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FTC Flunks Interim Report

Pharmacy Benefit Managers study fails on many levels

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Introduction

The Federal Trade Commission published its interim staff report on Pharmacy Benefit Managers (PBMs) on July 9, 2024, after launching an initial inquiry in 2022.[1] Entitled *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*,[2] the interim report's release faced pushback relating to both the process by which it was produced and its substance.

The FTC conducted its study of PBMs using its authority under Section 6(b) of the Federal Trade Commission Act, which is an important investigative tool that allows the agency to fulfill its research function. These 6(b) studies have long been held in high regard for their rigor and high-quality research. But concerns have been raised about the lack of economic rigor employed in some recent 6(b) studies, this PBM interim study among them.

Shortly after releasing the interim report, but without yet publishing its final findings, the FTC filed an administrative complaint against the three largest PBMs alleging violations of Section 5 of the FTC Act.[3] In the past, the Commission has used its 6(b) authority to study industries to inform its litigation. However, considering the rushed nature surrounding the release of the interim PBM study, there are doubts that the FTC has used its investigative authority to competently inform its administrative action.

The FTC's 6(b) authority

When establishing the FTC, Congress aimed to create an agency with expertise in competition policy.[4] This would allow the agency to conduct in-depth research and gather crucial information and data, to ensure informed decision making and effective enforcement actions. In fact, an early proposal gave the agency no enforcement powers. The FTC was to exist as investigative and research body that would provide information and consultation to the public, Congress, the US Attorney General, and courts, without the quasi-judicial powers it has today.[5] As President Woodrow Wilson described it in a special address to Congress, the planned commission would serve "as an indispensable instrument of information and publicity, as a clearing house for the facts."[6] But Congress ultimately created the FTC as both an investigative agency and one with adjudicative authority.

Much, if not most, of the FTC's investigative authority comes from Section 6 of the FTC Act. Notably, Section 6(b) of the FTC act empowers the agency to issue special orders to compel the production of information and data from businesses, even if the inquiry doesn't pertain to a particular enforcement matter.[7] This typically results in the production of a report,[8] often called a "6(b) report," which can help inform legislation, rulemaking, or litigation. Institutionally, the FTC's Office of Policy Planning plays a key role in coordinating 6(b) studies, working closely with the Bureau of Economics and either the Bureau of Competition or Consumer Protection.[9]

In recent history, the FTC's research and report function has been lauded, even by its biggest critics. In 1980, William Baxter, shortly before he became head of the DOJ's Antitrust Division, joined then-FTC Commissioner Robert Pitofsky for a debate about reforming the FTC. Baxter expressed doubt in the agency's ability to litigate antitrust cases, saying "I would like to see the FTC lose all its antitrust jurisdiction. I think it's done a deplorable

1 Federal Trade Commission, "FTC Releases Interim Staff Report on Prescription Drug Middlemen," press release, July 9, 2024, https://www.ftc.gov/news-events/news/press-releases/2024/07/ftc-releases-interim-staff-report-prescription-drug-middlemen.

2 Federal Trade Commission, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*, Interim Staff Report, July 2024, https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

3 Federal Trade Commission, "FTC Sues Prescription Drug Middlemen for Artificially Inflating Insulin Drug Prices," press release, September 20, 2024, https://www.ftc.gov/news-events/news/press-releases/2024/09/ftc-sues-prescription-drug-middlemen-artificially-inflating-insulin-drug-prices.

4 Hillary Greene, "Agency Character and Character of Agency Guidelines: An Historical and Institutional Perspective," *Antitrust Law Journal*, Vol. 72 (2005), p. 1045, https://digitalcommons.lib.uconn.edu/cgi/viewcontent.cgi?article=1308&context=law_papers; Paul A. Pautler, *A History of the FTC's Bureau of Economics* (American Antitrust Institute, Working Paper No. 15-03, September 8, 2025), https://www.antitrustinstitute.org/wp-content/uploads/2018/08/FTC-Bureau-of-Economics-History_0.pdf.

5 Milton Handler, "The Constitutionality of Investigations by the Federal Trade Commission," *Columbia Law Review*, Vol. 28, No. 6 (June 1928), pp. 722-729, https://www.jstor.org/stable/1113062.

6 Handler, "The Constitutionality of Investigations by the Federal Trade Commission," p. 725.

7 15 U.S.C. § 46(b).

8 15 U.S.C. § 46(f).

9 The Federalist Society, "FTC's Interim Pharmacy Benefit Manager Report – Assessing Vigor," YouTube, July 26, 2024, video, 3:13, https://www.youtube.com/watch?v=ooLSs-4hNyc.

job with it over the years."[10] However, he praised the FTC's Bureau of Economics. Baxter hoped that the Commission would maintain its research function and continue its report activities:

> *But I see no arguments whatsoever for preserving these two agencies. The FTC in my view has done a lousy job with its piece of the antitrust elephant. The Commission has a very important job that tends to get slighted. It has a very high quality economic section. In the recent years it has been successful in attracting highly intelligent and very competent people to run that section. It would very nicely complement advisory functions, perhaps some rule-making activities and report activities, an arm of the Congress.*[11]

As Commissioner Melissa Holyoak said in her dissent to the release of interim study, the FTC's 6(b) authority has historically provided "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."[12] And she acknowledged that "The standard of these reports has been nothing short of excellence." Until recently, this research function has been treated as an important institutional feature of the FTC, particularly in contrast with the more prosecutorial duties of the Department of Justice.[13]

