MEMORANDUM

TO: **REPUBLICAN MEMBERS OF THE SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION**

FROM: **COMMERCE COMMITTEE STAFF**

DATE: **MAY 2, 2022**

RE: **SUBCOMMITTEE ON CONSUMER PROTECTION, PRODUCT SAFETY, AND DATA SECURITY HEARING: "ENSURING FAIRNESS AND TRANSPARENCY IN THE MARKET FOR PRESCRIPTION DRUGS"**

On Thursday, May 5, 2022, at 10:00 a.m. in room 253 of the Russell Senate Office Building, the Senate Committee on Commerce, Science, and Transportation Subcommittee on Consumer Protection, Product Safety, and Data Security will hold a hearing entitled, "Ensuring Fairness and Transparency in the Market for Prescription Drugs." Chair Cantwell will preside.

The following witnesses will testify before the Committee:

- Mr. David Balto, Attorney, Law Offices of David A. Balto
- Ms. Robin Feldman, Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson '54 Distinguished Professor of Law Chair, and Director of the Center for Innovation, UC Hastings Law
- Mr. Craig Garthwaite, Professor of Strategy, Herman Smith Research Professor in Hospital and Health Services Management, and Director of Healthcare, Northwestern Kellogg
- Mr. JC Scott, President and Chief Executive Officer, Pharmaceutical Care Management Association

INTRODUCTION

Pharmacy benefit managers (PBMs) have been described as "the black box" in the market for prescription drugs. Studies suggest that how PBMs operate, and the lack of transparency about how they operate, have contributed to higher drug prices for consumers. This hearing will examine steps Congress can take to increase transparency in drug prices, require PBMs to operate fairly, and ensure the Federal Trade Commission has the authority it needs to stop unfair or anticompetitive practices in the prescription drug market.

BACKGROUND

Prescription drug spending has increased in recent years. In the United States, drug prices are 256 percent higher, on average, when compared to other developed nations with comparable economies.[1] Nationwide inflation-adjusted spending on prescription drugs has increased from

[1] The Rand Corporation, *Prescription Drug Prices in the United States are 2.56 Times Those in Other Countries* (2021) www.rand.org/pubs/research_reports/RR2956.html

$30 billion in 1980 to $355 billion in 2018.[2] The average net price of a prescription fell from $57 in 2009 to $50 in 2018 in the Medicare Part D program and from $63 to $48 in the Medicaid program.[3] This reflects an increase in the use of generic brand drugs. The average net price of brand-name drugs has increased over that period, from $149 to $353 in Medicare Part D and $147 to $218 in Medicaid.[4]

Pharmacy Benefits Managers (PBM)

PBMs are intermediaries in the payment flow system of the prescription drug supply chain and negotiate prices but do not distribute or dispense the products.[5] PBMs manage prescription drug benefits on behalf of health insurers, Medicare Part D drug plans, large employers, and other payers. Because of this, PBMs have significant influence in determining drug costs for insurers, patient access to medications, and pay for pharmacies.[6] In recent years, PBMs' role in rising prescription drug prices has been called into question.

PBMs produce formularies that outline medications covered by health insurers. Formularies influence which drugs individuals have access to and determine out-of-pocket costs.[7] PBMs generate profit through five income streams: rebate sharing, pharmacy spread, PBM-owned pharmacies, administrative fees, and direct and indirect remuneration (DIR) fees.[8]

In a market with smaller insurers and more competition, PBMs help insurers get beneficial drug payment arrangements.[9] With insurance market consolidation in recent years, insurers have begun to create their own PBMs. This vertical integration has led to higher rebates on drugs, pushing drug prices higher.[10] Insurers' profits are limited by the Medical Loss Ratio provision in the Affordable Care Act, which allows insurers to keep 20 percent of each premium to cover marketing, profits, salaries, administrative costs, and agent commissions.[11] However, PBM margins are not limited by any federal statute.

Pharmaceutical Market Consolidation

Currently, the United States is experiencing a wave of mergers and increased concentration in the pharmaceutical industry.[12] Between 1995 and 2015, the leading 60 pharmaceutical

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[2] Prescription Drugs: Spending, Use, and Prices, Congressional Budget Office (January 2022)
[3] *Id.*
[4] *Id.*
[5] Pharmacy Benefit Managers and Their Role in Drug Spending, *The Commonwealth Fund,* (April 22, 2019) https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending
[6] *Id.*
[7] Du, Jack. Pharmacy Benefit Management (PMB) Industry, *Investopedia.* (January 22, 2022) https://www.investopedia.com/articles/markets/070215/what-pharmacy-benefit-management-industry.asp
[8] How PBMs Make Money: PBM Practices & Profits, *RX Safe.* https://info.rxsafe.com/blog/pbms-make-money-infographic
[9] *Id.*
[10] Paavola, Alia. The Top Insurers All Have PBMs: Here's Who They Are. *Becker's Hospital Review.* (April 10, 2019) https://www.beckershospitalreview.com/pharmacy/the-top-insurers-all-have-pbms-here-s-who-they-are.html
[11] Medical Loss Ratio (MLR). HealthCare.gov, https://www.healthcare.gov/glossary/medical-loss-ratio-mlr/
[12] Steger, Craig. Pharma Services Sector Poised for Continued Growth and Consolidation, *BioPharm International*. (August 5, 2021) https://www.biopharminternational.com/view/pharma-services-sector-poised-for-continued-growth-and-consolidation

companies merged to just 10.[13] Today, four pharmaceutical companies produce more than 50 percent of all generic drugs.[14] Large pharmaceutical companies now outsource new high-risk research and early drug development to start-ups and small pharmaceutical firms.[15]

