition in the prescription drug market but rather simply describes the high-level nature of the healthcare system in the U.S., which is generally characterized with problems of coordination and misalignment of incentives. The Report's failure to offer empirical evidence to support claims about the market power of PBMs is particularly troubling. Even if the Report's assertions of increasing concentration are accurate, increased concentration "does not prove that competition in that market has declined."[20] Though the Report baldly asserts that PBMs "have gained significant power over prescription drug access and prices,"[21] the Report does not present empirical evidence that demonstrates PBMs have market power—*i.e.*, "the ability to raise price profitably *by restricting output*."[22] The Report does provide *two* examples of potentially troubling results.[23] But relying upon *two* examples, without any evidence (empirical or otherwise) that demonstrates they are representative, is not a substitute for rigorous analysis.

Chair Khan's statement attempts to rehabilitate her underwhelming Report by suggesting that my fidelity to good economics and statistics somehow lessens my concern for consumers.[24] Quite the opposite. First, Chair Khan's claim that PBMs are "overcharging by up to 4000 percent the average acquisition cost" attempts to mislead the public into thinking the Report draws any conclusion about the prices patients pay for healthcare. It does not. In fact, the Report says

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[20] Carl Shapiro, *Protecting Competition in the American Economy: Merger Control, Tech Titans, Labor Markets*, 33 J. ECON. PERSP. 69, 76 (2019); *see also* Carl Shapiro, *Antitrust in a Time of Populism*, 61 INT'L J. INDUS. ORG. 714, 724 (2018) ("Sheer size and market power are just not the same thing."); DENNIS W. CARLTON & JEFFREY M. PERLOFF, MODERN INDUSTRIAL ORGANIZATION 292 (4th ed. 2005) ("[P]erhaps the most significant criticism is that concentration itself is determined by the economic conditions of the industry and hence is not an industry characteristic that can be used to explain pricing or other conduct."); Timothy J. Muris, *Improving the Economic Foundations of Competition Policy*, 12 GEO. MASON L. REV. 1, 10 (2003) ("The [structural] paradigm was overturned because its empirical support evaporated."); Fiona Scott Morton, *Modern U.S. Antirust Theory and Evidence Amid Rising Concerns of Market Power and Its Effects*, WASH. CTR. FOR EQUITABLE GROWTH at 26 (2019) ("[I]t is widely understood that either vigorous competition could cause concentration to increase or increased concentration could reduce competition."); Herbert Hovenkamp, *The Looming Crisis in Antitrust Economics*, 101 BOSTON UNIV. L. REV. 489, 489 (2021) ("The pursuit of business concentration or bigness for its own sake will injure both consumers and labor far more than it benefits small business, the intended beneficiaries."); Timothy F. Bresnahan & Peter C. Reiss, *Entry and Competition in Concentrated Markets*, 99 J. POL. ECON. 977, 978 (1991) ("[O]nce a market has between three and five firms, the next entrant has little effect on competitive conduct. . . . These data show that prices fall when the second and third firms enter and then level off.").

[21] 2024 REPORT, *supra* note 7, at 3, 5.

[22] *Ohio v. American Express*, 585 U.S. 529, 549 (2018) (emphasis in original, citations and internal quotation marks omitted); *see also United States v. Grinnell Corp.*, 384 U.S. 563, 571 (1966) (defining "monopoly power as the power to control prices or exclude competition"(citations and internal quotation marks omitted)); Thomas G. Krattenmaker, Robert H. Lande & Steven C. Salop, *Monopoly Power and Market Power in Antitrust Law*, 76 GEORGETOWN L.J. 241, 247 (1987) (defining monopoly power as market power as "the ability to price above the competitive level."). Not only does the Report fail to present evidence of market power or price increases, it ignores contrary evidence. *See, e.g.*, Luke M. Froeb & Mikhael Shor, *Formularies, Rebates, and the Economics of PBM Bargaining* at 58 (Vanderbilt Owen Graduate School of Management Research Paper) (May 8, 2023), *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4442064 ("The empirical evidence is overwhelming. Numerous academic, industry, and government studies show that formularies elicit manufacturer competition and significant price concessions. Studies all support a conclusion that PBMs' negotiating function results in savings of roughly 20% off branded drugs. Further, PBMs have helped drive significant utilization of generic drugs. The resulting savings amount to billions of dollars each year.").

