IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

EXPRESS SCRIPTS, INC. Plaintiff, v. THE FEDERAL TRADE COMMISSION, – and – LINA M. KHAN, in her official capacity as Chair of the Federal Trade Commission, Defendants.	Case No._____ **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

Plaintiff Express Scripts, Inc. ("Express Scripts") brings this Complaint for declaratory and injunctive relief against the Federal Trade Commission ("FTC" or "Commission") and Lina M. Khan, in her official capacity as Chair of the FTC ("Commissioner" or "Chair," and together with the FTC, "Defendants"). Express Scripts alleges as follows:

INTRODUCTION

1. Express Scripts brings this Complaint to seek judicial relief from the Commission's unfair, biased, erroneous, and defamatory July 2024 "interim" report on the pharmacy benefit management ("PBM") industry—"Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies" ("Report"). According to the Commission's press release announcing the Report, the Report stems from special orders issued under Section 6(b) of the FTC Act to six PBMs, including Express Scripts, demanding data and information about the PBM industry. But the Report is not an analysis of the data and information produced by the PBMs. Instead, it is seventy-four pages of unsupported innuendo leveled against Express Scripts and other PBMs under a false and defamatory headline and

accompanied by a false and defamatory press release. The Commission disregarded the millions of documents and terabytes of data produced and relied instead on unverified comments from the very companies that PBMs negotiate against in order to help lower drug costs. Not surprisingly, those entities are incentivized to point the finger at PBMs for allegedly driving drug costs up, when it is PBMs who are, in fact, bringing drug costs down.

2. The Commission's Report followed prejudice and politics, not evidence or sound economics, and wrongly concluded that PBMs inflate drug costs and harm independent pharmacies. Express Scripts' business and reputation have been harmed by the Commission's unlawful, unconstitutional, and arbitrary and capricious conduct and defamatory statements.

3. Following the evidence and the public interest would have led the Commission to report the opposite conclusion: PBMs *lower* prescription drug costs for health plan sponsors (employers, unions, and governments) who use PBMs to negotiate with (among others) pharmaceutical manufacturers and retail pharmacies to drive cost savings. PBMs enable plan sponsors to offer prescription drug benefits to millions of Americans despite escalating drug prices. Without PBMs, plan sponsors may not be able to afford to provide prescription drug benefits at all.[1] Express Scripts' efforts to lower prescription drug costs have saved plan sponsors and their members *tens of billions* of dollars in drug costs over the past decade alone.[2] The Commission is well aware of these facts and, before Lina Khan became Chair, had repeatedly acknowledged the procompetitive benefits of PBMs. Yet the Commission has now

[1] *See* Dennis W. Carlton et al., *PBMs and Prescription Drug Distribution: An Economic Analysis of Criticisms Levied Against Pharmacy Benefit Managers*, Compass Lexecon (July 19, 2024) ("Carlton PBM Report"), *available at* https://carltonreport.org.

[2] Carlton PBM Report at 5-7 (explaining how PBMs have contributed to lower drug prices); Cong. Budget Off., *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*, at 1 (May 2019), https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf (noting that implementing a rule that would limit the ability of PBMs and plan sponsors to negotiate rebates from drug manufacturers would increase federal spending on Medicare and Medicaid by over $175 billion between 2020 and 2029).

issued a fundamentally flawed and biased Report that simply ignores the evidence and the Commission's own prior contrary conclusions about PBMs.

4. The Commission was intended to be a bipartisan defender of consumers and fair competition, not an ideological pawn driven by political winds and special interests. Indeed, the Federal Trade Commission Act empowers the Commission to issue reports about business practices only when doing so is "in the public interest."[3] The Constitution, federal law, and common-sense demand that the Commission exercise this important power consistent with due process, objective fact-finding, evidence-based inquiry, and sound economic analysis. The Commission did the opposite here.

5. It could have been different. Former Commissioner Christine Wilson presciently warned in voting against Chair Khan's initial, partisan, and abortive attempt to launch a PBM industry "study" in February 2022:

> I have observed previously that stakeholders frequently seek to coopt the government in their battles against rivals. I am wary of having the FTC used as a pawn to boost the profitability of certain sectors, or to insulate them from competition. 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 [of the PBM industry] with an objective design and credible guarantees that an expert-driven process will produce a data-driven report.[4]

6. When the Commission voted to release its Report two and a half years later, Commissioner Wilson had long since departed the agency. Her demand for an objective, evidence-based, and expert-driven process was ignored, and as she presciently warned, bias and partisanship took over.

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[3] 15 U.S.C. § 46(f).

[4] Christine S. Wilson, Commissioner, FTC, *Open Commission Meeting: 6(b) Orders to Study Pharmacy Benefit Managers' Relationships with Affiliated and Independent Pharmacies*, at 6 (Feb. 17, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/oral-remarks-wilson-open-meeting-february.pdf.

7. The fix was in before the "study" even started. Under Chair Lina Khan, the PBM industry never had a chance for a fair, objective assessment of the record or a neutral, evidence-driven, analytically rigorous report from the Commission. In the past, the Commission recognized the pro-competitive, pro-consumer benefits of PBMs in repeated studies, comment letters, and investigations. For example, after a comprehensive investigation of a merger in the PBM space, the FTC concluded that competition among PBMs "is intense, has driven down prices, and has resulted in declining PBM profit margins."[5] With Chair Khan running the Commission, however, the Commission abruptly turned away from the facts.

8. Before she was even appointed to the Commission, Chair Khan made clear that she thinks PBMs are responsible for increasing drug prices, despite the FTC's own previous findings to the contrary. As a law student in 2016 she had already made up her mind, decrying that a supposed PBM "conflict of interest" kept "drug prices high"[6]—directly contradicting factual findings at the time made by professional FTC staff with access to actual data and information from the PBMs and others in the industry. She cited no facts to support her views.

9. Her anti-PBM bias continued once she graduated law school and was appointed to the Commission. Within two weeks of the June 2022 vote to authorize the PBM 6(b) study, Chair Khan appeared at an event cohosted by a pharmacists' lobby group, funded in part by large drug wholesalers and pharmacies, and trashed PBMs to cheers and applause. In numerous speeches and writings since then, Chair Khan has continued her tirade against PBMs without factual support—falsely accusing them of "controlling" drug prices and access to drugs, of

[5] FTC, *Statement Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc.*, at 2, FTC File No. 111-0210 (Apr. 2, 2012), https://www.ftc.gov/sites/default/files/documents/closing_letters/proposed-acquisition-medco-health-solutions-inc.express-scripts-inc./120402expressmedcostatement.pdf.

[6] Lina Khan, *How to Reboot the FTC*, POLITICO (April 13, 2016), https://www.politico.com/agenda/story/2016/04/ftc-antitrust-economy-monopolies-000090/.

taking "kickbacks" from pharmaceutical manufacturers, and seeking to drive independent pharmacies out of business. All of these themes pervaded the July 2024 Report, with absolutely no data or evidence to support them.

10. Although Express Scripts and other PBMs produced, by Chair Khan's own written admission, "millions of documents and several terabytes of data" in response to the Commission's broad and burdensome requests for information,[7] it is obvious from the face of the Report that none of this evidence mattered. As FTC Commissioner Ferguson noted, the Report overwhelmingly cites "public information that was not collected from the PBMs or their affiliates during the 6(b) process," and instead "relies heavily on public comments," many of which were anonymous and unverifiable yet were treated "as fact" by the Commission.[8] Indeed, *over seventy-five percent* of the citations in the Report are to public sources, including cherry-picked third-party publications and anonymous public comments, not the voluminous data and information produced in response to the Commission's wide-ranging and burdensome requests for information to inform this supposed study.

11. In a scathing dissent, FTC Commissioner Holyoak objected to the Commission's decision to issue the Report because of the "politicized nature of the process" that drove it.[9] She noted that the Report contained no empirical work to rebut the Commission's past conclusions that PBMs are pro-competitive, much less to support its current conclusions that PBMs are

[7] Letter from Lina M. Khan, Chair, FTC, to Sen. Charles E. Grassley, at 3 (Feb. 13, 2024), https://www.grassley.senate.gov/imo/media/doc/ftc_to_grassley_-_pbm_6b_study.pdf.

[8] Andrew N. Ferguson, Commissioner, FTC, *Concurring Statement Regarding the Pharmacy Benefit Managers Interim Staff Report*, at 2-3, FTC Matter No. P221200 (July 9, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/Ferguson-Statement-Pharmacy-Benefit-Managers-Report.pdf.

[9] Melissa Holyoak, Commissioner, FTC, *Dissenting Statement in the Matter of the Pharmacy Benefit Managers Report*, at 2, FTC Matter No. P221200 (July 9, 2024) [hereinafter "Holyoak Dissenting Statement"], https://www.ftc.gov/system/files/ftc_gov/pdf/Holyoak-Statement-Pharmacy-Benefit-Managers-Report.pdf.

"powerful middlemen inflating drug costs."[10] As she emphasized: "The Report's failure to offer empirical evidence to support claims about the market power of PBMs is particularly troubling,"[11] which supported her conclusion that the July 2024 PBM Report "fails to meet [the FTC]'s rigorous standard"[12] to supply the public and Congress "with evidence-based, objective, and economically sound information that can shape the national debate on a wide range of important issues that affect consumers and competition."[13]

12. Given Chair Khan's and the Commission's bias against PBMs and failure to consider the evidence before them, it is not surprising that the July 2024 PBM Report gets nearly everything wrong. For example:

- It falsely accuses Express Scripts and other PBMs of "controlling" access to drugs and drug pricing when it is manufacturers who set drug prices and plan sponsors who decide which drugs to cover for their members.
- It attacks Express Scripts for disadvantaging independent pharmacies when the evidence produced shows that on average independent pharmacies not affiliated with PBMs receive *higher* reimbursements than unaffiliated chain pharmacies, independent pharmacies are profitable, and the number of prescriptions filled at independent pharmacies is increasing.
- It falsely claims that Express Scripts is "profiting by inflating drug costs," including by taking rebates from drug manufacturers in return for putting high-cost drugs on formularies when, in truth, the bulk of rebates and fees received by PBMs get passed through to plan sponsors and *lower* the net cost of drugs to plan sponsors and members.[14] Moreover, Express Scripts prefers drugs with the lowest net cost to its plan sponsors on its largest standard formularies.
- It makes the broad-brush claim that the PBMs failed to comply with the Commission's 2022 6(b) orders, which demanded extensive data and information for production—without identifying who the supposed offenders are—even while

[10] *Id.* at 3-5.

[11] *Id.* at 5.

[12] *Id.* at 2.

[13] *Id.* at 1.

[14] Pharmaceutical Strategies Group, *2023 Trends in Drug Benefit Design Report*, at 54 (2023), *available at* https://www.psgconsults.com/2023traditionalbdr ("[A] recent survey showed that majorities of both large and small employers received 100% of rebates (including all price protection payments and manufacturer administrative fees).").

Express Scripts had long ago complied with the Commission's requests, which the Commission knew and verbally acknowledged before and after issuing its Report.

- It falsely states that PBMs, including Express Scripts, "profit at the expense of patients by inflating drug costs" when the evidence shows that PBMs compete for the business of plan sponsors by offering lower costs for covered drugs than their competitors. PBMs have low and declining operating margins and any PBM that sought to inflate the cost of covered drugs would quickly lose its clients.

13. The Report's patent bias and false insinuations even moved one supporting Commissioner to try to correct the record. Commissioner Slaughter admitted in her statement supporting issuance of the Report that not all PBMs exclude lower cost drugs and cited a specific example relating to Express Scripts. This limited attempt to balance the Report, however, was too little, too late.

14. The Commission's July 2024 Report violates federal and state law several times over, including in at least the following ways:

- By exhibiting bias against PBMs and prejudgment of the facts, the Report violates Express Scripts' right to due process under the Fifth Amendment to the U.S. Constitution.

- It contains (i) assertions that will predictably be and have been interpreted as conclusions adverse to all PBMs and (ii) false statements unsupported by the record that demonstrate the Commission's failure to consider the available contrary evidence and render its decision arbitrary and capricious.

- It is not in the public interest and therefore exceeds the Commission's statutory authority under Section 6(f) of the FTC Act.

- It is unlawful because Commissioners exercise executive authority while enjoying statutory removal protections in violation of Article II of the U.S. Constitution.

