

Federal Trade Commission Statement Concerning Reliance on Prior PBM-Related Advocacy Statements and Reports That No Longer Reflect Current Market Realities

The Federal Trade Commission (“FTC” or “Commission”) cautions against reliance on certain of its prior advocacy statements and reports relating to the pharmacy benefit manager (“PBM”) market. The Commission is currently engaged in a major study of the PBM industry, undertaken in large part due to the Commission’s recognition that substantial changes have taken place over the last two decades.¹ This study will enable the Commission to consider the extent to which prior conclusions about the PBM industry remain valid. Accordingly, until it is completed, reliance on the Commission’s conclusions in certain prior statements and reports may be misplaced.

The eleven advocacy letters and reports enumerated below on which the FTC now warns against reliance were published or issued between 2004 and 2014. During that period, the FTC took the position that certain state and federal proposals to increase PBM transparency could undermine competitive processes.² However, the PBM industry has changed significantly over the last two decades with increased vertical integration and horizontal concentration; the growth

¹ See 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>.

² One Commissioner notably dissented from these policy positions on the basis of changing PBM market dynamics driven by consolidation. See Letter from Comm’r Julie Brill to Larry Good, Executive Secretary ERISA Advisory Council, U.S. Dep’t of Labor (Aug. 19, 2014), <https://www.ftc.gov/system/files/documents/public-statements/579031/140819erisaletter.pdf> (dissenting due to concerns that staff’s conclusions were based on outdated information). See also Dissenting Statement of Comm’r Julie Brill Concerning the Proposed Acquisition of Medco Health Solutions Inc. by Express Scripts, Inc., FTC File No. 110-0210 (Apr. 2, 2012), https://www.ftc.gov/sites/default/files/documents/public_statements/dissenting-statement-commissioner-julie-brill/120402medcobrillstatement.pdf.

of PBM rebates, list prices and DIR fees;³ and the expiration of prior FTC Consent Orders.⁴ The largest PBMs are now fully vertically integrated upstream with the largest health insurance companies and downstream with retail, mail order and specialty pharmacies.⁵

Since 2015, while largely refraining from issuing public policy statements, the FTC has closely followed the PBM industry and begun considering action given changes and emerging trends in the industry. In November 2017, the FTC held a workshop entitled “Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics,” which included numerous calls for a formal study of the PBM industry.⁶

The Commission’s current PBM study was unanimously approved in June 2022⁷ and reflects significant concerns about how current market structures and business practices may

³ CMS estimates that pharmacy DIR fees have increased 91,500% between 2010 and 2019. CENTERS FOR MEDICARE & MEDICAID SERVICES, DEP’T OF HEALTH AND HUMAN SERVICES, FY2022 CMS CONGRESSIONAL JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEE, at 242, <https://www.cms.gov/files/document/fy2022-cms-congressional-justification-estimates-appropriations-committees.pdf> (“Data that Part D sponsors submit to CMS as part of the annual required reporting of DIR show that pharmacy price concessions, net of all pharmacy incentive payments, have grown faster than any other category of DIR received by sponsors and PBMs. This means that pharmacy price concessions account for a larger share than ever before of reported DIR and thus a larger share of total gross drug costs in the Part D program. The data show that pharmacy price concessions, net of all pharmacy incentive payments, grew more than 91,500 percent between 2010 and 2019.”).

⁴ *In re Eli Lilly & Co., Inc.*, 120 FTC 243 (July 28, 1995) (consent order), https://www.ftc.gov/sites/default/files/documents/commission_decision_volumes/volume-120/ftc_volume_decision_120_july_-_december_1995pages_206_-_311.pdf#page=38; *In re Merck & Co., Inc.*, and Merck-Medco Managed Care, LLC, FTC File No. 9510097 (Aug. 27, 1998) (consent order), <https://www.ftc.gov/sites/default/files/documents/cases/1998/08/9510097agr.htm>.