In the current industry structure, large, powerful drug manufacturers are responsible for shuttling new drugs through regulatory processes, which often leaves smaller, innovative companies with no choice other than to partner with or be acquired by these large manufacturers.[16] The results of pharmaceutical consolidation is a decrease in new drug innovation, fewer treatment options, and higher prices.[17]

Federal Trade Commission (FTC)

On February 17, the FTC voted to carry out an investigation into anti-competitive practices within PBMs. The voted ended in a 2-2 split decision meaning the FTC will not carry out an investigation.[18] On February 24, the FTC issued a Request for Information on PBMs' practices, including contract terms, rebates, fees, pricing policies, steering methods, conflicts of interest, and consolidation.[19] The FTC's stated purpose for issuing this RFI is to examine how large, vertically integrated PBMs are affecting drug affordability and access. On April 13, the FTC extended the public comment period to May 25, 2022. [20]

[13] Feldman, Robin. Drug Companies Keep Merging. Why That's Bad for Consumers and Innovation. *The Washington Post.* (April 6, 2021) https://www.washingtonpost.com/outlook/2021/04/06/drug-companies-keep-merging-why-thats-bad-consumers-innovation/

[14] *Id.*

[15] *Id.*

[16] How Mergers and Acquisitions of Pharma Companies affect Regulatory Affairs?, BIOMAPAS, https://www.biomapas.com/how-mergers-and-acquisitions-of-pharma-companies-affect-regulatory-affairs/

[17] *Id.*

[18] Cohen, Joshua, FTC Lets PBMs Off The Hook: For Now It Won't Pursue A Formal Inquiry On Alleged PBM Anti-Competitive Practices, *Forbes* (March 1, 2022) https://www.forbes.com/sites/joshuacohen/2022/03/01/ftc-lets-pbms-off-the-hook-for-now-it-wont-pursue-a-formal-inquiry-on-pbm-anti-competitive-practices/?sh=40a2a6c44c16

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

[20]Federal Trade Commission Extends Public Comment Period for Request for Information on Impact of Pharmacy Benefit Managers, Press Release, Federal Trade Commission, April 13, 2022 https://www.ftc.gov/news-events/news/press-releases/2022/04/federal-trade-commission-extends-public-comment-period-request-information-impact-pharmacy-benefit

WITNESS BIOGRAPHIES:

David Balto: David Balto is an Attorney at The Law Offices of David Balto, where he provides counsel on antitrust law. Prior to being a sole practitioner, Mr. Balto was a Partner at Robins Kaplan LLP and a Partner at White & Case LLP. Mr. Balto joined private practice from the FTC, where he worked for nearly a decade. He began his career at the FTC in the Office of Planning and Evaluation, served as an Attorney Advisor to Chairman Robert Pitofsky from 1995 to 1997, and was the Policy Director of the Bureau of Competition from 1998 to 2001. Mr. Balto joined the FTC from the Department of Justice, where he was a Trial Attorney in the Antitrust Division. Mr. Balto began his legal career as an Associate at Sutherland, Ashland, and Brennan.

Mr. Balto received a B.A. from the University of Minnesota, and a J.D. from the Northeastern University School of Law.

Robin Feldman: Robin Feldman is the Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation at the University Of California Hastings School Of Law. Professor Feldman has published over 60 scholarly articles, primarily focused on intellectual property, health, and medicine. She has authored four books, the most recent being *Drugs, Money, & Secret Handshakes: The Unstoppable Growth of Prescription Drug Prices,* which was published in 2019. Prior to being a Professor at UC Hastings School of Law, she was a Lecturer at Stanford Law School. She served as a Law Clerk for The Honorable Joseph Sneed of the U.S. Court of Appeals for the Ninth Circuit.

Professor Feldman received a B.A. from Stanford University and a J.D. from Stanford Law School.

Craig Garthwaite: Craig Garthwaite is the Herman R. Smith Research Professor in Hospital and Health Services, a Professor of Strategy, and the Director of the Program on Healthcare at Northwestern University’s Kellog School of Management. Professor Garthwaite has written over 30 articles, primarily focused on the interaction of private healthcare firms and public polices and pricing and innovation in the biopharmaceutical industry. Professor Garthwaite joined Northwestern University’s faculty immediately after receiving his Ph.D. as a Senior Lecturer of Management and Strategy. Prior to receiving his Ph.D., he was an Economist at Public Sector Consultants and Director of Research and Chief Economist at the Employment Policies Institute.

Professor Garthwaite received a B.A. from the University of Michigan, a M.P.P. from the Gerald R. Ford School of Public Policy at the University of Michigan, and a M.A. and Ph.D. in Economics from the University of Maryland, College Park.

JC Scott: JC Scott is the President and Chief Executive Officer of the Pharmaceutical Care Management Association (PCMA). Mr. Scott joined PCMA in 2018. Previously, he was the Chief Advocacy Officer and Head of External Affairs for the Advanced Medical Technical Association (AdvaMed). Prior to AdvaMed, he was the Senior Vice President

for Federal Relations form the American Council of Life Insurers. Prior to his work in the private sector, Mr. Scott served as Deputy Policy Director for the House Republican Conference, Committee Associate with the Select Committee on Homeland Security, and Legislative Director for former-Representative Deborah Pryce (R-OH).

Mr. Scott received a B.A. from Duke University and a J.D. from Georgetown University Law Center.