Procedural concerns on 6(b) orders

In her dissent, Commissioner Holyoak expressed concern over procedural oddities surrounding the launch of the FTC's inquiry into PBMs. "To begin with, the Report was plagued by process irregularities and concerns over the substance—or lack thereof—of the original order," Holyoak said.[14] The FTC formally launched its inquiry into PBMs on June 7, 2022, issuing 6(b) orders to the six largest PBMs: CVS Caremark; Express Scripts; OptumRx; Humana; Prime Therapeutics; and MedImpact Healthcare Systems. The FTC then expanded its inquiry twice in the following year. On May 17, 2023, the FTC sent compulsory orders to two group purchasing organizations (GPOs), Zinc Health Services and Ascent Health Services, who negotiate rebates on behalf of PBMs.[15] Then, on June 8, 2023, the FTC issued orders to a third GPO, Emisar Pharma Services.[16]

Prior to the issuance of compulsory orders in June 2022, several drafts of the proposed PBM study were hastily circulated leading up to the February 17, 2022, FTC Open Commission Meeting. It was ultimately rejected by a 2-2 vote. On February 10, FTC Chair Lina Khan had announced that the FTC would be voting on a proposed PBM study and circulated the corresponding draft and subpoenas to the commissioners.[17] This first draft narrowly focused on PBM contracts, investigating whether they offer more advantageous terms to their affiliated pharmacies compared to independent pharmacies. It was also accompanied by a staff memo stipulating that the study would not evaluate the contracts' effects on consumer prices.

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[10] Miles W. Kirkpatrick et al., "Debate: The Federal Trade Commission under Attack: Should the Commission's Role Be Changed?" *Antitrust Law Journal,* Vol. 49, No. 4 (August 1980), p. 1495, https://www.jstor.org/stable/40842642.

[11] Kirkpatrick et al., "Debate: The Federal Trade Commission under Attack," p. 1496.

[12] Dissenting Statement of Commissioner Melissa Holyoak in the Matter of the Pharmacy Benefit Managers Report, FTC Matter No. P221200, July 9, 2024, p. 1, https://www.ftc.gov/system/files/ftc_gov/pdf/Holyoak-Statement-Pharmacy-Benefit-Managers-Report.pdf.

[13] William E. Kovacic, *The Federal Trade Commission at 100: Into Our 2nd Century* (Federal Trade Commission, January 2009), pp. 91-109, https://www.ftc.gov/sites/default/files/documents/public_statements/federal-trade-commission-100-our-second-century/ftc100rpt.pdf.

[14] Dissenting Statement of Commissioner Melissa Holyoak in the Matter of the Pharmacy Benefit Managers Report, p. 2.

[15] Federal Trade Commission, "FTC Deepens Inquiry into Prescription Drug Middlemen," press release, May 17, 2023, https://www.ftc.gov/news-events/news/press-releases/2023/05/ftc-deepens-inquiry-prescription-drug-middlemen.

[16] Federal Trade Commission, "FTC Further Expands Inquiry Into Prescription Durg Middlemen Industry Practices," press release, June 8, 2023, https://www.ftc.gov/news-events/news/press-releases/2023/06/ftc-further-expands-inquiry-prescription-drug-middlemen-industry-practices.

[17] Leah Nylen, "FTC's Top Economist Resigned Amid Dispute over Pharma Study," *Politico,* February 25, 2022, https://www.politico.com/news/2022/02/25/ftcs-top-economist-resigned-amid-dispute-over-pharma-study-00011878.

Then-Commissioners Christine Wilson and Noah Phillips both expressed concern over the limited scope of this first draft. Commissioner Phillips said:

> *The press release for today's meeting claims that "the proposed 6B study will study a competitive impact of contractual provisions, reimbursement adjustments, and other practices affecting drug prices, including those practices that may disadvantage independent or specialty pharmacies." But the 6B study was not designed to assess the competitive effects of those contractual provisions we would study in including on independent pharmacies. The study was one of trends, not outcomes. The study also would not tell us how the contractual provisions at issue might impact drug prices overall or the out of pocket drug costs consumers pay when they go to the pharmacy to get their prescriptions. To me, the most important things are the amount of money that Americans are spending on prescriptions and the kind of care they are getting.*[18]

A second draft of the PBM study proposal was circulated at 9pm the night before the February 17 open commission meeting. This followed concerns from other commissioners about the insufficient attention given to consumer prices. Commissioner Noah Phillips noted that he had neither the time to thoroughly review the new draft nor the chance to consult with relevant FTC staff to fully grasp the proposal's scope. In a final rush, a third, broader draft of the proposed PBM study was reportedly circulated mere minutes before the February 17 open commission meeting. The last-minute modifications were made unbeknownst to Commissioners Phillips and Wilson.[19]

The day before the initial 6(b) proposal failed, the FTC's Bureau of Economics director, Marta Wosińska, resigned amid reports of internal disagreement regarding the production of the study on PBMs.[20] Considered an expert in health care economics, Wosińka had served in her post at the FTC since April 2021 and had previously worked at the Food and Drug Administration. When the 6(b) study proposal was eventually approved by the full Commission nearly four months later, Commissioner Rebecca Slaughter thanked Wosińska, saying she "laid critical groundwork for the study we announce today."[21] However, Wosińska departed prior to approving any aspect of the study, including the design and order that were ultimately approved in June 2022.

Seemingly discontent with the failure to secure the votes for the 6(b) orders, the FTC announced a request for information on "Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers."[22] The interim staff report relied on over four dozen comments submitted in connection to this request for information, of over 1,200 comments total.[23]

What is a Pharmacy Benefit Manager?

Employers, unions, and insurers that sponsor drug plans hire Pharmacy Benefit Managers (PBMs) to manage their prescription drug benefits. PBMs negotiate to create lists of covered drugs, called formularies, seeking to obtain the cheapest effective drugs for their clients. In exchange for inclusion on those formularies and the resulting increased sales, drug manufacturers accept lower prices, often in the form of discounts and rebates off of the manufacturers' list prices.[24]

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[18] Transcript of February 17, 2022, Open Commission Meeting, Federal Trade Commission, February 22, 2022, p. 31, https://www.ftc.gov/system/files/ftc_gov/pdf/FTC%20Transcript%20February%2017%2C%202022%20Open%20Commission%20Meeting.pdf.

