

Oral Remarks of Commissioner Christine S. Wilson

Open Commission Meeting on February 17, 2022

Advanced Notice of Proposed Rulemaking Concerning Earnings Claims

6(b) Orders to Study Pharmacy Benefit Managers' (PBMs) Relationships
with Affiliated and Independent Pharmacies

I. Advanced Notice of Proposed Rulemaking Concerning Earnings Claims

Thank you, Madam Chair. And thank you also to Melissa Dickey for her excellent and informative presentation on the FTC's enforcement experience with earnings claims.

I remain skeptical of unleashing a tsunami of rulemakings to address common unfair or deceptive acts or practices. But I do not oppose seeking comment on today's ANPRM for three reasons.

First, we contemplate this rule against the backdrop of *AMG*.¹ The Supreme Court's recent decision limits the Commission's authority to use Section 13(b) of the FTC Act to obtain monetary relief for consumers harmed by misleading earnings claims. A rule would not prevent fraudsters from engaging in deceptive earnings claims, but it would enhance the FTC's ability to strip them of their ill-gotten gains and return that money to consumers. But for *AMG*, I would be skeptical about the need for rules regarding conduct frequently targeted by the FTC's extensive fraud program. That said, a 13(b) fix would be preferable to having the FTC pursue a cornucopia of rules. And if a 13(b) fix is enacted during the pendency of this rulemaking, I likely would ask the Commission to terminate the process.

Second, whether false earnings claims are made by frauds or legitimate businesses, no benefit accrues to consumers or competition. In fact, a 2020 FTC Data Spotlight about "income scams" stated that the median loss associated with business and work-at-home opportunities is \$3,000.² Losses for consumers related to deceptively marketed investment seminars are higher, exceeding \$16,000.³ But even in the face of decades of aggressive enforcement and extensive consumer and business education efforts, deceptive earnings claims persist.⁴

¹ *AMG Capital Mgmt., LLC v. FTC*, 141 S. Ct. 1341 (2021).

² Emma Fletcher, *Income scams: big promises, big losses*, FTC Consumer Protection Data Spotlight (Dec 10, 2020), available at https://www.ftc.gov/system/files/attachments/blog_posts/Income%20scams%3A%20big%20promises%2C%20big%20losses%20/incomescams.final_.correctlink.pdf.

³ *Id.*

⁴ See Notice of Penalty Offense Authority Concerning Money-Making Opportunities, available at <https://www.ftc.gov/MMO-notice>.

Third, consumers cannot analyze the costs and benefits of investing significant resources to pursue these opportunities without accurate representations from sellers. But the true value of these opportunities is best assessed by the entities offering them. As our academic commenters observed, we see significant information asymmetries between consumers and the entities that make earnings claims. The monetary value of an opportunity is likely the central, material claim that consumers consider before spending hundreds, thousands, or even tens of thousands of dollars on financial-improvement opportunities. This ANPRM seeks information on how to ensure that when disclosures are made, they are substantiated.

For these reasons, I do not oppose an ANPRM that explores ways to incentivize establishing a reasonable basis for earnings claims.

II. 6(b) Orders to Study Pharmacy Benefit Managers' (PBMs) Relationship with Affiliated and Independent Pharmacies

First, let me thank the Congressmen and members of the public for their input. As always, hearing directly from stakeholders is highly informative. Second, I want to thank staff and leadership in the Bureau of Economics, the Office of Policy Planning, Mergers I, and the Health Care Division for their efforts. The PBM Team has worked diligently on several iterations of a possible PBM study in recent months. And I know that members of the Chair's Office and staff worked hard in the last couple of days to prepare the latest permutation that I received at 9 pm last night. Unfortunately, I was unable to discuss this proposal with our experienced staff before this open Commission meeting.

As Commissioner Phillips described in his remarks, the latest version of the proposed study is far more comprehensive than what was originally envisioned, for which I am grateful. For example, I do think it is important to examine manufacturer rebate issues, which I have been advocating for months and which the latest version finally adds. But commenters raised other issues today that are not reflected in the current version of the study. It will be useful to reflect on the input from stakeholders to ensure we are addressing the most pertinent concerns. I am confident that the FTC can design a study that employs a data-driven approach to conduct an empirical and objective examination of important questions about competition in the PBM industry. But I am not yet confident that the latest permutation possesses those qualifications.