- And the Commission's claim both in the Report and the accompanying press release that PBMs, including Express Scripts, are "inflating drug costs" and "profit by inflating drug costs at the expense of patients," is false and defamatory.

15. Express Scripts has been harmed, and continues to be harmed, by the Commission's conduct. Express Scripts spent millions of dollars and thousands of hours

responding to a Commission "study" that ignored the evidence Express Scripts and others produced and turned out to be a cover for issuing the biased PBM Report that Chair Khan and the Commission had long planned. Since July, Express Scripts' business and reputation have been, and continue to be, harmed by the false statements in the Report about its business practices and the insinuation that Express Scripts' successful efforts to fight for lower prices for plan sponsors and members somehow violate the laws enforced by the Commission. And Express Scripts has since been named as a defendant in multiple lawsuits invoking the Report as evidentiary support for plaintiffs' claims, as well as multiple demands for information from state regulators and federal legislative committees. These harms have only just begun and will only be compounded over time if the Commission's unlawful Report is not vacated or set aside by this Court.

16. The Commission's unlawful Report must be vacated; the Commission should take steps to correct the false statements it has made about PBMs; and Chair Khan should be recused from further Commission proceedings regarding Express Scripts in light of her evident bias against PBMs, including Express Scripts.

PARTIES

17. Plaintiff Express Scripts, Inc., is a Delaware corporation with its principal office or place of business at 1 Express Way, Saint Louis, MO 63121.

18. Defendant Federal Trade Commission is an agency of the United States government. Its headquarters are located at 600 Pennsylvania Avenue, Washington, D.C. 20580.

19. Defendant Lina M. Khan is the Chair of the Federal Trade Commission. She was sworn in as Chair of the Commission on June 15, 2021. She is being sued in her official capacity.

JURISDICTION AND VENUE

20. This Action arises under the Constitution and laws of the United States, and this Court has federal question jurisdiction over this Action pursuant to the U.S. Constitution and 28 U.S.C. § 1331. This Court has supplemental jurisdiction over Express Scripts' state-law claim pursuant to 28 U.S.C. § 1367(a).

21. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (e), including because Express Scripts has its principal place of business in this district and a substantial part of the events or omissions giving rise to the claims occurred here.

22. This Court is authorized to grant the relief prayed for under the U.S. Constitution; the All Writs Act, 28 U.S.C. § 1651(a); and the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201(a)-2202.

BACKGROUND

A. The Procompetitive Pharmacy Benefit Management ("PBM") Industry

1. *PBMs Negotiate with Drug Manufacturers and Retail Pharmacies to Lower the Cost of Prescription Drugs*

23. Most Americans do not pay the list price for their prescription drugs. Instead, prescription drug purchases are paid for in part through health insurance plans which offer a prescription drug benefit. Some consumers purchase health insurance privately, such as on insurance exchanges, and others have health insurance provided by an employer, union, or the government (such as Medicare or Medicaid). PBM clients include employers (including major drug manufacturers offering prescription drug benefits to their employees), health insurance plans, labor unions, government programs, and other groups that offer prescription drug benefits. Generally, PBM clients are called "plan sponsors" and plan beneficiaries, *i.e.*, individual

Americans, are referred to as "members." PBMs can assist plan sponsors in managing all or just part of the prescription drug benefit offered to members.

24. PBMs do not set the prices of prescription drugs. Drug manufacturers set the list price for prescription drugs, called the wholesale acquisition cost (or "WAC") and also set net list prices (list prices net of any rebates or discounts) based on what they agree to offer to different groups in terms of rebates or other discounts.

25. PBMs provide valuable benefits to plan sponsors, primarily services that help plan sponsors reduce the cost of providing prescription drug benefits. Plan members also benefit from plan sponsors' use of PBMs, in significant part by paying less for their prescription drugs, which can improve drug adherence and medical outcomes.

26. PBMs can perform a host of services for plan sponsors, some of which involve complex administrative functions, like prescription claims processing. Express Scripts, for example, adjudicates over a billion prescription claims a year from its network pharmacies. Every prescription undergoes more than 18,000 safety, quality, and benefit checks in less than one second of being submitted at the pharmacy counter, resulting in millions of interventions to improve the health of patients.

27. PBMs also provide formulary development services for plan sponsors pursuant to plan sponsors' requests. A formulary is a list of drugs covered by a health plan. Plan sponsors typically design their prescription benefit plans so members pay less for drugs that are included or preferred on the plan sponsor's formulary compared to drugs not included or not preferred on the formulary. For example, Express Scripts' largest standard formulary includes 99% of all generic drugs. Plan sponsors may build their own formulary, adopt one of the standard

formularies offered by PBMs, or choose to create a custom formulary using one of the PBM standard formularies as a starting point.

28. Plan sponsors often choose to segment formularies into tiers, with drugs in each tier having different levels of member costs (such as different co-pays or deductible requirements, the levels of which are determined by the plan sponsor). Plan sponsors use formularies (and tiers within formularies) to design benefit plans that provide incentives to their members to choose lower-cost options, where clinically appropriate, which reduces the cost of prescription drugs for the plan sponsor and ultimately its members. For example, formularies may encourage generic substitution by placing generic drugs on the lowest-cost tier. This helps explain why generics represent about 91 percent of all prescriptions filled in the United States.[15] Though PBMs may develop several standard formularies, customization by plan sponsors results in PBMs administering thousands of different formulary and plan designs for their plan sponsor clients.

29. To facilitate formulary development, PBMs, including Express Scripts, negotiate with branded drug manufacturers to obtain discounts (rebates) to lower branded drug prices. Branded drug manufacturers often condition rebates on favorable placement of their drugs on standard or custom formularies used by plan sponsors. Manufacturers typically agree to larger discounts for formulary placements that they expect will drive higher volume than for formulary placements with lower expected volume.

30. To protect plan sponsors and their members from price increases, PBMs often seek price protection agreements from manufacturers, which moderate the impact of manufacturers' raising list prices above a specified level. One congressional committee

[15] U.S. Food and Drug Administration, *Office of Generic Drugs 2022 Annual Report,* at 1 (January 2023), https://www.fda.gov/media/165435/download?attachment.

observed "that PBMs secured contractual provisions that disincentivized drug companies from raising list prices. Without those provisions secured by PBMs, drug companies likely would have raised list prices more."[16]

31. The discounts and price protection payments offered by a drug manufacturer depend, in large part, on whether the drug faces competition from alternative branded or generic drugs. For branded drugs that do not face competition, manufacturers typically offer no rebates. But for branded drugs that do face competition, PBMs can use that competition to reduce net drug costs for plan sponsors and their members through rebates. Manufacturers of therapeutically comparable drugs typically compete for preferred placement on plan sponsor formularies by offering lower net prices via rebates or other discounts, such as price protection, with the expectation that more favorable placement in a particular formulary design will result in increased sales.

32. PBMs' negotiations with drug manufacturers for rebates and price protection is one of the many ways that PBMs help plan sponsors reduce the cost of prescription drug benefits.

33. Plan sponsors determine how manufacturer rebates are distributed. Plan sponsors may choose to allocate some or all of the rebates to members at the point-of-sale as one means of reducing out-of-pocket costs for the members who purchase the rebated drugs. Or the plan sponsor may specify that the PBM transfers all of the rebates to the plan sponsor, which it can use as it sees fit (*e.g.*, to reduce premiums, reduce out-of-pocket costs for members, or improve benefits). While plan sponsors sometimes allow a PBM to retain a small, negotiated percentage

[16] Staff of H. Comm. on Oversight and Reform, *Drug Pricing Investigation – Majority Staff Report*, at 47 (Dec. 10, 2021), https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf.

of the rebate payments as part of the compensation for the PBM's services, more often the entire rebate is passed through to the plan sponsor. Offering attractive payment terms is one of the ways PBMs compete with each other to win plan sponsors' business.

34. PBMs also negotiate with pharmacies for discounted drug reimbursement costs. PBMs create a variety of pharmacy networks that plan sponsors can choose from and also create custom networks at the request of plan sponsors. Pharmacy networks may include retail, mail-order, and specialty pharmacies and can range from open networks that include practically every pharmacy in the country to managed networks that include a smaller number of lower-priced pharmacies with sufficient geographic coverage to serve the plan sponsors' members. For managed networks, PBMs may negotiate with pharmacies to obtain greater discounts off pharmacies' reimbursement rates in exchange for being included or having a favored position in various pharmacy network designs. Because plan sponsors may give plan members financial incentives to choose less expensive, in-network or preferred pharmacies, pharmacies that offer lower drug reimbursement rates are more likely to achieve a higher sales volume; this helps plan sponsors and members save money.

35. As research co-authored by two economists (who are currently staff members of the Bureau of Economics at the FTC) and a professor at Ohio State University concluded in a study published in 2020, "the cost savings associated with selective contracting [*i.e.*, limited networks] may be substantial" and laws that require PBMs and plan sponsors to use open networks (*e.g.*, any-willing-provider laws) "reduc[e] competition by inhibiting the ability of insurers to move demand across competing pharmacies."[17]

[17] Daniel Hosken, David Schmidt & Matthew C. Weinberg, *Any Willing Provider and Negotiated Retail Pharmaceutical Prices*, 68 J. Indus. Econ. 1, 1 (2020).

36. Plan sponsors can choose pharmacy network options that best fit their budget and needs, which can vary across plans (*e.g.*, sufficient geographic coverage for the plan's members varies by plan). PBMs may manage thousands of different pharmacy network designs as they attempt to meet plan sponsors' needs.

2. Services Provided by Express Scripts Lower the Cost of Prescription Drugs for Its Clients

37. For decades, Express Scripts' mission has remained the same: helping plan sponsors reduce their drug spend and provide higher quality prescription benefits to their members. Through rebates, pharmacy network management, utilization management offerings, and other initiatives to reduce out-of-pocket costs, Express Scripts enables diverse sets of plan sponsors to access drugs at lower net costs and lower their members' total cost of care. Each year, Express Scripts delivers tens of billions annually in cost savings—including $38 billion in 2023 alone—for thousands of plan sponsors, including through rebates.

38. At Express Scripts, changes to its standard formularies are subject to a multi-stage approval process, incorporating therapeutic and financial factors. At the outset, Express Scripts' Therapeutic Assessment Committee ("TAC") and National Pharmacy and Therapeutics ("P&T") Committee undertake a "clinical first" analysis. Clinical determinations are made by the P&T Committee, a group of independent, actively practicing physicians and pharmacists who are not employed by Express Scripts.

39. The P&T Committee designates a drug as "include" when it addresses a "clinically significant unmet treatment need" (and therefore must be included on Express Scripts' formularies); as "exclude" (when it must be excluded); and as "optional" when it is "clinically similar to other currently available drug alternatives" or because it has greater efficacy than, or a superior safety profile compared to, existing therapy alternatives. "Optional" drugs for the

standard formularies are forwarded to Express Scripts' Value Assessment Committee ("VAC") for further analysis—obviously, VAC does not weigh in on drugs that have been designated "include" or drugs designated "exclude." The VAC is charged with making formulary placement recommendations for "optional" drugs, an assessment that involves a determination of which formulary scenario is likely to result in the lowest net cost for the clients using that formulary. VAC's formulary decisions are subject to final approval by the P&T Committee. Neither the VAC nor the P&T Committee consider profits to Express Scripts in their analysis. Through this process, Express Scripts ensures that its standard formularies include beneficial drugs and, where more than one alternative is available, that the standard formularies adopt the scenario with the lowest estimated net cost for plan sponsors.

40. In addition to offering standard formularies, Express Scripts also works with plan sponsors to develop custom formularies. In fact, for the majority of members in plans using Express Scripts, plan sponsors do not use one of Express Scripts' standard formularies. In 2022, at least 66% of members in plans using Express Scripts were on a custom formulary.

41. Plan sponsors—not Express Scripts—exercise control over the entirety of the prescription drug plan offered to their members. This includes wide discretion regarding aspects of the plan design, including but not limited to: (1) what formulary to use; (2) the pharmacies that will be included in the plan's pharmacy network; (3) whether there are premiums and the amount of those premiums; (4) whether there are deductibles and the amount of those deductibles; (5) whether there are co-insurance or co-pay obligations and the amounts of those obligations; (6) whether there are "flat" co-payments depending on the type of drug (brand, generic, retail, specialty, etc.); (7) whether utilization management will be applied to any

particular drug therapy or condition; and (8) the degree to which they use programs to mitigate member list price exposure.