[19] Concurring Statement of Commissioners Noah Joshua Phillips and Christine S. Wilson Regarding 6(b) Orders to Study Contracting Practices of Pharmacy Benefit Managers, Federal Trade Commission, June 6, 2022, https://www.ftc.gov/system/files/ftc_gov/pdf/P221200PhillipsWilsonPBMStatement.pdf.

[20] Nylen, "FTC's Top Economist Resigned."

[21] Statement of Commissioner Rebecca Kelly Slaughter Regarding the Use of Compulsory Process and Issuance of 6(b) Orders to Study Contracting Practices of Pharmacy Benefit Managers, Federal Trade Commission, June 7, 2022, https://www.ftc.gov/system/files/ftc_gov/pdf/P221200PBMSlaughterStatement.pdf. In April 2021, then Acting Chairwoman Slaughter appointed Wosińska to be Director of the FTC's Bureau of Economics. Federal Trade Commission, "Acting FTC Chairwoman Slaughter Appoints Marta E. Wosińska as Director of Bureau of Economics," press release, April 13, 2021, https://www.ftc.gov/news-events/news/press-releases/2021/04/acting-ftc-chairwoman-slaughter-appoints-marta-e-wosinska-director-bureau-economics.

[22] Federal Trade Commission, "FTC Requests Public Comments on the Impact of Pharmacy Benefit Managers' Practices," press release, February 24, 2022, https://www.ftc.gov/news-events/news/press-releases/2022/02/ftc-requests-public-comments-impact-pharmacy-benefit-managers-practices. For more on FTC activity concerning PBMs, see U.S. Chamber of Commerce, *PBMs and the FTC: A Timeline*, September 24, 2024, https://www.uschamber.com/assets/documents/PBMs-and-the-FTC-A-Timeline.pdf.

[23] Concurring Statement of Commissioner Andrew N. Ferguson Regarding the Pharmacy Benefit Managers Interim Staff Report, FTC Matter No. P221200, July 9, 2024, p. 2, https://www.ftc.gov/system/files/ftc_gov/pdf/Ferguson-Statement-Pharmacy-Benefit-Managers-Report.pdf.

[24] For a more complete discussion of PBMs and their role in the healthcare market, see Joel Zinberg, *A Free Market Solution for Drug Distribution: How PBMs Enhance Competition, Lower Costs, and Improve Drug Utilization and Health* (Competitive Enterprise Institute, September 2023), https://cei.org/wp-content/uploads/2023/09/prescribing-drugs-final.pdf.


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This so-called "selective contracting" is neither illegal nor rare. In fact, in 2014 FTC staff wrote:

> *The ability of health plans to construct networks that include some, but not all, providers (so called 'selective contracting') has long been seen as an important tool to enhance competition and lower costs in markets for health care goods and services. Both economic principles and empirical evidence support that view.*[25]

PBMs have faced extensive scrutiny from both federal and state authorities.[26] Government intervention in the healthcare sector, particularly the Affordable Healthcare Act (ACA), has fueled the growth and vertical integration of PBMs.[27]

What consumer welfare standard?

The FTC's interim report lacked sufficient economic analysis, as pointed out by Commissioner Holyoak's dissent. She said, "the Report fails to meet the standards of economic rigor expected of Commission reports more generally."[28] The most glaring omission from the FTC's interim PBM study is an evaluation of how PBMs affect consumer prices. This is concerning, since the inclusion of consumer price effects was essential to garner approval from Commissioners Phillips and Wilson in ultimately authorizing the 6(b) study.[29]

That the study was released as an interim report is no excuse for the absence of an analyses of consumer prices considering the FTC had two years to complete its work and no shortage of data. Further, Commission Holyoak's dissent pondered whether there will be a final report. "[T]he 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," she said.[30]

Instead of studying how PBMs might affect consumers' out-of-pocket expenses for prescription drugs, the interim study focuses more on structural descriptions of the PBM industry amidst "decades of mergers and acquisitions."[31] This shift in emphasis aligns with the FTC's approach under the leadership of Chair Lina Khan, as demonstrated by the 2023 Merger Guidelines.

Under Kahn's leadership at the FTC, antitrust policy has moved away from the consumer welfare standard, with its emphasis on individual evaluation of mergers and business practice's effect on prices, output, and innovation, and instead towards market-share in-and-of itself being problematic. That approach and a similar lack of rigorous economic analysis in the interim PBM study are related and troublesome developments.[32]

The interim report highlighted significant changes in the PBM industry over the last two decades, including horizonal consolidation among PBMs and vertical integration with other healthcare entities. It found that the largest three PBMs handled nearly 80 percent of prescription in 2023, and the top six accounted for 90 percent.[33]

However, the report lacked empirical evidence regarding the competitive landscape of the PBM market or the actual existence of PBM market power. According to Commissioner Holyoak's dissent:

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[25] Andrew I. Gavil, Martin S. Gaynor, and Deborah Feinstein, Comment Letter to Centers for Medicare and Medicaid Services on "Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs," Docket No. CMS-4159-P, March 7, 2014, https://www.ftc.gov/system/files/documents/advocacy_documents/federal-trade-commission-staff-comment-centers-medicaremedicaid-services-regarding-proposed-rule/140310cmscomment.pdf.

[26] Hannah-Alise Rogers, Alexandra H. Pepper, and Jennifer A. Staman, *Pharmacy Benefit Managers: Current Legal Framework* (Congressional Research Service, Report No. LSB11080, November 20, 2023), https://crsreports.congress.gov/product/pdf/LSB/LSB11080.

[27] Editorial Board, "The FTC's Anti-PBM Suit Could Mean Highter Health Premiums, *Wall Street Journal*, September 25, 2024, https://www.wsj.com/opinion/federal-trade-commission-pharmacy-benefit-managers-insulin-43b0a974.

[28] Dissenting Statement of Commissioner Melissa Holyoak in the Matter of the Pharmacy Benefit Managers Report, p. 4.