We have an excellent model to follow. Congress, in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), directed the FTC to study the PBM industry.⁵ Congress identified six questions for the FTC to analyze.⁶ The FTC's Bureau of Economics and our lawyers carefully crafted data requests to support the examination of these

⁵ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, tit. I, § 110, 117 Stat. 2066, 2174 (2003) (codified at 42 U.S.C. § 1395w-101 (Historical and Statutory Note)).

⁶ *Id.*; H.R. CONF. REP. NO. 108-391 at 519-520 (2003).

issues; the 6(b) Special Orders issued in May 2004 contained 34 detailed specifications.⁷ The ultimate result was a rigorous and data-driven report.⁸

Since the FTC issued the 2005 PBM report, the PBM industry has evolved. Mergers and acquisitions have been reversed through spin-offs, and new mergers have led to horizontal consolidation and vertical integration. New entry and emerging technologies have pressured legacy players in the industry. The growth of specialty drugs, manufacturer rebates, DIR fees, and other phenomena have led to increasing complexity in the supply chain. As a testimony to this complexity, purchasers of PBM services frequently retain specialized consultants to guide the process.

During this period, stakeholders have expressed concerns about PBMs. They allege that PBMs:

- Pressure drug makers to hike list prices for favorable formulary placement;⁹
- Design formularies to limit lower-rebate drugs;¹⁰
- Ignore high list prices in favor of generous rebates, discounts, and fees or repackage drugs as a method to increase prices;¹¹

⁷ Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies, Fed. Trade Comm'n at xxi & appendices A & C (Aug. 2005), https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitrpt_0.pdf.

⁸ *Id.*

⁹ Press Release, United States Senate Committee on Finance, Grassley, Wyden Release Insulin Investigation, Uncovering Business Practices Between Drug Companies and PBMs That Keep Prices High (Jan. 14, 2021), <https://www.finance.senate.gov/chairmans-news/grassley-wyden-release-insulin-investigation-uncovering-business-practices-between-drug-companies-and-pbms-that-keep-prices-high>.

¹⁰ Press Release, Senator James Lankford, Lankford Joins Grassley to Require FTC Study of the Role, Behavior, and Recent Merger Activity of Prescription Drug Supply Chain Middlemen (April 3, 2019), <https://www.lankford.senate.gov/news/press-releases/lankford-joins-grassley-to-require-ftc-study-of-the-role-behavior-and-recent-merger-activity-of-prescription-drug-supply-chain-middlemen>.

¹¹ Josh Cohen, *Capital Rx Aims To Disrupt The PBM Market*, FORBES (Feb. 2, 2022), <https://www.forbes.com/sites/joshuacohen/2022/02/02/capital-rx-aims-to-disrupt-the-pbm-market/?sh=1d7494d319ae>; United States Senate Finance Committee, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug, Staff Report at 88 (Jan. 14, 2021) [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf); Rachel Garfield, Rachel Dolan, & Elizabeth Williams, Costs and Savings under Federal Policy Approaches to Address Medicaid Prescription Drug Spending, Kaiser Family Foundation (June 22, 2021), [https://www.kff.org/medicaid/issue-brief/costs-and-savings-under-federal-policy-approaches-to-address-medicaid-prescription-drug-spending/#:~:text=Spread%20pricing%20refers%20to%20the,a%20%E2%80%9Creasonable%E2%80%9D%20administrative%20fee](https://www.kff.org/medicaid/issue-brief/costs-and-savings-under-federal-policy-approaches-to-address-medicaid-prescription-drug-spending/#:~:text=Spread%20pricing%20refers%20to%20the,a%20%E2%80%9Creasonable%E2%80%9D%20administrative%20fee;); American Hospital Association, Will Startup PBMs Drive Drug Price Transparency? (Nov. 2, 2021), <https://www.aha.org/aha-center-health-innovation-market-scan/2021-11-02-will-startup-pbms-drive-drug-price-transparency>.