3. PBM Competition Lowers Drug Costs

42. Express Scripts and other PBMs compete with each other to offer valuable PBM services to plan sponsors. Plan sponsors are free to choose among the PBMs that compete for their business, which includes the six PBMs that received 6(b) orders and the many PBMs that did not receive orders. To foster competition among PBMs and to elicit information on what different PBMs can offer, and at what cost, plan sponsors typically utilize highly detailed RFPs that require responses from several competing PBMs. Plan sponsors' use of an RFP process provides incentives for PBMs to compete aggressively on price and value. If a PBM does not make an attractive offer to a plan sponsor, it risks losing that plan sponsor as a customer until the next bidding cycle. If no PBM is able to deliver value to a plan sponsor, that plan sponsor may choose not to use any PBM at all and self-supply the necessary services.

43. As the Commission itself has recognized, this competition among PBMs is "intense, has driven down [drug] prices, and has resulted in declining PBM profit margins."[18] In fact, PBM operating margins were *lower* in 2022 than they were in 2017 and are below 5% in recent years.[19]

44. PBMs lower the price of prescription drugs for plan sponsors. This has been repeatedly demonstrated by studies, academic articles, and analyses conducted by government agencies, including the FTC. For example:

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[18] FTC, *Statement Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc*, at 2, FTC File No. 111-0210 (Apr. 2, 2012), https://www.ftc.gov/sites/default/files/documents/closing_letters/proposed-acquisition-medco-health-solutions-inc.express-scripts-inc./120402expressmedcostatement.pdf.

[19] Carlton PBM Report at 2.

- The Government Accountability Office ("GAO") found that PBMs helped Medicare Part D plan sponsors reduce their overall expenditures on prescription drugs by negotiating discounts (in the form of rebates) and other price concessions from manufacturers that face competition for their drugs.[20] The GAO estimated that the negotiated savings reduced total drug spending by Medicare Part D plan sponsors by 20% in 2016 and, for the 200 most utilized drugs, the negotiated savings reduced drug spending by Medicare Part D plan sponsors by 36%.[21]

- A forthcoming academic study of the statin market estimated that doing away with PBMs' negotiation of rebates and having drug manufacturers simply set prices would increase plan sponsors' spending on those drugs, ultimately increasing payments to the drug manufacturers by almost 50%.[22] The study's conclusion that PBMs' involvement in negotiating discounts off list prices significantly lowers drug costs for payors is not altered when "[a]ccounting for payments to PBMs."[23]

- A 2019 study by the Congressional Budget Office estimated that a proposed rule essentially prohibiting manufacturers from paying rebates to PBMs would have increased net federal spending on Medicare alone by $170 billion over the 10-year period between 2020 and 2029.[24]

- A recent study by academic economist Casey B. Mulligan, chief economist for the White House Council of Economic Advisers in 2018-2019 ("Mulligan study"), estimated "the annual value to society of PBM services to be at least $145 billion beyond its resource costs."[25] Moreover, the study concluded that a significant fraction of this value (40%) would be lost if plan sponsors had to self-supply PBM services rather than working with third parties specializing in their provision.[26]

- Another study estimated that PBMs help plan sponsors and their members "save 40-50% on their annual drug – and related medical costs compared to what they

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[20] *See* U.S. Gov't Accountability Off., *Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization* (July 2019), https://www.gao.gov/assets/gao-19-498.pdf.

[21] *See id.*

[22] See Josh Feng & Luca Maini, *Demand Inertia and the Hidden Impact of Pharmacy Benefit Managers*, at 5 (Feb. 28, 2023), https://static1.squarespace.com/static/5b3660f9b98a78542ce0faa9/t/65cbbc8f2c423019dadb1c34/1707850895874/PBM_MS_Final_luca_web_version.pdf.

[23] *Id.* at 34.

[24] *See* Cong. Budget Off., *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*, at 1 (May 2019), https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf.

[25] Casey B. Mulligan, *The Value of Pharmacy Benefit Management*, at 2, NBER Working Paper No. 30231 (July 2022), https://www.nber.org/system/files/working_papers/w30231/w30231.pdf.

[26] *See id.* at 30.

would have spent without the PBMs."[27] Of the 40-50 percent of savings, 35-40 percentage points stem from manufacturer rebates and pharmacy discounts, 5-10 percentage points result from encouraging plan members to buy generics and lower-cost preferred brands, and 5-10 percentage points result from reducing inappropriate drug usage and improving patient adherence.[28] These estimated savings for plan sponsors and members combined translate into roughly $878 per plan member, per year.[29] Plan sponsors were estimated to have received $10 in savings for every $1 spent on PBMs.[30]

- A 2023 survey of the economic literature on PBMs found that "[t]he empirical evidence is overwhelming" in showing the cost savings driven by PBMs. "Numerous academic, industry, and government studies show that formularies elicit manufacturer competition and significant price concessions. Studies all support a conclusion that PBMs' negotiating function results in savings of roughly 20% off branded drugs. Further, PBMs have helped drive significant utilization of generic drugs. The resulting savings amount to billions of dollars each year."[31]

45. The overwhelming evidence shows that PBMs are the *only* actor in the prescription drug supply chain whose purpose is to *help* the payors of prescription drug benefits *pay less for prescription drugs*, not pay more. If plan sponsors were not able to manage prescription drug costs, plan sponsors may decide that it is too costly to offer drug benefits to their members, potentially leaving millions of Americans to have to pay for prescription drugs on their own.

[27] Visante, *The Return on Investment (ROI) on PBM Services*, at 2 (Jan. 2023), https://www.pcmanet.org/wp-content/uploads/2023/01/The-Return-on-Investment-ROI-on-PBM-Services-January-2023.pdf.

[28] *See id.* at 4.

[29] *See id.* at 5.

[30] *See id.* at 2.

[31] Luke M. Froeb & Mikhael Shor, *Formularies, Rebates, and the Economics of PBM Bargaining*, at 58 (Vanderbilt Owen Graduate School of Management Research Paper) (May 8, 2023), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4442064.

B. The Commission's Section 6(b) and 6(f) Authority

46. Section 6(b) of the FTC Act grants the Commission authority to order persons, partnerships, and corporations to provide documents and information to the Commission.[32] The FTC describes its Section 6(b) prerogatives as one of its "specific investigative powers."[33]

47. Section 6(f) of the FTC Act, meanwhile, empowers the Commission to make public certain information that it obtains when doing so is "in the public interest."[34]

C. The Commission Initiates an Inquiry into PBMs and Issues Section 6(b) Orders to Express Scripts and Other PBMs

48. In February 2022, Chair Khan proposed using "the Commission's investigative authority under Section 6(b) of the Federal Trade Commission Act to issue orders to large pharmacy benefit managers (PBMs) to study a range of their commercial practices."[35] The Commission at the time had two Republican and two Democratic commissioners. Chair Khan's proposal failed to garner support from a majority of the commissioners.

49. After Commissioner Bedoya's appointment provided Chair Khan a majority of commissioners from the same political party, Chair Khan again proposed using the FTC's 6(b) authority to issue orders to PBMs, including Express Scripts. On June 6, 2022, the Commission voted to issue the orders. While the purpose of the orders was ostensibly to learn about PBM practices, Chair Khan stated in a press release announcing the orders that "[i]n many instances, PBMs practically determine which medicines are prescribed, which pharmacies patients can use,

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[32] 15 U.S.C. § 46(b).

[33] FTC, *A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority* (revised May 2021), https://www.ftc.gov/about-ftc/mission/enforcement-authority.

[34] 15 U.S.C. § 46(f).

[35] Lina M. Khan, Chair, FTC, *Remarks Regarding the 6(b) Study on Pharmacy Benefit Managers Commission*, at 1, File No. P221200 (Feb. 17, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/p221200khanstatementrepbms.pdf.

and the amount patients will pay at the pharmacy counter."[36] These premature conclusions, which reflect Chair Khan's longstanding bias against PBMs, were plainly wrong. First and foremost, doctors decide what medications are prescribed to their patients.[37] And plan sponsors, not PBMs, decide how their plans are designed, including applicable formularies, pharmacy networks, and co-pay amounts. Chair Khan's statement plainly foreshadowed the bias, disregard of the facts, and fundamental lack of understanding of the industry that ultimately pervaded the Commission's Report.

50. On June 7, 2022, the FTC issued a press release announcing an "inquiry" into what it called the "prescription drug middleman industry."[38] The press release featured Chair Khan's description of "powerful middlemen [that] have enormous influence over the U.S. prescription drug system"[39]—a description provided by Chair Khan before the FTC received any documents from PBMs pursuant to the 6(b) orders and before the staff commenced its study.

51. The orders issued by the FTC to Express Scripts and other PBMs were enormously burdensome. Including subparts, the orders contained over 180 requests and sought data and information for over a five-and-a-half-year period. Among other things, the FTC demanded detailed data about every pharmacy network administered by PBMs and the production of every document relating to the negotiation of pharmacy networks. The FTC required Express Scripts to produce a wide array of data related to plan sponsor benefit design,

[36] Lina M. Khan, Chair, FTC, *Statement Regarding 6(b) Study of Pharmacy Benefit Managers Commission*, at 1, File No. P221200 (June 8, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Statement-Khan-6b-Study-Pharmacy-Benefit-Managers.pdf.

[37] Express Scripts, *White Paper: Formulary Development at Express Scripts*, at 1 (December 2020), https://www.express-scripts.com/aboutus/formularyinformation/development/formularyDevelopment.pdf.

[38] Press Release, FTC, *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.

[39] *Id.*

including formulary rules and utilization management criteria employed by plan sponsors. Likewise, the FTC demanded an incredible volume of claims and rebate data.

52. Express Scripts devoted substantial resources to complying with the FTC's demands, spending millions of dollars and tens of thousands of hours to respond to the FTC's expansive 6(b) order. Express Scripts produced over 3.3 million pages of documents and more than 769 million rows of data consisting of more than 11 billion observations to the Commission, complying in full with the 6(b) order. FTC staff has confirmed in verbal communications with counsel for Express Scripts that Express Scripts was in full compliance with the PBM 6(b) order.

53. While purporting to study issues relating to drug pricing, upon information and belief, the Commission did not issue any 6(b) orders to the parties that actually set prices: drug manufacturers. Likewise, while purporting to study issues related to pharmacies unaffiliated with PBMs, upon information and belief, the Commission did not issue any 6(b) orders to such pharmacies.

D. The Commission Receives Congressional Pressure to Issue PBM Report

54. On January 22, 2024, certain members of Congress wrote a letter to Chair Khan to "urge the FTC to complete the [PBM] study without delay" and "to issue a progress report"[40]—and do so "in a timely manner."[41]

55. On February 13, 2024, Chair Khan responded to the Congressional letter. She wrote that she "share[d] your sense of urgency regarding timely completion of the study"[42] and—undeterred by the FTC staff's supposedly pending work—again prejudged the

[40] Letter from Sen. Charles E. Grassley, et al. to Lina M. Khan, Chair, FTC, at 1-2 (Jan. 22, 2024), https://www.grassley.senate.gov/imo/media/doc/grassley_cantwell_colleagues_to_ftc_-_pbm_investigation.pdf.

[41] *Id.* at 2.

[42] Letter from Lina M. Khan, Chair, FTC, to Sen. Charles E. Grassley, at 1 (Feb. 13, 2024), https://www.grassley.senate.gov/imo/media/doc/ftc_to_grassley_-_pbm_6b_study.pdf.

Commission's findings (echoing the language she used in 2022 in launching the "study"). Chair Khan stated that "PBMs … have substantial influence over independent pharmacies, which have collectively voiced concern that PBMs impose contractual terms with these pharmacies that are confusing, unfair, arbitrary, and harmful to their businesses."[43] And she asserted that "[d]ecisions by PBMs and their affiliates" "can have dire consequences for Americans."[44]

56. At the time of this letter, the FTC staff had not done the work necessary to come to conclusions like those expressed by Chair Khan. Indeed, Chair Khan claimed the staff were still "diligently … sifting through, reviewing, and analyzing the *millions of documents and several terabytes of data that have been produced to date*."[45] Although this was a "significant and complex undertaking,"[46] Chair Khan already knew what the outcome would be because the "study" was simply cover to deliver a Report attacking the PBM industry.