[29] Concurring Statement of Commissioners Noah Joshua Phillips and Christine S. Wilson Regarding 6(b) Orders to Study Contracting Practices of Pharmacy Benefit Managers, Federal Trade Commission, June 6, 2022, https://www.ftc.gov/system/files/ftc_gov/pdf/P221200PhillipsWilsonPBMStatement.pdf.

[30] Dissenting Statement of Commissioner Melissa Holyoak in the Matter of the Pharmacy Benefit Managers Report, p. 6.

[31] Federal Trade Commission, *Pharmacy Benefit Managers*, Interim Staff Report, p. 3.

[32] Ted Bolema, *Decoding the 2023 FTC and DOJ Merger Guidelines: Insights into Shifting Antitrust Enforcement* (Mercatus Center, George Mason University, February 2024), https://www.mercatus.org/research/policy-briefs/decoding-2023-ftc-and-doj-merger-guidelines-insights-shifting-antitrust

[33] Federal Trade Commission, Pharmacy Benefit Managers, Interim Staff Report, p. 4.

> *[T]he Report does not provide any empirical evidence as 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." Though the Report baldly asserts that PBMs "have gained significant power over prescription drug access and prices," the Report does not present empirical evidence that demonstrates PBMs have market power—* ***i.e.****, "the ability to raise price profitably by restricting output."*[34]

A pattern of inadequate economic analysis is emerging in the FTC's 6(b) studies, as seen in another report released earlier this year. In March 2024, the FTC published its report on grocery supply chains and the COVID-19 pandemic.[35] According to Fred Ashton, director of competition policy at the American Action Forum, "When it came to writing the report, it's as if the FTC locked the economists out of the room."[36]

Ashton reported on the FTC's supply chain study and concluded that it taught us nothing.[37] He points to a number of caveats in the study to illustrate the limited utility of the agency's finding. The supply chain study stipulates that "the conclusions reported here are based on specific information, but they do not measure the wider prevalence of observed practices or the magnitude of their impact on competition."[38] Ashton avers that this undermines the report's conclusions as well as their applicability to any stage of the grocery supply chain.[39]

Further, the FTC's supply chain study highlighted increased markups in the grocery industry. The Commission interpreted this as evidence of companies exploiting rising costs to increase profits, even as supply chain issues eased. However, as indicated in the supply chain study, the FTC "did not test whether the specific companies that received 6(b) Orders increased their prices by more or less than their input cost increases."[40] Ashton points out that "the FTC was armed with information directly from nine companies in the supply chain" and that "[p]assing over this information calls into question the validity of the conclusions."[41]

The FTC was similarly armed with information for its 6(b) study on PBMs and still is. But the agency used very little of it in compiling its interim staff report. According to Ashton, the FTC "failed to answer even the most basic questions related to the competitive dynamics of the industry and the effect on consumer costs, despite having troves of data provided by the PBMs."[42] Instead of utilizing information gathered directly from PBMs, the interim report depended heavily on publicly accessible data, a criticism Commissioner Ferguson embraced in his concurring statement.[43]

Both the PBM and supply chain reports underutilized data and information gathered using the FTC's 6(b) authority, and that authority has teeth. The Commission can ultimately take companies to court if they fail to furnish the requested information. When then-Commissioner Noah Phillips delivered his oral remarks at the February 17, 2022, open commission

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[34] Dissenting Statement of Commissioner Melissa Holyoak in the Matter of the Pharmacy Benefit Managers Report, pp. 4-5.

[35] Federal Trade Commission, "FTC Releases Report on Grocery Supply Chain Disruptions," press release, March 21, 2024, https://www.ftc.gov/news-events/news/press-releases/2024/03/ftc-releases-report-grocery-supply-chain-disruptions.

[36] Competitive Enterprise Institute, "Who's Canning Competition? The FTC's Trip Down the Grocery Aisle," Youtube, July 9, 2024, video, 33:24, https://www.youtube.com/watch?v=UL7h1WXJk7w&t=2004s.

[37] Fred Ashton, *FTC's COVID-19 Grocery Supply Chain Study Taught Us…Nothing* (American Action Forum, April 3, 2024), https://www.americanactionforum.org/insight/ftcs-covid-19-grocery-supply-chain-study-taught-usnothing/.

[38] Federal Trade Commission, *Feeding America in a Time of Crisis: The United States Grocery Supply Chain and the COVID-19 Pandemic*, Staff Report, March 21, 2024, p. 3, https://www.ftc.gov/system/files/ftc_gov/pdf/p162318supplychainreport2024.pdf.

[39] Ashton, *FTC's COVID-19 Grocery Supply Chain Study*, p. 8.

[40] Federal Trade Commission, *The United States Grocery Supply Chain and the COVID-19 Pandemic*, p. 2.

[41] Ashton, *FTC's COVID-19 Grocery Supply Chain Study*, p. 10.

[42] Fred Ashton, *FTC PBM Study: Another 6(b) Report, Hold the Economists* (American Action Forum, August 7, 2024), p. 5, https://www.americanactionforum.org/print/?url=https://www.americanactionforum.org/insight/ftc-pbm-study-another-6b-report-hold-the-economists/.

[43] Concurring Statement of Commissioner Andrew N. Ferguson Regarding the Pharmacy Benefit Managers Interim Staff Report, p. 2.

meeting where an earlier version of the proposed study was voted down, he said, "6(b) studies are serious and expensive matters."[44] They likely aren't just expensive for the FTC, but they're expensive for the companies that are tasked with complying with those orders.

The FTC's access to non-public information under Section 6(b) uniquely positions it to conduct research. The data provides a crucial advantage in understanding market dynamics and competitive practices. That unique position is devalued when the FTC fails to use it adequately. Furthermore, both Commission and private enterprises' resources are scarce. When the FTC demands extensive information from businesses without a clear intention to analyze and apply it, it raises questions of whether the agency is carrying out its research function under Section 6(b) responsibly or wasting limited resources.