⁵ HOUSE COMM. ON OVERSIGHT AND REFORM MINORITY STAFF REPORT, A VIEW FROM CONGRESS: ROLE OF PHARMACY BENEFIT MANAGERS IN PHARMACEUTICAL MARKETS (2021), at 6–7, <https://oversight.house.gov/wp-content/uploads/2021/12/PBM-Report-12102021.pdf>. These Payer-PBM-Pharmacy entities control or influence which drugs are covered on formularies, which pharmacies are included within a patient’s network, as well as the negotiated price and cost-sharing that determines how much payers and patients ultimately pay for medicine at the pharmacy counter. *See generally Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers*, Senate Fin. Comm., 118th Cong. (2023) (statement of Jonathan Levitt, Counsel, Frier Levitt) https://www.finance.senate.gov/imo/media/doc/-Jonathan%20Levitt%20Testimony%20US%20Senate%20Committee%20on%20Finance%20-%20Frier%20Levitt%20-%20March%202023_Redacted1.pdf (explaining how PBMs influence different aspects of the pharmaceutical system).

⁶ Press Release, Fed. Trade Comm., Understanding Competition in Prescription Drug Markets Entry and Supply Chain Dynamics (Nov. 8, 2017), <https://www.ftc.gov/news-events/events/2017/11/understanding-competition-prescription-drug-markets-entry-supply-chain-dynamics>.

⁷ June 7, 2022 FTC Press Release, *supra* note 1.

undermine patients, pharmacies, and fair competition. The study is a culmination of the FTC's long-standing and bipartisan interest in promoting competition in pharmaceutical markets,⁸ its concerns about how PBMs may be using market power to undermine competition from independent pharmacies,⁹ and its concerns about the role of PBMs in determining the prices consumers pay for prescription drugs,¹⁰ including the impact of PBM rebates.¹¹

Despite these changes in market realities, advocates continue to cite prior Commission work in opposition to efforts by lawmakers, enforcers, and regulators to mandate PBM

⁸ See Press Release, Fed. Trade Comm'n, FTC and Justice Department to Hold Two-Day Virtual Public Workshop Examining Antitrust Enforcement in the Pharmaceutical Industry (May 31, 2022), <https://www.ftc.gov/news-events/news/press-releases/2022/05/ftc-justice-department-hold-two-day-virtual-public-workshop-examining-antitrust-enforcement>; FED. TRADE COMM'N, OVERVIEW OF FTC ACTIONS (Jan. 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Overview-Pharma.pdf (providing general overview of FTC healthcare actions).

⁹ See Remarks of Chair Lina M. Khan before the American Economic Liberties Project and the National Community Pharmacists Association: How Pharmacy Benefit Managers Impact Drug Prices, Communities, and Patients (June 22, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Remarks-Lina-Khan-Economic-Liberties-National-Community-Pharmacists-Association.pdf.

¹⁰ Previous discussions of the potential for pharmaceutical rebate agreements to foreclose competition were discussed at an FDA-FTC Workshop on a Competitive Marketplace for Biosimilars and an FTC workshop on prescription drug markets. See *Public Workshop: FDA/FTC Workshop on a Competitive Marketplace for Biosimilars*, U.S. Food and Drug Admin. (Mar. 9, 2020), <https://www.fda.gov/drugs/news-events-human-drugs/public-workshop-fdaftc-workshop-competitive-marketplace-biosimilars-03092020>; Nov. 8, 2017 FTC Press Release, *supra* note 6.