E. A Splintered Commission Issues an "Interim" PBM Report Over a Dissent and Other Criticism Over Process, Politicization, and Lack of Rigor

57. On July 9, 2024, the FTC issued what it styled as an "interim" Report on PBMs titled, "Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies."[47]

[43] *Id.* at 1.

[44] *Id.*

[45] *Id.* at 3 (emphasis added).

[46] *Id.*

[47] FTC, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies, Interim Staff Report (July 2024) [hereinafter "Report"], https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

58. Also on July 9, 2024, the FTC issued a press release touting the Report. The press release's subtitle asserted that the "[r]eport details how prescription drug middleman profit at the expense of patients by inflating drug costs and squeezing Main Street pharmacies."[48]

59. Commissioner Ferguson concurred in issuing the Report but identified numerous major concerns with it,[49] including (1) the irregular and "unusual" step of issuing an "interim" Report in the first place, which the Commission "rare[ly]" does; (2) the Report's excessive reliance on anonymous public comments, which should be treated "with circumspection," rather than materials submitted by PBMs pursuant to the Commission's 6(b) orders; and (3) the Report's overreliance on a single "case study" of two drugs, rather than thousands and thousands of drugs available in the United States today, which is "hardly definitive."

60. Commissioner Holyoak, in a scathing statement, dissented at length about the issuance of the Report. She explained, in particular, that the Report fell short of the standards of rigor and excellence of other FTC reports and would "only exacerbate ideological schisms and further degrade the legitimacy of the Commission."[50] As to the substance of the Report, Commissioner Holyoak observed that "the Report leaves us without a better understanding of the competition concerns surrounding PBMs or how consumers are impacted by PBM practices."[51]

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[48] Press Release, FTC, *FTC Releases Interim Staff Report on Prescription Drug Middlemen* (July 9, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/07/ftc-releases-interim-staff-report-prescription-drug-middlemen.

[49] Andrew N. Ferguson, Commissioner, FTC, *Concurring Statement in the Matter of the Pharmacy Benefit Managers Repor*t, at 2-3, FTC Matter No. P221200(July 9, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/Ferguson-Statement-Pharmacy-Benefit-Managers-Report.pdf.

[50] Holyoak Dissenting Statement at 2-3.

[51] *Id.*

F. The Unconstitutional Structure of the Federal Trade Commission

61. All of the agency actions described above—including initiating the PBM study and issuing the July 2024 Report—were undertaken by a Commission whose structure violates Article II of the U.S. Constitution.

62. The Federal Trade Commission is composed of five Commissioners who are appointed by the President by and with the advice and consent of the United States Senate. The President can remove an FTC Commissioner only "for inefficiency, neglect of duty, or malfeasance in office,"[52] affording Commissioners near total insulation from presidential removal.

63. The Commission has statutory authority to exercise a host of executive functions. In particular, the Commission has broad investigative powers, including under Section 6 of the FTC Act, which the FTC describes as an "investigative tool" to support its "law enforcement" efforts.[53] The Commission can bring administrative proceedings against persons subject to its jurisdiction for allegedly engaging in unfair methods of competition or unfair or deceptive acts or practices.[54] In the 1970s, Congress amended the FTC Act by giving the Commission substantial additional enforcement authority—authority that the Supreme Court has recently characterized as "quintessentially executive power."[55] Specifically, Congress amended the FTC Act to vest in FTC Commissioners the power to seek injunctive relief in federal district court.[56] Today, the Commission heavily relies on this enforcement power, bringing numerous actions in U.S. District Court.

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[52] 15 U.S.C. § 41.

[53] FTC, *A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority* (revised May 2021), https://www.ftc.gov/about-ftc/mission/enforcement-authority.

[54] 15 U.S.C. § 45.

[55] *Seila Law LLC v. Consumer Fin. Prot. Bureau*, 591 U.S. 197, 219 (2020).

[56] *See* 15 U.S.C. § 53(b) (amended in Pub. L. No. 93-153, § 408(f), 87 Stat. 576, 592 (1973)).

64. In short, it is not true that the Commission's present-day powers and prerogatives "are neither political nor executive, but predominantly quasi[-]judicial and quasi[-]legislative."[57]

65. Because FTC Commissioners wield substantial investigative and executive power over large swaths of the U.S. economy, the Commissioners' statutory insulation from presidential removal is incompatible with Article II's vesting of all executive power in the President and the President's sole responsibility to take care that the laws be faithfully executed.

ALLEGATIONS

A. The Report Violates Plaintiff's Due Process Rights

66. The Fifth Amendment to the Constitution requires government bodies and officials to accord basic due process to private parties. Due process requires, at a minimum, impartial treatment unblemished by bias and prejudgment when wielding investigative powers and releasing information.

67. Here, the Commission demonstrated actual bias against Express Scripts and other PBMs. Today's FTC is led by Commissioners and a Chair who came to the agency having already prejudged the PBM industry and with an agenda to advance objectives of favored constituents. These groups have exerted enormous political pressure on the Commission to "do something" about PBMs. And so they did.

68. The Commission issued a Report supposedly stemming from its fig leaf "study" that reached pre-baked conclusions based on shoddy argumentation without analytical rigor. It disregarded and ignored the bulk of the extensive evidence submitted by PBMs in favor of anonymous comments organized by powerful special interests, and falsely cast blame on PBMs in intentionally imprecise terms for a laundry list of challenges, real or imagined, in the

[57] *Humphrey's Ex'r v. United States*, 295 U.S. 602, 624 (1935).

healthcare sector. Ultimately, the Commissioners who approved the Report failed to do justice to the facts and instead favored the pursuit of political interests. That is not only wrong and unfair to the American public, but the methods that the Commission is using are unconstitutional and exceed the Commission's statutory remit.

1. The FTC's Prior Statements Recognize Competitive Benefits of PBMs

69. Time and again, the Commission has recognized on a bipartisan basis across administrations of different political parties the benefits of PBMs, including that PBMs have the "ability to negotiate lower prices for prescription drugs,"[58] create incentives "for pharmacies to bid aggressively on prescription drug prices,"[59] and that PBM formulary and generic substitution practices "lowers prescription drug costs" and "lower prices for health care"[60] for consumers.

70. The FTC engaged in a detailed study of PBMs in 2005. Even prior to completing that study, the Commission's view was that, "[t]o date, empirical evidence suggests that PBMs have saved costs for payors."[61] In the 2005 study, the Commission found that "competition among PBMs for contracts with plan sponsors is 'vigorous.'"[62] The Commission explained that PBMs' creation of retail pharmacy networks works to *lower* drug costs. "By forming a preferred

[58] Letter from Susan S. DeSanti, Joseph Farrell & Richard A. Feinstein, FTC to State Rep. Mark Formby, Miss. H.R., at 4 (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.

[59] *Id*. at 4.

[60] Letter from Maureen K. Ohlhausen, Michael A. Salinger & Jeffrey Schmidt, FTC to Terry G. Kilgore, Member, Commonwealth of Virginia House of Delegates, at 4, 6 (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.

[61] Fed. Trade Comm'n & U.S. Dep't of Justice, *Improving Healthcare: A Dose of Competition*, at 20 (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.

[62] Letter from Maureen K. Ohlhausen, Michael A. Salinger & Jeffrey Schmidt, FTC to Terry G. Kilgore, Member, Commonwealth of Virginia House of Delegates, at 7 (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.

or exclusive network, a PBM is able to guide plan beneficiaries to certain pharmacies. The promise of increased customer volume creates an incentive for pharmacies to bid aggressively on drug prices."[63] In 2011, the Commission reiterated that "PBMs negotiate lower pharmacy costs by forming a preferred or exclusive network of retail pharmacies."[64] And nearly a decade after issuing the 2005 report, the Commission found that "[m]any of the economic principles and market characteristics that the FTC's 2005 study identified as important determinants of competition continued to be significant in 2012."[65]

71. After its 2012 "comprehensive investigation" of the Express Scripts acquisition of Medco Health Solutions, which involved interviews of "over 200 market participants, including customers, other PBMs, retail and specialty pharmacies, pharmacy trade groups, pharmaceutical manufacturers, and healthcare benefit consulting firms" and the review of "[m]illions of documents," the Commission concluded that competition among PBMs "is intense, has driven down prices, and has resulted in declining PBM profit margins."[66] The Commission further noted that "[o]ur investigation revealed a competitive market for PBM services characterized by numerous, vigorous competitors who are expanding and winning business from traditional market leaders."[67]

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[63] *Id.* at 5.

[64] Letter from Susan S. DeSanti, Joseph Farrell & Richard A. Feinstein, FTC to State Rep. Mark Formby, Miss. H.R., at 4 (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.

[65] Letter from Andrew I. Gavil, Martin S. Gaynor & Deborah Feinstein, FTC to Larry Good, Executive Secretary, ERISA Advisory Council, at 4 (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.

[66] FTC, *Statement Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc.*, at 2, FTC File No. 111-0210 (Apr. 2, 2012), https://www.ftc.gov/system/files/ftc_gov/pdf/Holyoak-Statement-Pharmacy-Benefit-Managers-Report.pdf.

[67] *Id*. at 9.

2. Current Commission Abandons the FTC's Evidence-Based Approach

72. In July 2023, the Commission voted to withdraw numerous prior letters, studies, and reports concerning the PBM industry. Those letters and reports had been produced by the FTC on a bipartisan basis over the course of multiple decades across the administrations of both political parties. Yet, the decision to disavow these letters and reports was made only by Chair Khan and the two other Democratic Commissioners—Commissioners Slaughter and Bedoya. The agency "warn[ed]" or "caution[ed]" "against relying" on the following nine letters and two reports/studies:[68]

- 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;
- The Commission's July 2004 joint report with the Department of Justice entitled "Improving Healthcare: A Dose of Competition";
- September 7, 2004 letter to California Assembly Member Greg Aghazarian regarding California Assembly Bill No. 1960;
- The Commission's August 2005 study entitled "Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies."
- March 8, 2005 letter to North Dakota State Senator Richard L. Brown regarding North Dakota House Bill 1332;
- October 2, 2006 letter to Commonwealth of Virginia Delegate Terry G. Kilgore regarding Virginia House Bill No. 945;
- April 17, 2007 letter to New Jersey Assembly Member Nellie Pou regarding Assembly Committee Substitute for Assembly No. 320;
- March 31, 2009 letter to New York State Senator James L. Seward regarding New York Senate Bill 58;

[68] FTC, *Statement Concerning Reliance on Prior PBM-Related Advocacy Statements and Reports That No Longer Reflect Current Market Realities* (July 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/CLEANPBMStatement7182023%28OPPFinalRevisionsnoon%29.pdf.

- March 22, 2011 letter to Mississippi State Representative Mark Formby regarding Mississippi Senate Bill 2445;
- 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;
- August 19, 2014 letter to the U.S. Department of Labor's ERISA Advisory Council regarding PBM compensation and fee disclosures.

73. Chair Khan claimed that the withdrawal of the FTC's prior data-driven and scholarly work was necessary because "these previous [FTC] documents may not reflect the current reality of the marketplace with respect to PBMs"[69] on the ostensible ground that the earlier work was "based on outdated market conditions and assumptions."[70] Yet Chair Khan never identified these new "realities" that supposedly warranted withdrawal of the prior letters and reports, nor identified what assumptions and market conditions were "outdated." Seemingly, the only new "reality" was that Chair Khan was now in charge of the Commission.

74. The Commission also never explained how it identified the eleven letters and reports that it warned were now outdated, or why the Commission decided to withdraw those letters and reports while it was "currently engaged in a major study of the PBM industry" and had not yet released any findings.[71] The Commission explained that its withdrawal of these statements was motivated by the fact that "advocates continue to cite prior Commission work" in an effort to oppose the Commission's political anti-PBM agenda.[72] The issuance of this

[69] Lina M. Khan, Chair, FTC, *Statement Regarding the Policy Statement Concerning Reliance on Prior PBM-Related Advocacy Statements and Reports*, at 1, FTC File No. P230100 (July 20, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/StatementofChairLinaMKhanrePBMLetterWithdrawal.pdf.

[70] *Id*. at 3.