Anonymous gripes

In addition to criticizing the over-reliance on public data, Ferguson's concurrence notes that the interim report relies significantly on public comments, some submitted anonymously and others submitted by parties that contract with PBMs. The interim report contains over 50 citations to such comments. Regarding anonymous comments, Commissioner Ferguson said:

> *[W]e ought to treat anonymous comments with circumspection. After all, we cannot know who submitted the comments, nor do we have any method for verifying the accuracy of a single word they contain. We therefore cannot be sure how much weight, if any, to accord them as we try to understand these markets. The PBM Interim Staff Report nevertheless ascribes those anonymous submissions to independent pharmacies, or pharmacies generally, and treats their contents as fact.*[45]

Further, Ferguson points out that many of the comments cited were submitted by firms that contract with PBMs who "may have an incentive to instigate regulatory action against PBMs to improve their bargaining position."[46]

Chair Lina Khan's leadership has been marked by criticism of the agency's research quality, particularly in the context of rulemaking. In August 2022, the Commission released an Advanced Notice of Proposed Rulemaking (ANPRM) on "Commercial Surveillance and Data Security."[47] Some former FTC staff have called it "one of the most ambitious rulemakings in agency history," one that would govern "nearly every facet of the U.S. internet economy."[48] Other former staff have criticized the ANPRM for its flimsy reliance on media sources.

The majority (58%) of the cited material consisted of law review articles or media sources, like the ***New York Times*** or ***The Atlantic***, according to Dr. James C. Cooper, former Deputy and Acting Director of the FTC's Office of Policy Planning and former Deputy Director of the Bureau of Consumer Protection.[49] "In fact, media is by far the biggest. It's about 30 percent of the original citations," Dr. Cooper said during an online webinar hosted by the International Center for Law & Economics. He warned:

> *This isn't how you make policy. I can say this going back from my days in the policy shop. If you tried to get a report past the Chairman's office that cited newspaper, . . . you should either be doing your own original research or citing the extant empirical research to support your propositions. . . . Investigative journalism is no substitute for good causal evidence . . . .*[50]

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[44] Transcript of February 17, 2022, Open Commission Meeting, p. 31.

[45] Concurring Statement of Commissioner Andrew N. Ferguson Regarding the Pharmacy Benefit Managers Interim Staff Report, p. 3.

[46] Concurring Statement of Commissioner Andrew N. Ferguson Regarding the Pharmacy Benefit Managers Interim Staff Report, p. 3.

[47] Federal Trade Commission, "Trade Regulation Rule on Commercial Surveillance and Data Security," advanced notice of proposed rulemaking, *Federal Register*, Vol. 87, No. 161 (August 22, 2022), pp. 51273-51299, https://www.federalregister.gov/documents/2022/08/22/2022-17752/trade-regulation-rule-on-commercial-surveillance-and-data-security.

[48] Svetlana S. Gans and Natalie J. Hausknecht, "FTC Launches Commercial Surveillance Rulemaking," Truth on the Market (blog), August 17, 2022, https://truthonthemarket.com/2022/08/17/ftc-launches-commercial-surveillance-rulemaking/.

[49] International Center for Law & Economics, "Commenting on the Comments: An Expert Take on the Direction of the FTC Privacy Rulemaking," Youtube, October 20, 2022, video, 30:53, https://youtu.be/sjKLv7vLFcw?feature=shared&t=1853.

[50] International Center for Law & Economics, "Commenting on the Comments: An Expert Take on the Direction of the FTC Privacy Rulemaking."

Light on the economics

Commissioner Holyoak wrote in her dissent that the interim report does not attempt a comprehensive analysis of "how PBM practices affect consumer prices."[51] Nor does the report explain how the case studies of two drugs are representative of anything beyond their specific circumstances.

Instead, the report focuses on general statements that may or may not be problematic, like market share of the three largest PBMs and their role as "middlemen" in the healthcare system. The report's lack of broad-based empirical data and economic analysis leaves the reader without well-established conclusions concerning PBMs' larger effect on consumers.

The FTC has previously demonstrated its ability to conduct thorough research on the PBM industry, supported by robust economic analysis. In 2005, the agency released a report entitled "Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies."[52]

At the request of Congress, the 2005 study examined "how PBMs' use of mail-order pharmacies that they own affects their clients' prescription drug costs."[53] The study found that the data studied "provide(d) strong evidence that in 2002 and 2003, PBMs' ownership of mail-order pharmacies generally did not disadvantage plan sponsors," and that data "suggest(s) that competition in this industry can afford plan sponsors with sufficient tools to safeguard their interests."[54] Overall, the report found no evidence that PBMs were systemically increasing costs to generate additional profits through mail-order pharmacies.

Subsequent economic analysis of PBMs' role in the healthcare ecosystem from the University of Southern California's Leonard D. Schaeffer Center for Health Policy and Economics in 2017, found that PBMs are not generating out-sized profits in the industry. The study found that net margins for PBMs were 2.3 percent, while drug manufacturers were 26.3 percent, pharmacies were 4 percent, and insurers were 3 percent.[55]

In 2022, economist Casey Mulligan estimated that PBMs generate $145 billion of value annually in terms of consumer savings through manufacturer and pharmacy rebates and discounts, improved drug utilization to prevent more serious illness, accelerated drug development, and decreased government spending.[56]

More recently, Professor Dennis Carlton of the University of Chicago was given the same data from the top three PBMs that the FTC requested under its Section 6(b) authority.[57] Supplemented with further requested and public information, his report, "included a review of data on approximately 20 billion 30-day equivalent prescriptions representing more than a trillion dollars in drug expenditures, [and] was conducted over 16 months."[58] With much of the same data the FTC possessed, the Carlton report "does not rely on anecdotes, case studies of individual drugs, or selected complaints from individuals but instead conducts a systematic study of data on prescriptions, rebates, PBM conduct, and the state of the pharmacy industry to evaluate common criticisms of the PBM industry."[59]

Specifically, Carlton and his team sought to answer questions about PBMs including their role in high drug prices, the effects of rebates, if generics were being restricted, and if their existence was driving independent pharmacies out of business. The report found that PBMs were not responsible for the high cost of drugs, nearly all rebates are passed along to plan sponsors, the PBMs studied do not favor brand name

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51 Dissenting Statement of Commissioner Melissa Holyoak in the Matter of the Pharmacy Benefit Managers Report, p. 4.