¹¹ In May 2021, the FTC sent a report to Congress about the effects of so-called rebate walls, in which a dominant pharmaceutical manufacturer uses rebate strategies to maintain market power, give its products preferred status on drug formularies, and prevent sales of competing products. FED. TRADE COMM'N, REPORT ON REBATE WALLS (May 2021), https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-report-rebate-walls/federal_trade_commission_report_on_rebate_walls.pdf. In June 2022, the Commission issued a policy statement regarding rebates and fees paid by drug manufacturers to PBMs and other intermediaries to favor high-cost drugs in a way that ultimately increases patients' costs and stifles competition, especially generic and biosimilar drugs. Fed. Trade Comm'n, Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower Cost Drug Products, FTC File No. P221201 (June 16, 2022), <https://www.ftc.gov/legal-library/browse/policy-statement-federal-trade-commission-rebates-fees-exchange-excluding-lower-cost-drug-products>. And in May 2023, the Commission voted to block pharmaceutical giant Amgen's \$27.8 billion acquisition of Horizon Therapeutics plc over concerns the deal would allow Amgen to use rebates on its existing blockbuster drugs to pressure insurers and PBMs to favor Horizon's two monopoly products. Press Release, Fed. Trade Comm'n, FTC Sues to Block Biopharmaceutical Giant Amgen from Acquisition That Would Entrench Monopoly Drugs Used to Treat Two Serious Illnesses (May 16, 2023), <https://www.ftc.gov/news-events/news/press-releases/2023/05/ftc-sues-block-biopharmaceutical-giant-amgen-acquisition-would-entrench-monopoly-drugs-used-treat>.

transparency requirements.¹² We believe this reliance is misplaced in light of significant changes in market conditions. Pharmaceutical markets have evolved, and the Commission is concerned that these older statements, studies, and reports may no longer reflect current market realities.

Accordingly, the FTC warns against relying on the following nine Commission advocacy letters advocating against proposals to increase regulatory oversight and transparency of PBMs:

- April 8, 2004 letter to Rhode Island Attorney General Patrick C. Lynch and Rhode Island State Senator Juan M. Pichardo regarding Rhode Island General Assembly Bills e 2004-H 7042, 2004-H 7047, 2004-H 7129, 2004-H 7131, 2004-H 7417, 2004-S 2015, and 2004-S 2140;¹³
- September 7, 2004 letter to California Assembly Member Greg Aghazarian regarding California Assembly Bill No. 1960;¹⁴
- March 8, 2005 letter to North Dakota State Senator Richard L. Brown regarding North Dakota House Bill 1332;¹⁵

¹² See Complaint and Prayer for Declaratory and Injunctive Relief at 19, *Pharmaceutical Care Management Association v. HHS et al.* (Jan. 11, 2021) (citing Sept. 7, 2004 Letter from FTC Staff to Greg Aghazarian, California State Assembly Member, California State Assembly (Sept. 7, 2004), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-comment-hon.greg-aghazarian-concerning-ca.b.1960-requiring-pharmacy-benefit-managers-make-disclosures-purchasers-and-prospective-purchasers/v040027.pdf); Pharmaceutical Care Management Association, Public Comment in Response to FTC Solicitation for Public Comments on the Business Practices of PBMs (May 25, 2022), <https://www.pcmagnet.org/wp-content/uploads/2022/05/PCMA-FTC-Public-Comment-Letter-May-25-20221.pdf> (citing Letter from FTC Staff to Hon. James L. Seward, New York Senator, 51st District (Mar.31, 2009), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf).

¹³ Letter from FTC Staff to Patrick C. Lynch, Attorney General, State of Rhode Island and Providence Plantations, and Juan M. Pichardo, Senate Deputy Majority Leader, Rhode Island Senate (Apr. 8, 2004), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-hon.patrick-c.lynch-and-hon.juan-m.pichardo-concerning-competitive-effects-ri-general-assembly-bills-containing-pharmaceutical-freedom/ribills.pdf.

¹⁴ Letter from FTC Staff to Greg Aghazarian, California State Assembly Member, California State Assembly (Sept. 7, 2004), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-comment-hon.greg-aghazarian-concerning-ca.b.1960-requiring-pharmacy-benefit-managers-make-disclosures-purchasers-and-prospective-purchasers/v040027.pdf.