[71] FTC, *Statement Concerning Reliance on Prior PBM-Related Advocacy Statements and Reports That No Longer Reflect Current Market Realities*, at 1 (July 20, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/CLEANPBMStatement7182023%28OPPFinalRevisionsnoon%29.pdf.

[72] *Id.* at 3-4.

guidance in advance of any findings from the PBM study suggests that, well before the investigation was done, at least three of the Commissioners had already reached their conclusion.

3. Release of the Interim PBM Report Reflects Bias

75. In July 2024, the Commission issued its Report of the "findings" of its 6(b) "study" of PBMs, over the dissent of one of the Commissioners. If there was any question that the Commission's study of PBMs was biased, that dissent provides the answer.

76. In her dissent, Commissioner Holyoak objected to the issuance of the Report, challenging the "politicized nature of the process" and noting that the Report reflected no new empirical analysis to rebut the FTC's 2005 PBM report.[73] Commissioner Holyoak continued, "[t]he 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.'"[74]

77. Commissioner Ferguson separately lamented the lack of rigorous analysis underlying the Report's findings. He noted the Report's "reli[ance], throughout, in large part on public information that was not collected from the PBMs or their affiliates during the 6(b) process."[75] Commissioner Ferguson explained that the Report "relies heavily on public comments," many of which were anonymous, in which case the Commission "cannot know who

[73] Holyoak Dissenting Statement at 2-4.

[74] *Id*. at 5 (emphasis and internal citations omitted).

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

submitted the comments, nor [does the Commission] have any method for verifying the accuracy."[76] Commissioner Ferguson also criticized the Report for treating the contents of unverifiable anonymous comments "as fact."[77]

4. Chair Khan's Own Statements Reflect Bias and Prejudgment

78. From the beginning of her tenure at the Commission, and indeed as far back as law school, Chair Khan made clear that she thinks PBMs are to blame for higher drug prices. For example:

- In 2016, as a law student with no experience in the PBM industry, the pharmaceutical industry, the retail pharmacy industry, or in investigating mergers under the antitrust laws, Chair Khan decried how "the FTC has permitted pharmacies to merge with pharmacy benefits managers" and asserted—contrary to the facts—that "PBMs joined to pharmacies tend to steer plan members away from independent entities" and wrongly asserted this supposed PBM "conflict of interest" kept "drug prices high."[78]

- On June 22, 2022—within two weeks of issuing its demands for information to Express Scripts and other PBMs—Chair Khan spoke at an event cohosted by the National Community Pharmacists Association (NCPA), a lobbyist organization funded in part by large drug wholesalers and pharmacies.[79] The NCPA has commissioned public advertisements critical of PBMs and has extensively lobbied the government, including the FTC, to take law enforcement or legislative action against PBMs. In her remarks at the event, Chair Khan mischaracterized the nature of the PBMs' role, claiming that PBMs "and other intermediaries … have enormous consequences on people's day-to-day lives" and PBMs' "decisions help to determine which medicines are prescribed, which pharmacies patients can use, and the prices that patients ultimately pay at the pharmacy counter."[80]

- In September 2022 testimony before a Subcommittee of the Senate Judiciary Committee, just months after the PBM study was announced in June 2022, Chair Khan prejudged its outcome. Painting with untenably broad brushstrokes, Chair

[76] *Id*. at 2-3.

[77] *Id*.

[78] Lina Khan, *How to Reboot the FTC*, POLITICO (April 13, 2016), https://www.politico.com/agenda/story/2016/04/ftc-antitrust-economy-monopolies-000090/.

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

[80] *Id*. at 1.

Khan pilloried PBMs for having "opaque operations" and an ostensible ability to "dictate the pricing and access to life-saving drugs for so many Americans."[81]

- On October 3, 2022, Chair Khan headlined the NCPA's annual convention in Kansas City, Missouri, where she participated in a public discussion with NCPA's CEO.[82] In her remarks, Chair Khan pledged to crack down on illegal practices and to investigate the causes of high drug prices. At this conference, NCPA executives described PBMs as "bloodsuckers," and wore shirts depicting PBMs as vampires.[83] The NCPA has depicted PBMs in similar ways for years, including depicting PBMs as wolves or vicious dogs.[84] Chair Khan praised the NCPA for "help[ing] shape" the FTC's anti-PBM work.

- On May 4, 2023, Chair Khan spoke at the 2023 American Economic Liberties Project's "Anti-Monopoly Summit."[85] In her remarks, Chair Khan once again blamed PBMs, stating: "[In the healthcare sector,] we see these Pharmacy Benefit Managers that are sitting right in the middle and controlling the types of practices that independent pharmacies are facing, the medicines consumers are or have not been able to access, so we are looking at the magnitude of harm and who are the most significant players in the supply chain."[86]

- On February 14, 2024, Chair Khan again articulated the entirely false idea that PBMs increase costs and "control" access to drugs. She addressed the American Medical Association and discussed "concerns from patients and medical

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[81] Lina M. Khan, Chair, FTC, *Oversight of the Enforcement of the Antitrust Laws*, Prepared Statement of the Federal Trade Commission Before the United States Senate Committee on the Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights (Sept. 20, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/P210100SenateAntitrustTestimony09202022.pdf.

[82] *See* Lina Khan (@linakhanFTC), Twitter/X (Oct. 3, 2022, 2:37 PM), https://x.com/linakhanFTC/status/1577004971664384000 ("Many thanks to @Commpharmacy for the invitation and thoughtful discussion. Addressing unlawful business practices that are depriving Americans of affordable medicines and impeding fair competition is a top priority").

[83] *See* Cami Mondeaux, *FTC Chairwoman Lina Khan faces ethics complaint over alleged bias against pharmacy benefit managers*, WASHINGTON EXAMINER (Sept. 7, 2023), https://www.washingtonexaminer.com/news/2449295/ftc-chairwoman-lina-khan-faces-ethics-complaint-over-alleged-bias-against-pharmacy-benefit-managers/ ("During the conference, Khan appeared alongside NCPA executives who wore shirts depicting PBMs as vampires and labeling them as 'bloodsuckers' as the chairwoman spoke about her work.").

[84] *See Independent Pharmacies: Myths Versus Reality*, at 8-9, CVSHEALTH (Aug. 10, 2024), https://www.cvshealth.com/content/dam/enterprise/cvs-enterprise/pdfs/2024/drug-costs/2024-08-10-FTC-White-Paper-on-Independent-Pharmacies.pdf.

[85] One of the summit's sponsors was the NCPA. *See* Economic Liberties, *2023 Anti-Monopoly Summit*, YOUTUBE (May 4, 2023), https://www.youtube.com/watch?v=_MUdBWApI9k&t=3928s.

[86] *Id*. at 1:22:40.

professionals that the rebates that PBMs demand may function as kickbacks that raise costs and limit access to affordable medicines."[87]

- On March 4, 2024, while the FTC's 6(b) PBM "study" was ongoing, Chair Khan attended a partisan political event at the White House regarding drug costs. Without citing any evidence, pointing the finger at PBMs, she lamented that Americans are "[t]oo often … price gouged for [life-saving] medications[,] … sometimes with devasting results."[88]

79. As her statements confirm, Chair Khan came into office having already decided, as a law student, that PBMs are the bad actors. Chair Khan's mind is irrevocably closed to contrary views on PBMs and the overwhelming evidence that supports those contrary views.

80. This prejudgment by Chair Khan is fully consistent with findings of the Judiciary Committee of the U.S. House of Representatives which gathered extensive evidence of disillusionment at the FTC by its staff, including due to the Chair's politicization of the Commission's other work. In the report, one FTC manager explained that "outside influences ... have an undue impact on [FTC] priorities, investigation management, and enforcement decisions," and warned that the agency "should never make an enforcement-related decision for the sake of PR."[89]

B. The FTC Defamed Express Scripts By Falsely Declaring That Express Scripts is Inflating Drug Costs

81. The Commission gave its Report the false and defamatory title "Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street

[87] Lina M. Khan, Chair, FTC, *Remarks at the American Medical Association National Advocacy Conference*, at 4 (Feb. 14, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/remarks-chair-khan-ama-national-advocacy-conference.pdf.

[88] Lina M. Khan, Chair, FTC, *Remarks at the White House Roundtable on PBMs*, at 1 (Mar. 4, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/2024.03.04-chair-khan-remarks-at-the-white-house-roundtable-on-pbms.pdf.

[89] H. Comm. of the Judiciary, Interim Staff Report, *Abuse of Power, Waste of Resources, and Fear: What Internal Documents and Testimony from Career Employees Show About the FTC Under Chair Lina Khan*, at 2 (Feb. 22, 2024), https://judiciary.house.gov/sites/evo-subsites/republicans-judiciary.house.gov/files/evo-media-document/2024-02-22%20Abuse%20of%20Power%20Waste%20of%20Resources%20and%20Fear_0.pdf.

Pharmacies." The false statement that PBMs are "inflating drug costs" appears in large type on the front page of the report, and on multiple pages on the FTC's website.[90]

82. The Commission published its defamatory statement *again* in a press release announcing the Report. In the subtitle of the press release, appearing in large bold type at the top of the page, the FTC falsely declared that its "Report details how prescription drug middleman profit at the expense of patients by inflating drug costs and squeezing Main Street pharmacies." The press release further identified exactly who the "drug middlemen" it was defaming were: "The Commission's interim report stems from special orders the FTC issued in 2022, under Section 6(b) of the FTC Act, to the six largest PBMs—Caremark Rx, LLC; Express Scripts, Inc.; OptumRx, Inc.; Humana Pharmacy Solutions, Inc.; Prime Therapeutics LLC; and MedImpact Healthcare Systems, Inc."

83. The FTC intended to, and did, convey to readers that the named PBMs, including Express Scripts, are "inflating drug costs" and that the PBMs, including Express Scripts, "profit at the expense of patients by inflating drug costs." These statements are plainly false in several respects.

84. First, as described above, PBMs do not set drug prices at all. Drug prices are set by drug manufacturers, which decide the WAC for their drugs and what discount off of WAC (if any) to offer.

85. Second, PBMs, including Express Scripts, are responsible for *lowering* drug costs for plan sponsors and their members, as the Commission long recognized before Chair Khan took control of the agency. The Report fails to cite any data or evidence demonstrating that

[90] *See, e.g.*, Report at Cover; Press Release, FTC, *FTC Releases Interim Staff Report on Prescription Drug Middlemen* (July 9, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/07/ftc-releases-interim-staff-report-prescription-drug-middlemen (The "Report details how prescription drug middleman profit at the expense of patients by inflating drug costs and squeezing Main Street pharmacies.").

PBMs generally, or Express Scripts specifically, inflated drug costs.[91] For example, Express Scripts saved its clients and their patient-members over $38 billion last year alone through negotiated lower prices and formulary designs that encourage the use of lower cost drugs. Numerous academic and government studies and investigations, including several by the Commission, have demonstrated and quantified the magnitude of these savings to plan sponsors and patients. As described below, the evidence and data produced to the Commission in response to its 2022 6(b) orders once again demonstrate that PBMs lower drug costs for their clients.

86. Third, contrary to the Commission's assertions, Express Scripts and other PBMs do not "profit" by "inflating drug costs." To the contrary, Express Scripts competes with other PBMs based on its ability to *lower* drug costs through manufacturer discounts, negotiated pharmacy reimbursement rates, and formulary design. If Express Scripts were "inflating" its clients' or their members' drug costs, it would lose business and its profits would diminish, not increase.