52 Federal Trade Commission, "FTC Issues Report on PBM Ownership of Mail-Order Pharmacies," press release, September 6, 2005, https://www.ftc.gov/news-events/news/press-releases/2005/09/ftc-issues-report-pbm-ownership-mail-order-pharmacies.

53 Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail Order Pharmacies,* August 2005, p. i, https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitrpt_0.pdf.

54 Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail Order Pharmacies,* p. ii.

55 By Neeraj Sood, PhD, Tiffany Shih, Karen Van Nuys, PhD and Dana Goldman, PhD, "Flow of Money Through the Pharmaceutical Distribution System," University of Southern California Leonard D. Schaeffer Center for Health Policy and Economics, June 6, 2017, Neeraj Sood et al., *The Flow of Money Through the Pharmaceutical Distribution System* (University of Southern California Leonard D. Schaeffer Center for Health Policy & Economics, June 2017), p. 5, https://healthpolicy.usc.edu/research/flow-of-money-through-the-pharmaceutical-distribution-system/.

56 Casey B. Mulligan, "The Value of Pharmacy Benefit Management" (NBER Working Paper No. 30231, National Bureau of Economic Research, July 2022), https://www.nber.org/papers/w30231.

57 Dennis W. Carlton et al., *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticism Levied Against Pharmacy Benefit Managers* (Compass Lexecon, October 2024), https://compass-lexecon.files.svdcdn.com/production/files/documents/PBMs-and-Prescription-Drug-Distribution-An-Economic-Consideration-of-Criticisms-Levied-Against-Pharmacy-Benefit-Managers.pdf?dm=1728503869.

58 *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticism Levied Against Pharmacy Benefit Managers,* Summary of the Report (Compass Lexecon, October 2024), p. 2, https://carltonreport.org/wp-content/uploads/2024/10/Summary-PBMs-and-Prescription-Drug-Distribution.pdf.

59 Carlton et al., *PBMs and Prescription Drug Distribution,* p. 1.

drugs over generics, and that PBMs are not driving independent pharmacies to extinction.[60]

With substantive evidence that rebuts its interim report's conclusions, it is especially irresponsible that the FTC did not conduct the most rigorous economic evaluation possible. Just the opposite, the FTC produced what our CEI colleague, Dr. Joel Zinberg, described in the pages of *The Wall Street Journal* as "an evidence-free interim report."[61]

FTC's premature, uninformed lawsuit

Two months after the release of the interim report, the FTC filed an administrative complaint against the three largest PBMs: Caremark Rx; Express Scripts; and OptumRx.[62] The complaint alleges that the PBMs' rebating practices are unfair under Section 5 of the FTC Act and have artificially inflated the list price of insulin drugs. The FTC specifically claims that the three PBMs fueled a 1,200 percent surge in the price of Humalog, an Eli Lilly insulin medication, over an 18-year period from 1999 to 2017.[63]

In the past, the FTC has used its investigative authority to better understand certain industries and inform its enforcement, especially in healthcare markets. Antitrust regulators faced a significant losing streak in hospital merger challenges between 1995 and 2002, failing to win a single case out of seven brought before federal courts.[64] The FTC and DOJ had won five out of six hospital merger challenges in the ten years prior.[65]

Recognizing the ineffectiveness of the previous approach to challenging hospital mergers, the Commission used its 6(b) authority to gain a better understanding of how these mergers affected competition within the healthcare sector.[66] Then-FTC Chair Timothy J. Muris spoke about the study before the 7th Annual Competition in Healthcare Forum in 2002:

> *[T]he Commission is in the midst of a retrospective study of consummated hospital mergers. The Bureaus of Economics and Competition are evaluating the effects of hospital mergers in several cities. The agency will announce the results of these studies regardless of the outcome. If the studies find efficiencies associated with some or all of the mergers, the staff will say so. If, on the other hand, the studies indicate that the mergers were anticompetitive, then [**sic**] Commission will carefully consider whether administrative litigation is appropriate. Whether or not there is an appropriate remedy will obviously influence the Commission's analysis of whether to pursue such a proceeding. In either event, the agency will obtain useful real-world information, allowing the Commission to update its prior assumptions about the consequences of particular transactions and the nature of competitive forces in healthcare.*[67]

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60 *PBMs and Prescription Drug Distribution*, Summary of the Report, p. 4.

61 Joel Zinberg, "The FTC Goes Evidence-Free," *Wall Street Journal*, July 23, 2024, https://www.wsj.com/articles/the-ftc-goes-evidence-free-lina-khan-pbm-healthcare-14076225.

62 Federal Trade Commission, "FTC Sues Prescription Drug Middlemen for Artificially Inflating Insulin Drug Prices," press release, September 20, 2024, https://www.ftc.gov/news-events/news/press-releases/2024/09/ftc-sues-prescription-drug-middlemen-artificially-inflating-insulin-drug-prices.

63 Alden Abbott, "Federal Trade Commission Sues Big 3 Pharmaceutical Benefit Managers," *Forbes*, October 4, 2024, https://www.forbes.com/sites/aldenabbott/2024/10/04/federal-trade-commission-sues-big-3-pharmaceutical-benefit-managers/.