[23] 2024 REPORT, *supra* note 7, at Section III.B.

[24] Chair Khan asserts that I do not consider the two examples to be "worth releasing." At this juncture, she is correct. However, if the Commission is able to verify that they are representative of the broader industry, they certainly will be relevant.

nothing about consumer costs. Nor does the Chair's statement specify who is being overcharged, or who bears what portion of the claimed overcharge (*e.g.*, patients or Plan Sponsors). Second, without understanding whether the examples are representative and without examining the overall price for the services Plan Sponsors purchase—and most importantly, the impact on consumer prices—the Commission has failed to advance the public's understanding of PBM practices. Our job is not to score cheap points for transient political favor—it is to identify and protect against anticompetitive harm.

Applying an "interim" label to the report does not relieve the Commission from its duty as a competition thought leader to generate reports that are rigorous and objective in tone. Nor does the specter of an upcoming Presidential election.[25] If data are still being analyzed, then the Commission should delay the report until the analyses are complete, rather than producing a premature and deficient report.[26] And if parties have failed to produce requested information, then the Commission should utilize the courts to compel production.[27] Publicly browbeating parties for allegedly delinquent productions—in a Commission report—does not advance the debate. Moreover, the Commission's failure to provide a specific date as to when it will release a future report—or provide any discussion of what analysis it intends to do in a future report—suggests to me that this "interim" Report may be the only and final PBM report from this 6(b) study.

Understanding the role that PBMs play in the competitive process in our healthcare system is an important goal. Though facile arguments that rely on ideologically loaded buzzwords such as "control"[28] or "power[29]" may stir emotions and make for entertaining social media posts and television interviews, ideological buzzwords are no substitute for rational, evidence-based research. A proper and thorough study of PBMs would shed light on how well the relevant markets are performing, determine whether PBM business practices increase the cost of prescription drugs for consumers, and inform the Commission's future investigations and enforcement decisions. Moreover, it would illuminate legitimate concerns over PBMs' opaque business model and price-making decisions. But instead of providing this much needed evaluation of a critical area of our healthcare system, the Report fails to provide the guidance the

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[25] *See, e.g.*, Readout of White House Roundtable on Lowering Healthcare Costs and Bringing Transparency to Prescription Drug Middlemen (Mar. 5, 2024), https://www.whitehouse.gov/briefing-room/statements-releases/2024/03/05/readout-of-white-house-roundtable-on-lowering-healthcare-costs-and-bringing-transparency-to-prescription-drug-middlemen/.

[26] A letter from 14 U.S. Senators asking for a "*progress* report" does not justify the publication of a deficient report.

[27] 15 U.S.C. § 50; Fed. Trade Comm'n, *A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority* (May 2021), https://www.ftc.gov/about-ftc/mission/enforcement-authority ("As with subpoenas and CIDs, the recipient of a 6(b) order may file a petition to limit or quash, and the Commission may seek a court order requiring compliance. If a party fails to comply with a 6(b) order after receiving a notice of default from the Commission, the Commission may commence suit in federal court under Section 10 of the FTC Act, 15 U.S.C. Sec. 50.").

[28] 2024 REPORT, *supra* note 7, at 6 ("This increased concentration and vertical integration has resulted in enormous healthcare conglomerates that can exercise vast *control* over huge swaths of the healthcare sector.") (emphasis added).

[29] 2024 REPORT, *supra* note 7, at 3 ("As a result of this high degree of consolidation and vertical integration, the leading PBMs can now exercise significant *power* over Americans' access to drugs and the prices they pay.") (emphasis added).

Commission needs or the public demands. And most importantly, it fails to provide a credible basis for future Commission action that can benefit consumers.[30]

[30] I would encourage the Commission to continue its investigation of PBMs and create a final report that provides an objective assessment of the role of PBMs based upon "current market conditions." Statement on Prior PBM-Related Advocacy, supra note 16 at 6.