- Steer patients to vertically integrated pharmacies and mandate the use of mail order pharmacy services against patient wishes;¹²
- Require prior authorization and step therapy to the point of delaying or denying patient access to needed medication;¹³
- Drive independent pharmacies out of business, thereby creating pharmacy deserts;¹⁴ and
- Lessen competition through mergers.¹⁵

The PBMs respond that many of these accusations are baseless, and point to data demonstrating that PBMs:

- Receive compensation primarily through fees from plan sponsors, not by keeping a portion of rebates;¹⁶
- Pass through an increasing percentage of rebates to health plans;¹⁷
- Reduce plan sponsor and consumer drug spending;¹⁸
- Have significantly lower margins than the drug manufacturers that capture a large proportion of drug supply chain profits;¹⁹
- Do not reimburse independent pharmacies at lower rates than PBM-owned pharmacies;²⁰

¹² NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, PHARMACY BENEFIT MANAGERS: MAIL ORDER SERVICES 101, http://www.ncpa.co/pdf/leg/aug11/pbm_mailorder101.pdf.

¹³ Robert Kings, *PBM industry report claims greater use of tools can generate \$1T in savings over next decade*, FIERCE HEALTHCARE (Fe. 19, 2020), <https://www.fiercehealthcare.com/payer/pbm-industry-report-claims-greater-use-tools-can-generate-1t-savings-over-next-decade>.

¹⁴ Markian Hawryluk, *How Rural Communities Are Losing Their Pharmacies*, KAISER HEALTH NEWS (Nov. 15, 2021), <https://khn.org/news/article/last-drugstore-how-rural-communities-lose-independent-pharmacies/>.

¹⁵ Press Release, Senator James Lankford, Lankford Joins Grassley to Require FTC Study of the Role, Behavior, and Recent Merger Activity of Prescription Drug Supply Chain Middlemen (April 3, 2019), <https://www.lankford.senate.gov/news/press-releases/lankford-joins-grassley-to-require-ftc-study-of-the-role-behavior-and-recent-merger-activity-of-prescription-drug-supply-chain-middlemen>.

¹⁶ U.S. GOVERNMENT ACCOUNTABILITY OFFICE, MEDICARE PART D: USE OF PHARMACY BENEFIT MANAGERS AND EFFORTS TO MANAGE DRUG EXPENDITURES AND UTILIZATION, <https://www.gao.gov/products/gao-19-498> (analyzing Medicare Part D).

¹⁷ Susan K. Urahn et al., *The Prescription Drug Landscape, Explored*, PEW CHARITABLE TRUSTS (March 2019), <https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored> (“PBMs passed through 78 percent of manufacturer rebates to health plans in 2012 and 91 percent in 2016.”).

¹⁸ Press Release, Pharmaceutical Care Management Association, PBMs Will Save Health Plan Sponsors and Consumers More Than \$1 Trillion on Prescription Drugs (Feb. 19, 2020), <https://www.pcmanet.org/pbms-will-save-health-plan-sponsors-and-consumers-more-than-1-trillion-on-prescription-drugs/>; PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, THE VALUE OF PBMS <https://www.pcmanet.org/value-of-pbms/>.

¹⁹ COALITION FOR AFFORDABLE PRESCRIPTION DRUGS, U.S. RETAIL DRUG EXPENDITURES, <https://www.affordableprescriptiondrugs.org/app/uploads/2020/05/drug-supply-chain-expenditures.png>.

²⁰ OHIO DEPARTMENT OF MEDICAID, EXECUTIVE SUMMARY: REPORT ON MCP PHARMACY BENEFIT MANAGER PERFORMANCE at 5 (June 15, 2018), <https://www.fdanews.com/ext/resources/files/2018/06-25-18-Ohio.pdf?1529950959>.