87. Fourth, these statements were intended to convey the false impression that they are based on, and supported by, "findings" made by the Commission using the data and information produced by the PBMs (and presumably other market participants). While the

[91] *See, e.g.*, U.S. Gov't Accountability Off., *Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization* (July 2019), https://www.gao.gov/assets/gao-19-498.pdf; Josh Feng & Luca Maini, *Demand Inertia and the Hidden Impact of Pharmacy Benefit Managers*, at 5 (Feb. 28, 2023), https://static1.squarespace.com/static/5b3660f9b98a78542ce0faa9/t/65cbbc8f2c423019dadb1c34/1707850895874/PBM_MS_Final_luca_web_version.pdf; Cong. Budget Off., *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*, at 1 (May 2019), https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf; Casey B. Mulligan, *The Value of Pharmacy Benefit Management*, at 2, NBER Working Paper No. 30231 (July 2022), https://www.nber.org/system/files/working_papers/w30231/w30231.pdf; Visante, *The Return on Investment (ROI) on PBM Services*, at 2 (Jan. 2023), https://www.pcmanet.org/wp-content/uploads/2023/01/The-Return-on-Investment-ROI-on-PBM-Services-January-2023.pdf; Luke M. Froeb & Mikhael Shor, Formularies, Rebates, and the Economics of PBM Bargaining, at 58 (Vanderbilt Owen Graduate School of Management Research Paper, May 8, 2023), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4442064.

widely disseminated FTC press release states that the Report "stems" from Section 6(b) orders issued to Express Scripts and five other PBMs and that the report "details" how PBMs "profit at the expense of patients by inflating drug costs" the Report not only fails to provide any "detail," it fails to identify any data or information supporting the inflammatory title at all. As described below, the evidence produced (which was seemingly ignored) contradicts this false assertion.

88. Fifth, these statements are even false as to the text of the Report itself, which does not "detail" PBMs "inflating" drug costs at the "expense of patients." The Report never reaches the conclusion that PBMs *are* profiting by inflating drug costs or raising costs to patients at all, and never provides the "detail" that the widely disseminated press release claims it contains. As Commissioner Holyoak observed, the Commission and Chair Khan have "attempt[ed] to mislead the public into thinking the Report draws any conclusion about the prices patients pay for healthcare. It does not. In fact, the Report says nothing about consumer costs."[92]

89. The Commission and Chair Khan knew that their assertions were factually false at the time they made these statements. The Commission and Chair Khan were aware of the prior investigative and analytical work by the Commission showing that PBMs lowered drug costs. Indeed, at Chair Khan's direction, the Commission withdrew those statements before the issuance of the Report, and without a basis to repudiate them, precisely because they conflicted with the defamatory message the Commission and Chair Khan intended to convey. As Commissioner Ferguson noted, nothing in the Report contradicts or even grapples with these prior findings. The Commission and Chair Khan were also aware of the academic and other government studies showing that PBMs lower drug costs for plan sponsors and patients. Chair Khan and the Commission also knew that drug manufacturers, not PBMs, decide how much to

[92] Holyoak Dissenting Statement at 5-6.

charge for pharmaceuticals and that PBMs do not profit by inflating drug costs but succeed by lowering them. And as Commissioner Holyoak noted, the Commission and Chair Khan knew that the Report itself does not support their false claims that Express Scripts was "inflating" patients' drug costs at the expense of patients, much less profiting by doing so.

90. The false and defamatory statements were not only prominently published by the Commission, but were repeated by numerous news outlets, as the Commission intended. For example, CBS News reported that the Report finds that PBMs "are lining their pockets by inflating drug prices"; the New York Times reported that that the Report explains how "'these powerful middlemen may be profiting by inflating drug costs'"; and Reuters reported that "[t]he FTC argues the three biggest PBMs … have greatly enriched themselves at the expense of smaller pharmacies and consumers."[93]

91. The Federal Trade Commission is supposed to be an expert agency, committed to analytical rigor and publishing industry information only when doing so is in the "public interest." Its statements are accorded great weight by lawmakers, states, plan sponsors, investors, and consumers. Falsely stating that the PBMs who received 6(b) orders are inflating drug prices is defamatory on its face. But the Commission did not stop there. The press release not only accuses Express Scripts and other PBMs of inflating drug prices, it also links those

[93] Kate Gibson, *FTC Says Prescription Middlemen are Squeezing Main Street Pharmacies*, CBS NEWS (July 9, 2024), https://www.cbsnews.com/news/ftc-pbm-investigation; Reed Abelson & Rebecca Robbins, *F.T.C. Slams Middlemen for High Drug Prices, Reversing Hands-Off Approach*, N.Y. TIMES (July 9, 2024), https://www.nytimes.com/2024/07/09/health/ftc-pharmacy-benefit-managers-drug-prices.html; Ahmed Aboulenein & Jody Godoy, *Middlemen Have Outsized Influence on US Drug Prices, FTC Says*, REUTERS (July 9, 2024), https://www.reuters.com/business/healthcare-pharmaceuticals/middlemen-have-outsized-influence-us-drug-prices-due-market-consolidation-ftc-2024-07-09/; *see also, e.g.*, Christopher Snowbeck, *FTC Report Slams Pharmacy Benefit Managers, Says Firms Inflate Drug Costs, Squeeze Competitors*, MINNESOTA STAR TRIBUNE (July 9, 2024), https://www.startribune.com/ftc-pbm-report-pharmacy-benefit-managers-optumrx-prime-therapeutics-antitrust-drug-costs/600379411; Celine Castronuovo, *FTC Blames Pharmacy Benefit Managers for Raising Drug Costs*, BLOOMBERG LAW (July 9, 2024), https://news.bloomberglaw.com/health-law-and-business/ftc-blames-pharmacy-benefit-managers-for-inflating-drug-costs.

supposedly inflated prices to supposed "dire consequences" to patients, claiming that "nearly 30 percent of Americans surveyed report[ed] rationing or even skipping doses of their prescribed medicines due to high costs."

92. But the Commission knows that this is false. The Commission did not itself conduct any survey, as the press release implies. While the FTC falsely conveyed to readers that supposed price inflation *by PBMs* caused 30% of consumers to skip prescribed medication, that is not what its source material says. The FTC cites one private opinion poll conducted by KFF that shows that three in ten respondents reported not taking prescription drugs because of cost, but KFF does not say whether the respondents who reported skipping prescriptions due to cost had prescription drug benefits. In contrast, a National Center for Health Statistics data sheet, also cited by the FTC but *not* highlighted in the text, finds that the percentage of adults who did not take medications as prescribed due to costs was highest among those *without prescription drug coverage* and patients *with* prescription drug benefits *rarely* report that they skipped taking prescribed drugs due to cost.[94] That is because plan sponsors, working with PBMs, successfully lower the cost of prescription drugs for their members. Throughout the Report, the FTC routinely manipulates data and evidence in this way—taking evidence that shows that prescription drug benefits increase patient adherence and patient health, and twisting it to support the false narrative that PBM pricing practices are causing "dire consequences" for patients.

93. Express Scripts' business is providing services to plan sponsors that lower the cost of providing prescription drug benefits. Express Scripts competes against other PBMs — including the many PBMs that did not receive 6(b) orders and were not the subjects of the

[94] Laryssa Mykyta & Robin A. Cohen, *Characteristics of Adults Aged 18–64 Who Did Not Take Medication as Prescribed to Reduce Costs: United States, 2021*, at 5, NCHS Data Brief No. 470 (June 2023), https://www.cdc.gov/nchs/data/databriefs/db470.pdf.

Commission's Report—based on its proven ability to deliver cost savings. The Commission's decision to prominently publish the defamatory lie that Express Scripts is inflating drug costs at the expense of patients, and causing "dire consequences" for patients, has harmed Express Scripts' reputation with its clients and investors, harmed its business prospects, led to lawsuits from states and private parties, and has even led to demands from members of Congress to correct allegedly false testimony.[95]

C. The FTC Ignored the Evidence Painstakingly Gathered and Produced Pursuant to its Orders and Issued a Misleading and Erroneous Report that Does Not Support its Defamatory Assertions

94. Given the biased and politicized tone set at the very top, it is not surprising that the Report is false, politicized, slanted, and unserious. As Commissioner Holyoak put it, "the Report fails to meet the standards of economic rigor expected of Commission reports."[96]

95. After forcing PBMs, including Express Scripts, to spend millions of dollars and tens of thousands of hours to produce millions of documents and over 11 billion data points, the FTC—remarkably—proceeded to ignore nearly all of it. The biased and inaccurate Report contents itself with relying overwhelmingly on information cherry-picked from public sources and anonymous comments to fit the Commission's predetermined narrative that PBMs drive up drug prices and disadvantage independent pharmacies.

96. The FTC repeatedly represents that the Report relies on non-public information collected from the 6(b) orders.[97] In reality, the Report overwhelmingly relies on public

[95] *See* Letter from Rep. James Comer, Chair, H. Comm. on Oversight & Accountability, to Adam Kautzner, President, Express Scripts (Aug. 28, 2024), https://oversight.house.gov/wp-content/uploads/2024/08/Letter-to-Kautzner-FINAL-re-PBM-Hearing-Testimony.pdf.

[96] Holyoak Dissenting Statement at 4.

[97] *See* Report at 2 ("The FTC's ongoing review of materials produced by the PBMs to date …."); *id.* ("This Interim Report accordingly provides the following key insights supported by the documents and data obtained to date …."); *id.* at 4 ("To date, FTC staff has reviewed … initial submissions of internal documents and data from PBM respondents and their affiliates.").

information. In fact, over 75 percent of the footnotes in the Report cite only to public sources, rather than documents or other information submitted in response to the Commission's own 6(b) orders. Entire sections of the Report rely wholly on public information or have no more than a handful of references to the 6(b) record.

97. In addition to overreliance on public sources in lieu of analyzing the copious substantive data and information submitted by PBMs, the Report contains a litany of false and harmful conclusions about the role of PBMs in the healthcare industry. The title alone—"Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies"—categorically condemns PBMs, belying the sham "interim" label. As described above, the Report cites no evidence or analysis to support this conclusion.[98] In fact, drug prices are set by drug manufacturers, and PBMs negotiate for *lower* pricing for plan sponsors. The Commission's analysis nowhere addresses whether plan sponsors obtain lower drug costs when they use PBMs than when they do not.

98. Throughout its Report, the Commission makes statements that will predictably be interpreted as conclusions adverse to all PBMs, including Express Scripts. The Commission suggests that the Report is grounded in information obtained from responses to the Commission's 6(b) orders and offers sweeping statements about PBMs harming rival pharmacies and patients. The Commission intentionally speaks in generalities that make for good publicity but lack a factual foundation and have caused substantial harm to Express Scripts.

99. Despite the mountains of data and documents produced to the Commission, the Report contents itself with generalized soundbites filled with buzzwords about PBMs unbothered by any need for evidence:

[98] The report cherry-picks two drugs as purported "case studies" but the report does not address whether those drugs are indicative of a broader pattern across all drugs. (In Express Scripts' case, they are not.)

- "[T]hese powerful middlemen may be profiting by inflating drug costs and squeezing Main Street pharmacies."[99]

- "[T]he dominant PBMs can often exercise significant control over which drugs are available, at what price, and which pharmacies patients can use to access their prescribed medications."[100]

- "PBMs increasingly control Americans' access to drugs and the prices they pay."[101]

- "[O]ur initial review of documents received thus far reveals that PBMs can have the ability and incentive to put downward pressure on reimbursement rates for rival, unaffiliated pharmacies—including to a degree that may be unsustainable for small, independent pharmacies."[102]

100. Making matters worse, the Report systematically fails to distinguish among PBMs, grouping them together as though they were a single entity. In particular:

- "[W]e also confirm several troubling rebating practices and report evidence raising concerns that brand manufacturers and PBMs may be entering into rebate contracts designed to cut off access to generic and biosimilar competitors."[103]

- "[T]he PBM respondents have produced certain of their rebate contracts with drug manufacturers. While our analysis is ongoing, our initial review of these contracts shows rebate structures that may impede and impair competition and patient access to affordable medicines."[104]

- "The Commission has also received reports of concerning methods to enhance the financial gains from rebate contracts, including the use of rules to indicate when the pharmacy's substitution of a particular product is not permitted …."[105]

101. Likewise, on the issue of whether PBMs have abided by the Commission's 6(b) orders, the FTC is inexcusably imprecise as to which PBMs have responded fully and which have not. According to the FTC's press release, "the report notes that several of the PBMs that

[99] *Id.*
[100] *Id.* at 3.
[101] *Id.* at 9.
[102] *Id.* at 53.
[103] *Id.* at 66.
[104] *Id.*
[105] *Id.* at 68.

were issued orders have not been forthcoming and timely in their responses, and they still have not completed their required submissions, which has hindered the Commission's ability to perform its statutory mission. FTC staff have demanded that the companies finalize their productions required by the 6(b) orders promptly."[106] In the Report itself, the FTC asserts that "some of the PBM respondents have not yet fully complied; they have not yet completed their required submissions" two years after receiving the FTC's orders.[107] By leveling such undifferentiated allegations, the Commission unfairly implies that Express Scripts is being uncooperative when—as the Commission well knows—Express Scripts has exhaustively complied with the FTC's burdensome requests.