64 Thomas L. Greaney, "Whither Antitrust? The Uncertain Future of Competition Law in Healthcare," *Health Affairs*, Vol. 21, No. 2 (March/April 2022), pp. 185-186, https://www.researchgate.net/profile/Thomas-Greaney/publication/11464041_Whither_Antitrust_The_Uncertain_Future_Of_Competition_Law_In_Health_Care/links/55648ad508ae06101abdf643/Whither-Antitrust-The-Uncertain-Future-Of-Competition-Law-In-Health-Care.pdf. The seven challenges included one from state enforcers.

65 Greaney, "Whither Antitrust? The Uncertain Future of Competition Law in Healthcare," pp. 185-186.

66 Maureen K. Ohlhausen, "Administrative Litigation at the FTC: Effective Tool for Developing the Law or Rubber Stamp?," *Journal of Competition Law & Economics*, Vol. 12, No. 4 (December 2016), pp. 649-650, https://academic.oup.com/jcle/article/12/4/623/2547756; Edith Ramirez, "Retrospectives at the FTC: Promoting an Antitrust Agenda," remarks before ABA Retrospective Analysis of Agency Determinations in Merger Transactions Symposium, George Washington University Law School, Washington, DC, June 28, 2013, pp. 3-4, https://www.ftc.gov/sites/default/files/documents/public_statements/retrospectives-ftc-promoting-antitrust-agenda/130628aba-antitrust.pdf.

67 Timothy J. Muris, "Everything Old is New Again: Health Care and Competition in the 21st Century," prepared remarks before 7th Annual Competition in Health Care Forum, Chicago, Illinois, November 7, 2022, https://www.ftc.gov/sites/default/files/documents/public_statements/everything-old-new-again-health-care-and-competition-21st-century/murishealthcarespeech0211.pdf.

The FTC's Bureau of Economics published four empirically driven retrospectives using data collected with its 6(b) authority,[68] and the Commission won nearly every healthcare merger challenge in the next decade.[69]

The Commission's strategy for studying and challenging hospital mergers differs significantly from its approach to PBMs. First, unlike its approach to hospital mergers, the agency did not appear to seek an objective evaluation when studying PBMs. According to Daniel J. Gilman, former attorney advisor in FTC's Office of Policy Planning, "Even the report's title was a bold announcement of something other than the sober assessment we would expect of an FTC Bureau of Economics report, or, traditionally, the FTC's Office of Policy Planning."[70]

The decision to rescind previous guidance before completing new analysis further demonstrates a lack of objectivity. On July 20, 2023, nearly a year before releasing the interim report, the FTC voted to issue a statement that cautioned against reliance on prior statements and studies related to PBMs.[71] While those materials are still available on the FTC website, prior work like the 2005 study on PBMs is labeled with a disclaimer stating "This material is for reference only" and "should not be assumed to reflect current market conditions."[72] But when the FTC withdrew the previous PBM materials, "there were no preliminary findings from that study, and the repudiation was not accompanied by any account, however preliminary, of specific findings or policy recommendations that should no longer be considered reliable," according to Gilman.[73]

Second, instead of updating its prior assumptions and comparing the results to its previous analysis, the Commission generally failed to engage with its 2005 PBM report. When voting to approve the 6(b) study of PBMs in June 2022, Commissioners Wilson and Phillips professed that they hoped "that the study being voted out today will allow the FTC to update the findings of the 2005 study, a task that will require resources and commitment to finishing the task."[74] Not only did the Commission not update its findings from the 2005 PBM study, it didn't finish the task, seemingly rushing to release an interim report and issuing the subsequent administrative complaint.

Commission Holyoak provided a scathing critique of the failure to engage with the 2005 report in her dissent:

> *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. 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.*[75]

Third, it's not at all clear that the FTC has contemplated an appropriate remedy. And former FTC staff members have shed doubt on whether the contemplated relief is clear or whether it would cure the purported harms. According to Gilman, despite a clear intent to restrict pricing and plan design, the proposed remedies are vague, as the FTC's prayer for relief simply mentions "drugs" rather than addressing insulin specifically.[76] Crucially, Gilman writes that it's uncertain that the Commission proposed remedies would increase competition or lower prices:

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[68] Edith Ramirez, "Retrospectives at the FTC: Promoting an Antitrust Agenda," remarks before ABA Retrospective Analysis of Agency Determinations in Merger Transactions Symposium, George Washington University Law School, Washington, DC, June 28, 2013, pp. 3-4, https://www.ftc.gov/sites/default/files/documents/public_statements/retrospectives-ftc-promoting-antitrust-agenda/130628aba-antitrust.pdf.

[69] Ohlhausen, "Administrative Litigation at the FTC," p. 649.

[70] Daniel J. Gilman, "Antitrust at the Agencies: PBM Madness at the FTC, Part 1," Truth on the Market (blog), October 11, 2024, https://truthonthemarket.com/2024/10/11/antitrust-at-the-agencies-pbm-madness-at-the-ftc-part-1/.

[71] Federal Trade Commission, "FTC Votes to Issues Statement Withdrawing Prior Pharmacy Benefit Manager Advocacy," press release, July 20, 2023, https://www.ftc.gov/news-events/news/press-releases/2023/07/ftc-votes-issue-statement-withdrawing-prior-pharmacy-benefit-manager-advocacy.

[72] Daniel J. Gilman, "Reports of the Current FTC's Intellectual Integrity Have Been Greatly Exaggerated," Truth on the Market (blog), July 10, 2024, https://truthonthemarket.com/2024/07/10/reports-of-the-current-ftcs-intellectual-integrity-have-been-greatly-exaggerated/.

[73] Gilman, "Reports of the Current FTC's Intellectual Integrity Have Been Greatly Exaggerated."

[74] Concurring Statement of Commissioners Noah Joshua Phillips and Christine S. Wilson Regarding 6(b) Orders to Study Contracting Practices of Pharmacy Benefit Managers, p. 1.

[75] Dissenting Statement of Commissioner Melissa Holyoak in the Matter of the Pharmacy Benefit Managers Report, p. 4.