¹⁵ Letter from FTC Staff to Richard L. Brown, Senator, North Dakota Senate (Mar. 8, 2005), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-richard-l.brown-concerning-north-dakota-h.b.1332-regulate-contractual-relationship-between-pharmacy-benefit-managers-and-covered-entities/050311northdakotacomnts.pdf.

- October 2, 2006 letter to Commonwealth of Virginia Delegate Terry G. Kilgore regarding Virginia House Bill No. 945;¹⁶
- April 17, 2007 letter to New Jersey Assembly Member Nellie Pou regarding Assembly Committee Substitute for Assembly No. 320;¹⁷
- March 31, 2009 letter to New York State Senator James L. Seward regarding New York Senate Bill 58;¹⁸
- March 22, 2011 letter to Mississippi State Representative Mark Formby regarding Mississippi Senate Bill 2445;¹⁹
- March 4, 2014 letter to Centers for Medicare & Medicaid Services (CMS) regarding Contract Year 2015 Policy and Technical Changes to Medicare Advantage and Medicare Prescription Drug Benefit Programs;²⁰ and
- August 19, 2014 letter to the U.S. Department of Labor’s ERISA Advisory Council regarding PBM compensation and fee disclosures.²¹

In addition to these nine documents, the FTC cautions against reliance on two reports: the Commission’s July 2004 joint report with the Department of Justice entitled “Improving Healthcare: A Dose of Competition” and the Commission’s 2005 study entitled “Pharmacy

¹⁶ Letter from FTC Staff to Terry G. Kilgore, Member Commonwealth of Virginia House of Delegates (Oct. 2, 2006), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-hon.terry-g.kilgore-concerning-virginia-house-bill-no.945-regulate-contractual-relationship-between-pharmacy-benefit-managers-and-both-health-benefit/v060018.pdf.

¹⁷ Letter from FTC Staff to Nellie Pou, Assembly Member, 35th District, and Appropriations Committee Chair, New Jersey General Assembly (Apr. 17, 2007), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-hon.nellie-pou-concerning-new-jersey.b.310-regulate-contractual-relationships-between-pharmacy-benefit-managers-and-health-benefit-plans/v060019.pdf.

¹⁸ Letter from FTC Staff to Hon. James L. Seward, New York Senator, 51st District (Mar.31, 2009), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf.

¹⁹ Letter from FTC Staff to Hon. Mark Formby, Representative, Mississippi House of Representatives (Mar. 22, 2011), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-letter-honorable-mark-formby-mississippi-house-representatives-concerning-mississippi/110322mississippipbm.pdf.

²⁰ Letter from FTC Staff to Dep’t of Health and Human Services, Centers for Medicare & Medicaid Services (Mar. 7, 2014), https://www.ftc.gov/system/files/documents/advocacy_documents/federal-trade-commission-staff-comment-centers-medicare-medicaid-services-regarding-proposed-rule/140310cmscomment.pdf.

²¹ Letter from FTC Staff to Larry Good, Executive Secretary ERISA Advisory Council, U.S. Dep’t of Labor (Aug. 19, 2014), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-erisa-advisory-council-u.s.department-labor-regarding-pharmacy-benefit-manager-compensation-fee-disclosure/140819erisaadvisory.pdf.

Benefit Managers: Ownership of Mail-Order Pharmacies.”²² These reports may no longer accurately reflect the current state of the PBM industry.

The Commission discourages reliance on these advocacy letters and Commission reports until its current PBM study is complete and earlier materials can be reevaluated in light of current market conditions.

²² FED. TRADE COMM’N AND DEP’T OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION (July 2004), <https://www.ftc.gov/sites/default/files/documents/reports/improving-health-care-dose-competition-report-federal-trade-commission-and-department-justice/040723healthcarerpt.pdf>; FED. TRADE COMM’N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES (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.