102. FTC staff confirmed in verbal communications with counsel for Express Scripts that Express Scripts has complied with the 6(b) orders. The Commission nonetheless refused to correct the record and publicly state that Express Scripts has complied. There is no plausible justification for the Commission's repeated public statements that some PBMs have not complied with 6(b) orders and its refusal to publicly state that Express Scripts has complied.

103. By failing to distinguish among PBMs, the Commission conveys to readers that PBMs as a group have engaged in harmful or even illegal conduct. Commissioner Slaughter, however, has rightly acknowledged that not to be true. In her statement accompanying issuance of the Report, Commissioner Slaughter observed that "[n]ot all PBMs exclude more affordable alternatives to brand medications."[108] For support, she cited an article identifying Express

[106] Press Release, FTC, *FTC Releases Interim Staff Report on Prescription Drug Middlemen* (July 9, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/07/ftc-releases-interim-staff-report-prescription-drug-middlemen.

[107] Report at 2.

[108] *See* Rebecca Kelly Slaughter, Commissioner, FTC, *Statement Regarding FTC Staff Interim Report: Pharmacy Benefit Managers*, at 2 n.7 (Aug. 1, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/bks-statement-pbm-interim-report.pdf (citing Paige Minemyer, *Express Scripts Puts Insulin Biosimilar Semglee on Preferred Formulary*, FIERCE HEALTHCARE (Oct. 20, 2021)).

Scripts as including a more affordable biosimilar for insulin on its preferred formulary, resulting in an estimated $20 million in savings to diabetic patients in 2022 alone. But the Commission's Report does not include that important caveat and instead indiscriminately asserts that all PBMs "inflat[e] drug costs."[109]

104. The FTC has already received the data necessary to reach evidence-based, analytically rigorous conclusions about the PBM industry. Instead, the Commission has chosen to publish a Report that paints Express Scripts and the other PBMs as responsible for nearly every problem associated with prescription drug access in the United States. In doing so, the Commission ignores the intense competition among PBMs for the business of plan sponsors, which includes competition to offer lower prescription drug costs.[110]

105. **Profitability**. The Report states that four entities—UnitedHealth Group Inc., CVS Health Corp., The Cigna Group, and Humana Inc.—"greatly expanded their profits as combined adjusted operating profits and net income grew by 133 and 159 percent, respectively, over the 2016 to 2023 period."[111] Here, the FTC paints a misleading picture by presenting an analysis on the *change* in profits of healthcare entities *as a whole* without regard to acquisitions or other material changes in those companies. Had the FTC analyzed the profits of PBMs using the data it received, as the Report insinuates that it does, it would have found that the responding PBMs average operating margins were below 5% in recent years and sharply lower in 2022 than

[109] Report at 30.

[110] *See* FTC, Majority Statement, *Statement of the Federal Trade Commission Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc.*, at 6-7, FTC File No. 111-0210 (Apr. 2, 2012), https://www.ftc.gov/sites/default/files/documents/closing_letters/proposed-acquisition-medco-health-solutions-inc.express-scripts-inc./120402expressmedcostatement.pdf ("[T]he PBM industry has not shown itself to be conducive to coordination, and there is little reason to believe that the transaction will change that or eliminate an existing impediment to coordination.").

[111] Report at 6-7.

they were in 2017.[112] Likewise, the average gross margins of the responding PBMs also declined over this period to approximately 8% in 2022.[113] Ironically, had the Commission bothered to compare the responding PBMs' gross margins to the gross margins of pharmaceutical manufacturers—the entities that set the prices of drugs—it would have found that pharmaceutical manufacturers have average gross margins of nearly 40%. Similarly, if the Commission bothered to look at the margins of independent pharmacies—the supposed victims of PBMs' "enormous power" over prescription drug reimbursement—it would have found that, on average, these pharmacies have gross margins about *three times higher* than that of PBMs—around 23% according to data reported by the National Community Pharmacists Association, the pharmacists' trade association.

106. **Purported Harm to Independent Pharmacies**. The Report purports to "highlight examples of affiliated pharmacies receiving significantly higher reimbursement rates than those paid to unaffiliated pharmacies for two case study drugs."[114] From a cherry-picked sample of two drugs—out of the more than 30,000 drugs on which Express Scripts produced data—the FTC generalizes that "PBMs are not lowering prices for drugs used by patients to treat severe diseases like prostate cancer and leukemia." In so doing, the Commission takes out of context a very small sample of the data to support Chair Khan's preferred narrative, ignoring the fact that a thorough analysis of the data from Express Scripts would show that total payments by plan sponsors and patients for drugs dispensed at Express Scripts' affiliated pharmacies were lower than at unaffiliated pharmacies across the basket of all drugs. The only plausible

[112] Carlton PBM Report at 2 (showing that PBM operating margins and gross margins were lower in 2022 than they were in 2017).

[113] *Id.*

[114] Report at 3.

conclusion is that the Commission is deliberately ignoring market realities to maintain its preferred narrative in spite of the facts.

107. While the Report claims that PBMs are "squeezing" independent pharmacies, an analysis of data produced by three of the PBMs across *all* drugs shows that the reimbursement rates paid to independent pharmacies are generally *higher* than reimbursement rates paid to non-affiliated chain pharmacies across both non-specialty branded and generic drugs. Indeed, independent pharmacies are paid approximately 4% more than non-affiliated chains for non-specialty branded drugs and approximately 24% more than non-affiliated chains for non-specialty generic drugs.[115] Furthermore, as noted above, the pharmacists' own data show that the average gross margins of its member independent pharmacies have been stable at around 23%, while the margins of the largest chain pharmacies fell between 2011 and 2021.[116]

108. The FTC also makes unsubstantiated claims that PBMs are responsible for driving independent pharmacies out of business through consolidation and vertical integration with mail-order pharmacies.[117] But according to industry data, the number of independent pharmacy locations *increased* by approximately 9% between 2011 and 2021, while the number of chain pharmacy locations *decreased* by more than 5% in that same period.[118]

109. **Costs to Patients**. In the last section of its Report, the FTC also falsely and irresponsibly insinuates that PBMs are to blame for rising drug costs due to drug manufacturer rebates. But the text of the Report never directly makes the false accusation that the FTC included in its defamatory headline and press statements and which the Commission wants the

[115] Carlton PBM Report at 10.

[116] *Id.* at 13.

[117] *See* Report at 55.

[118] *See* Carlton PBM Report at 11 (analyzing data from National Council of Prescription Drug Programs ("NCPDP")).

public to adopt. Instead, it hides behind words such as "may" or "could," and repeatedly expresses "concerns" that rebates could increase costs or be anticompetitive, using similar careful phrasing—or sometimes quoting directly—from the Chair Khan's own prior conclusions about the purported evils of PBMs from *before* the Commission's study. This careful avoidance of the very question the "study" was meant to address—in favor of merely reraising the same "concerns"—is at best highly suspicious, given the millions of documents and massive amounts of data on drug costs that Express Scripts and other PBMs produced in response to the FTC's orders.

110. In fact, "suspicious" dramatically understates the issue. Based on the data it required the PBMs to produce, the Commission either knows, or should know, that its concerns about drug rebates are not true. For example, prior third-party studies have found no evidence that drugs with higher rebates are associated with higher rates of growth in list prices.[119] Furthermore, the Commission has the data to calculate out-of-pocket patient costs on rebated and non-rebated drugs. The Commission is either withholding from the public what it knows the evidence shows or willfully choosing to remain ignorant by directing its staff to write an interim Report and release it to the public before actually reviewing the evidence.

111. If the FTC had actually reviewed the data that it ordered the PBMs to produce, it would have found that list prices of rebated drugs are not increasing at a higher rate than list prices of non-rebated drugs. In fact, the opposite is true: The net cost to patients and plan sponsors of rebated drugs actually *declined* during the study period, while the net price of non-

[119] *See, e.g.*, Medicare Part D, 2013–2016; Nicholas J. Johnson, Charles M. Mills & Matthew Kridgen, *Prescription Drug Rebates and Part D Drug Costs*, Milliman (July 16, 2018), *available at* https://ahiporg-production.s3.amazonaws.com/documents/AHIP-Part-D-Rebates-20180716.pdf; Visante, *Increasing Prices Set by Drugmakers Not Correlated with Rebates*, at 2 (June 2017), https://www.pcmanet.org/wp-content/uploads/2017/06/Visante-Study-on-Prices-vs.-Rebates-FINAL.pdf (prepared on behalf of PCMA).

rebated drugs paid by plan sponsors and patients *increased*.[120] The Commission either buried this finding, or willfully chose not to look in the first place because it contradicts Chair Khan and the Commission's "powerful middleman" narrative and demonstrates that Express Scripts does what it says it does: lower drug costs for plan sponsors and their members.

D. The Report Is Not in the Public Interest

112. The FTC is statutorily authorized to issue reports only if they are "in the public interest."[121] The Report falls dramatically short of this standard and is therefore unlawful.

113. A Report that prejudges its conclusions, fails to engage with extensive evidence submitted by industry participants, and makes numerous false, inaccurate and misleading claims cannot advance the public's understanding of the PBM industry or contribute constructively to policy discussions and public discourse. Indeed, such a Report does the opposite by perpetuating a misleading and political narrative that falsely impugns the reputations of PBMs and, in turn, unfairly places the burden on PBMs to set the record straight without providing a forum for them to do so. Issuing a report with inaccurate and misleading claims—and a false and defamatory title—cannot be in the public interest.

114. As Commissioner Holyoak aptly stated in her dissent from issuance of the Report, while the Report's "facile arguments that rely on ideologically loaded buzzwords such as 'control' or 'power' may stir emotions and make for entertaining social media posts and television interviews, ideological buzzwords are no substitute for rational, evidence-based research."[122] Such a deeply flawed, ideological Report is not in the public interest.

[120] *See* Carlton PBM Report at 7.

[121] 15 U.S.C. § 46(f).

[122] Holyoak Dissenting Statement at 6.

115. The Commission's issuance of the Report, accordingly, exceeds the agency's statutory authority under Section 6(f) of the FTC Act.

E. The Report Is Fit for Judicial Review

116. Fairly read, the Report's bottom-line message is crystal clear: PBMs are villains in the healthcare industry and their business practices are harmful to consumers and others. It is obvious that the Commission will not revisit its unequivocally condemnatory verdict even if the agency produces a subsequent analysis (which itself is not guaranteed).

117. Despite its "interim" label, the Report consummates the agency's deliberation with respect to the Commission's view of PBMs. For all intents and purposes, the Report reflects the Commission's indictment of PBMs. While certain details or points of emphasis might change, the Commission's casting of PBMs as bogeymen of the healthcare industry will not. In light of the Report's sharply negative characterizations of PBMs, its pejorative title, and Chair Khan's litany of biased and incorrect statements about PBMs—including statements predating the Report's release by nearly 8 years—it is clear that the Commission's mind is now made up. Moreover, as Commissioner Holyoak recognized, "the Commission's failure to provide a specific date as to when it will release a future report … suggests … that this 'interim' Report may be the only and final PBM report from this 6(b) study."[123]

118. The Report, moreover, has real-world legal consequences for Express Scripts. The Report in effect announces that various business practices of PBMs disfavored by the Commission are unlawful, must cease, and are—very likely—targets of enforcement actions and litigation. For example, the Report itself asserts there are supposedly "exclusionary rebates" that provide a basis for potential future enforcement by the FTC under Section 2 of the Sherman Act,

[123] *Id.* at 6.

Section 5 of the FTC Act, and Section 2(c) of the Robinson Patman Act.[124] In this practical sense, by announcing the purported illegality of certain of Express Scripts' business practices and threatening enforcement action, the Report "has a 'direct effect on … [the] day-to-day business'"[125] of Express Scripts.