[76] Daniel J. Gilman, "Antitrust at the Agencies: PBM Madness at the FTC, Part 1."

While we're on remedies, is it likely that price competition would be more vigorous with the contemplated relief? If PBMs are—as the FTC subtitled its recent interim staff report on PBMs—"inflating drug costs and squeezing Main Street pharmacies," would they not otherwise, absent the conduct at-issue, be able to inflate drug costs (prices)?[77]

Former FTC General Counsel Alden Abbott paints an even dimmer picture of the proposed remedies, arguing that they would have economically harmful consequences. He wrote in a recent *Forbes* article that "consumers as well as businesses would likely be the long-term losers."[78] Others argue that the Commission's contemplated relief would essentially prohibit PBM rebates, which would lead to higher health premiums.[79]

In early 2019, the Department of Health and Human Services (HHS) announced a proposed rule that would prohibit drug manufacturers from providing rebates to health plans or PBMs (in Medicare Part D and Medicaid managed care) in exchange for securing coverage of preferred formulary placement for their drug.[80] The Congressional Budget Office determined that the rule would increase government spending for Medicare and Medicaid by about $177 billion over ten years.[81]

Conclusion

Many have criticized Khan's leadership at the FTC. She has lost a string of high-profile merger cases.[82] And a federal court rejected the FTC's attempt to ban employee noncompete agreements, holding that the rule exceeded authority granted to the agency by Congress.[83] The Commission's administrative action against the three largest PBMs is the first standalone Section 5 case since the agency issued its new Section 5 policy statement in 2022.[84] While the FTC's complaint could survive its internal administrative law court, where the FTC typically rules in its own favor, the agency is less likely to find success if the decision is appealed to a federal court.[85]

The Commission published a report at the behest of Congress in June 2019 on the viability of using the agency's standalone Section 5 authority to address high drug prices.[86] The report acknowledged that "courts have been reluctant to expand the reach of Section 5 beyond the scope of the Sherman and Clayton Acts."[87] Further, "In the 1970s, the Commission attempted to expand the use of its standalone Section 5 authority and suffered a string of federal court losses."[88]

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77 Gilman, "Antitrust at the Agencies: PBM Madness at the FTC, Part 1."

78 Abbott, "Federal Trade Commission Sues Big 3 Pharmaceutical Benefit Managers."

79 Editorial Board, "The FTC's Anit-PBM Suit Could Mean Higher Health Premiums," *Wall Street Journal*, September 25, 2024, https://www.wsj.com/opinion/federal-trade-commission-pharmacy-benefit-managers-insulin-43b0a974

80 Department of Health and Human Services, "Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees," *Federal Register*, Vol. 84, No. 25 (February 6, 2019), https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals.

81 Congressional Budget Office, *Incorporating the Effects of the Proposed Rule on Safe Harbors for Pharmaceutical Rebates in CBO's Budget Projections—Supplemental Material for Updated Budget Projections: 2019 to 2029*, May 2019, p. 1, https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf.

82 Ankush Khardori, "Lina Khan's Rough Year," *New York Magazine*, December 12, 2023, https://nymag.com/intelligencer/2023/12/lina-khans-rough-year-running-the-federal-trade-commission.html; Robert H. Bork Jr., "Internal Emails Show FTC's Lina Khan Is Trying to Wine by Losing," *The Hill*, March 3, 2024, https://thehill.com/opinion/finance/4490640-internal-ftc-emails-show-ftcs-khan-is-actually-trying-to-win-by-losing/.

83 Dave Michaels, "Judge Tosses FTC Ban on Noncompete Agreements," *Wall Street Journal*, August 20, 2024, https://www.wsj.com/us-news/law/judge-tosses-ftc-ban-on-noncompete-agreements-ae517b48.

84 Fred Ashton, *FTC Sues PBMs over Insulin Prices* (American Action Forum, September 26, 2024), https://www.americanactionforum.org/insight/ftc-sues-pbms-over-insulin-prices/.

85 "Nevertheless, it is doubtful that merely favoring higher-priced formulary drugs over lower-priced ones – which lies at the heart of the PBM case – would be viewed as a form of problematic *competition* on review by federal judges. (There are no federal court holdings that would support such a result.)" Abbott, "Federal Trade Commission Sues Big 3 Pharmaceutical Benefit Managers."

86 Federal Trade Commission, *Report on Standalone Section 5 to Address High Pharmaceutical Drug and Biologic Prices*, June 2019, https://www.ftc.gov/system/files/documents/reports/ftc-report-standalone-section-5-address-high-pharmaceutical-drug-biologic-prices/p180101_drug_prices_appropriations_report_6-27-19.pdf; Daniel J. Gilman, "Antitrust at the Agencies: PBM Madness at the FTC, Part 2," Truth on the Market (blog), October 15, 2024, https://truthonthemarket.com/2024/10/15/antitrust-at-the-agencies-pbm-madness-at-the-ftc-part-2/.

87 Federal Trade Commission, *Report on Standalone Section 5 Authority to Combat Unfair Methods of Competition*, p. 2.

88 Federal Trade Commission, *Report on Standalone Section 5 Authority to Combat Unfair Methods of Competition*, p. 2.

Former FTC Chair Timothy J Muris and former FTC bureau director J. Howard Beales contrasted past attempts to reshape the Commission with the present mission of Chair Khan. They illustrate that Khan's "impressive norm-busting campaign" is unlikely to bear fruit.[89] Ushering in a revolution at the FTC requires doing one's homework. The FTC's case against PBMs is an ambitious one. But the Commission's "interim" PBM study doesn't pass the grade.

About the authors

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[89] J. Howard Beales III and Timothy J. Muris, *Achieving Change at the Federal Trade Commission: Success and Failure* (Competitive Enterprise Institute, May 2024), p. 72, https://cei.org/wp-content/uploads/2024/05/Achieving-Change-at-the-Federal-Trade-Commission.pdf.

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