- Have not impacted independent pharmacy margins, which have remained relatively flat pre-Covid from 2010-2019;²¹ and
- Have not led to a decrease in the number of independent pharmacies, which have remained relatively flat pre-Covid from 2015-2019.²²

Given the concerns that have been raised about PBMs, members of Congress have introduced legislation directing the FTC to again examine the PBM industry. For example, Congresswoman Cathy McMorris Rodgers sponsored legislation asking the FTC to analyze whether PBMs charge payers a higher price than the reimbursement rate at which PBMs charge competing pharmacies, steer patients to PBM-owned pharmacies, use proprietary data of competitors for anticompetitive purposes, and design formularies to boost usage of higher cost prescriptions.²³ Senator Chuck Grassley has sponsored legislation in the Senate with the same requests.²⁴

I support an FTC analysis of this industry. In fact, one of the first staff briefings I requested as a Commissioner focused on PBMs. If there is anticompetitive conduct in the supply chain for prescription drugs, I want to know about it. The FTC has a long history of investigating health care concerns on both the consumer protection and competition sides of the house. It has maintained this focus because health care represents a large and growing percentage of our economy, and these expenses are felt by consumers every day. At an open Commission meeting on October 21, 2021, we heard from patients struggling with skyrocketing insulin costs.²⁵ Insulin is only one example; total retail prescription drug spending in the U.S. reached \$348.4 billion in 2020.²⁶ PBMs play an important role in the drug distribution chain; studying this component of the supply chain is critical to informed policy and law enforcement.

Through careful preparation and a bipartisan effort, I expect the FTC to launch a 6(b) study on the PBM industry. I certainly have questions I would like answered. How do patient experiences – including price, quality, convenience, and access – vary depending on whether customers fill their prescriptions at independent pharmacies, PBM-owned chains, or non-PBM-owned chains? What factors drive formulary design? What mechanisms do manufacturers use to disincentivize PBMs from placing their rivals on formularies? And using retrospectives, I would

²¹ NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, 2020 NCPA DIGEST at 7 <https://ncpa.org/sites/default/files/2020-10/2020-Digest.pdf>.

²² *Id.* at 9.

²³ Lower Costs, More Cures Act of 2021, H.R. 19, 117th Cong. § 113 (2021).

²⁴ Prescription Pricing for the People Act of 2021, S. 1388, 117th Cong. (2021).

²⁵ Fed. Trade Comm'n, Transcript FTC Open Commission Meeting (Oct. 21, 2021), https://www.ftc.gov/system/files/documents/public_events/1597522/20211021opencommissionmeetingtranscript.pdf.

²⁶ U.S. CENTERS FOR MEDICARE & MEDICAID SERVICES, NHE FACT SHEET, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet>.

like to example the impact of PBM mergers, both vertical and horizontal, on competition and consumers.

But we must use our significant authority and scarce resources judiciously. I have observed previously that stakeholders frequently seek to coopt the government in their battles against rivals.²⁷ I am wary of having the FTC used as a pawn to boost the profitability of certain sectors, or to insulate them from competition.²⁸ It is not the role of the FTC to pick winners and losers. Our mission is to protect consumers and competition, not competitors. For these reasons, the FTC must develop a 6(b) study with an objective design and credible guarantees that an expert-driven process will produce a data-driven report. I look forward to working with Chair Khan, my colleagues, and our experienced staff to make this happen.

Finally, it will be useful to reflect on the input we received today from stakeholders to ensure we are addressing the most pertinent concerns. As I noted, commenters highlighted important issues today that are not covered by the study as currently drafted. I look forward to discussing the study with our staff and working with my colleagues to get the study across the finish line.

²⁷ Oral Remarks of Commissioner Christine S. Wilson at the Open Commission Meeting on September 15, 2021, https://www.ftc.gov/system/files/documents/public_statements/1598839/annual_regulatory_plan_and_semi-annual_regulatory_agenda_wilson_final.pdf.

²⁸ Dissenting Statement of Commissioner Christine S. Wilson on the Annual Regulatory Plan and Semi-Annual Regulatory Agenda (December 10, 2021), https://www.ftc.gov/system/files/documents/public_statements/1598839/annual_regulatory_plan_and_semi-annual_regulatory_agenda_wilson_final.pdf.