119. Indeed, the Report has already given rise to enforcement actions and litigation against Express Scripts. The Vermont Attorney General filed a complaint against Express Scripts in Vermont state court just days after the Commission issued the Report, citing the Report and alleging that PBMs "further use the manner in which they classify a drug to steer patients to their own pharmacies" and that the FTC found that PBMs use this tactic to "profit at the expense of independent pharmacies" through "opaque reimbursement calculations."[126] Nine days later, a specialty pharmacy filed a lawsuit in the U.S. District Court for Eastern District of Missouri seeking damages and other relief under the Sherman Act and state law, attaching the entire 74-page Report as an exhibit to its 41-page complaint.[127] The Report was also cited by the U.S. House of Representatives Committee on Oversight and Accountability in a letter demanding that Express Scripts retract truthful testimony that contradicted the FTC Commission's alleged (and wholly unsupported) "findings."[128] The President of Express Scripts now faces the specter

[124] Report at 70.

[125] *Franklin v. Massachusetts*, 505 U.S. 788, 797 (1992) (citation omitted).

[126] Complaint, *State of Vermont v. Evernorth Health, Inc., et al.*, No. _____ ¶¶ 323, 342 (Vt. Super. Ct. July 17, 2024), *available at* https://ago.vermont.gov/sites/ago/files/2024-07/2024-7-17%20PBM%20Complaint.pdf.

[127] Complaint, *AIDS Healthcare Foundation v. Express Scripts, Inc.*, No. 4:24-cv-01043 (E.D. Mo. July 26, 2024).

[128] *See* Letter from Rep. James Comer, Chair, H. Comm. on Oversight & Accountability, to Adam Kautzner, President, Express Scripts (Aug. 28, 2024), https://oversight.house.gov/wp-content/uploads/2024/08/Letter-to-Kautzner-FINAL-re-PBM-Hearing-Testimony.pdf.

of perjury allegations due in part to the Report's falsehoods, even though his testimony was entirely truthful.[129]

F. Express Scripts Is Injured by Issuance of the Report

120. As a result of the FTC's issuance of a biased, poorly researched, and error-riddled Report, Express Scripts has Article III standing and has suffered injury under the Administrative Procedure Act, 5 U.S.C. § 702, and under Missouri state law.[130]

121. The Report names Express Scripts and damages Express Scripts' reputation.

122. The Report is defamatory and interferes with Express Scripts' business relationships. The Report is designed to, and does, create the false impression that an agency of the federal government has examined substantial non-public evidence supplied by industry participants and reached the conclusion from that evidence that Express Scripts' business practices inflate prescription drug prices and cause "dire consequences" for patients, when that is not true and the Commission knows it is untrue.

123. Express Scripts has been harmed, and continues to be harmed, by the Commission's conduct. It spent millions of dollars and thousands of personnel hours responding to a Commission "study" that turned out to be a facade—mere cover for issuing the biased PBM Report that the Commission and its Chair planned to issue all along. Since the Commission issued its unlawful Report in July, Express Scripts' business and reputation have been, and continue to be, damaged by the false statements in the Report about its business practices and rank insinuations that its successful efforts to lower prices for plan sponsors and members

[129] Express Scripts fully stands behind its President's testimony, as it has conveyed in writing to the House Oversight Committee. Ironically, the House Committee on Oversight and Accountability is relying on a politicized sham Report issued under the very Commission Chair that the House Judiciary Committee previously criticized for politicizing the agency's work.

[130] *See, e.g.*, *Cockram v. Genesco, Inc.*, 680 F.3d 1046, 1050 (8th Cir. 2012); Mo. Rev. Stat. § 509.210 (2023).

somehow violate the law as anticompetitive practices, kickbacks, or otherwise. And the Report falsely insinuates that PBMs cause physical harm to American consumers by driving up prescription drug prices and causing certain consumers to skip their prescribed medication doses, without any basis for the claims.[131] Moreover, Express Scripts has been named as a defendant in multiple lawsuits seeking damages and other relief that invoke the Report as a basis for their claims.

124. Express Scripts expects the harm to its reputation and legal risks it faces to compound over time as other entities consider filing copycat suits that latch onto the Commission's prejudiced, demonstrably inaccurate, and deeply irresponsible Report on PBMs.

G. FTC Commissioners Exercise Executive Authority While Enjoying Statutory Removal Protections in Violation of Article II of the U.S. Constitution

125. The FTC functions primarily as a law enforcement agency,[132] just like the Department of Justice. It initiates formal investigations and routinely exercises prosecutorial discretion, and the Commissioners execute the law. Each of these powers is an exercise of executive authority that Article II vests exclusively in the President.[133]

126. Under the Federal Trade Commission Act, Commissioners of the FTC may only be removed by the President for "inefficiency, neglect of duty, or malfeasance while in

[131] See Report at 1, 69; Press Release, FTC, *FTC Releases Interim Staff Report on Prescription Drug Middlemen* (July 9, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/07/ftc-releases-interim-staff-report-prescription-drug-middlemen (describing "dire consequences" of PBMs' alleged "enormous power over patients' ability to access and afford their prescription drugs," such that certain people "skip[] doses of their prescribed medicines due to high costs").

[132] Matthew Perlman, *FTC's Ferguson Says He's a Law Enforcer, Not a Policymaker*, LAW360 (June 13, 2024), https://www.law360.com/competition/articles/1847801.

[133] Article II of the U.S. Constitution provides that "[t]he executive Power shall be vested in a President of the United States." U.S. Const. art. II, § 1, cl. 1. It also provides that the President "shall take Care that the Laws be faithfully executed." *Id.* § 3. In order to exercise this responsibility, the President must have the "power to oversee executive officers through removal," *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 492 (2010), a power that necessarily extends to any officers who "wield executive power on his behalf," *Seila Law LLC v. Consumer Fin. Prot. Bureau*, 591 U.S. 197, 204 (2020).

office."[134] That is, the Commissioners get an extra layer of for-cause removal protection, allowing them to act with less concern that they will be removed by the President as a consequence.

127. The Commission's law enforcement actions are an exercise of executive authority and the Commission's members must therefore be subject to unqualified removal by the President.[135] The Commission itself touts its "investigative" and "law enforcement" authorities,[136] which are quintessentially executive (rather than legislative or judicial) functions under the U.S. Constitution. In particular, the Commission describes its Section 6(b) authority—which it used to issue the order to Express Scripts—as an "investigative tool," and closely tethers this "investigative tool" to the Commission's Section 6(f) authority to issue reports, which was the basis for the PBM Report.[137]

128. Thus, on the Commission's own telling, it exercised investigative powers in connection with the PBM 6(b) orders and Report, which are plainly executive functions.

129. While the Commission, as it concedes, routinely exercises executive authorities, FTC Commissioners are insulated from presidential removal except for very limited circumstances of "inefficiency, neglect of duty, or malfeasance in office."[138] This insulation is incompatible with Article II's vesting of all executive power in the President and the President's

[134] 15 U.S.C. § 41.

[135] *Cf.* Daniel A. Crane, FTC Independence *After Seila Law*, at p. 3 (Antonin Scalia L. Sch., CSAS Working Paper No. 22-02, August 2022), https://administrativestate.gmu.edu/wp-content/uploads/2022/08/Crane-FINAL.pdf ("[I]n its antitrust capacity the FTC has historically done relatively little 'judicial' work and virtually no 'legislative' work, but has instead become a thoroughly executive agency, enforcing the antitrust laws against alleged violat[o]rs.").

[136] *See* FTC, A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority (revised May 2021), https://www.ftc.gov/about-ftc/mission/enforcement-authority.

[137] *Id.*

[138] 15 U.S.C. § 41.

sole duty to take care that the laws be faithfully executed. The Commission's structure therefore violates Article II of the Constitution.

130. Accordingly, all of the Commission's actions—including issuance of the PBM Report—are unlawful.[139]

COUNT ONE

Defamation Under Missouri Common Law

131. Express Scripts incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

132. The FTC has defamed Express Scripts in the title of the FTC's Report and in the FTC's press release.

133. The FTC's Report and press release are published and publicly accessible.

134. The Report title and press release state that PBMs "inflat[e] drug costs" and that PBMs "profit at the expense of patients by inflating drug costs." These statements—read in context of the FTC's naming six PBMs, including Express Scripts, as the target of its Report—clearly refer to Express Scripts.

135. The FTC's statements that PBMs, including Express Scripts, "inflat[e] drug costs," and "profit at the expense of patients by inflating drug costs" are false.

136. The FTC's statements that PBMs, including Express Scripts, "inflat[e] drug costs," and "profit at the expense of patients by inflating drug costs" are defamatory as to Express Scripts by harming Express Scripts' business reputation.

137. In making the defamatory statements that PBMs, including Express Scripts, "inflat[e] drug costs" and "profit at the expense of patients by inflating drug costs" the FTC acted

[139] To the extent the Court concludes that *Humphrey's Executor* is controlling, Express Scripts reserves all rights to argue the Supreme Court should overrule *Humphrey's Executor*.

with actual knowledge of those statements' falsity, or at least with reckless disregard as to their truth or falsity.

138. Express Scripts has suffered and continues to suffer a quantifiable professional injury. Express Scripts' business and reputation have been damaged as a result of the Commission's defamatory statements. In addition to multiple lawsuits invoking the Report as the basis of the plaintiffs' claims, a number of Express Scripts' clients and consultants working with current and prospective plan sponsors have raised concerns with Express Scripts about the Commission's alleged "findings" outlined in the Report. Express Scripts has incurred significant costs as a result.

COUNT TWO

Violation of the Fifth Amendment to the U.S. Constitution

139. Express Scripts incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

140. The FTC must comply with the Fifth Amendment's Due Process Clause, including when issuing 6(b) orders, undertaking quantitative and qualitative analyses, initiating and carrying out studies, and drafting and issuing reports.

141. In the case of the July 2024 PBM Report, the FTC flouted basic constitutional due process requirements by treating Express Scripts (and other PBMs) in a biased fashion and prejudging the Report's conclusions about the role of PBMs in the healthcare sector.

142. Indeed, the Commissioners, including Chair Khan, have already expressed actual bias against Express Scripts, as illustrated by Chair Khan's critical, inaccurate, but definitive public statements about PBMs even while the Report was being prepared by FTC staff.

143. This bias and prejudgment violate Express Scripts' due process rights under the Fifth Amendment.

COUNT THREE

Violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A)

144. Express Scripts incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

145. An agency's action is "arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Moreover, where an agency changes position, it "must at least … 'show that there are good reasons for [its change in position].'" *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)).

146. The Report, among other things, (i) endorses inaccurate and misleading conclusions; (ii) contains numerous findings unsupported by evidence; (iii) ignores crucial evidence provided to the FTC by Express Scripts; and (iv) fails seriously to grapple with the Commission's prior and contrary findings about PBMs in the FTC's 2005 report.

147. For all of these reasons and more, the Report is arbitrary and capricious in violation of the Administrative Procedure Act.

COUNT FOUR

Violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(C)

148. Express Scripts incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

149. The FTC may issue reports only when doing so is "in the public interest."[140]

150. The Report is not in the public interest for the reasons set forth in Counts 1, 2, and 3—namely, the biased Report is overwhelmingly motivated by prejudgment rather than objective factfinding and analyses, and it is marred by arbitrary and capricious reasoning.

151. Because the Report is not in the public interest, its issuance is an unlawful exercise of the FTC's power, exceeding the agency's authority under 15 U.S.C. § 46(f).

COUNT FIVE

Violation of Article II of the U.S. Constitution

152. Express Scripts incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

153. Article II, Section 1, provides that "[t]he executive Power shall be vested in a President of the United States of America."[141]

154. Article II, Section 3 provides that the President must "take Care that the Laws be faithfully executed,"[142] and grants the President appointment and removal powers over executive officers.

155. FTC Commissioners are executive officers because they exercise executive authority delegated to them by the President, including the authority to exercise prosecutorial discretion and initiate enforcement proceedings. FTC Commissioners are vested with powers to deprive citizens of their private rights and are not subject to unqualified presidential removal.

156. The Commissioners may only be removed from their positions for "inefficiency, neglect of duty, or malfeasance in office."[143]

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[140] 15 U.S.C. § 46(f).
[141] U.S. Const. art. II, § 1.
[142] U.S. Const. art. II, § 3.
[143] 15 U.S.C. § 41.

157. Because FTC Commissioners exercise executive authority but are not freely removable by the President, the Commissioners' insulation under Section 41 of the FTC Act violates Article II, Sections 1 and 3 of the U.S. Constitution.

PRAYER FOR RELIEF

Wherefore, Plaintiff respectfully requests that this Court enter judgment in its favor and against Defendants as follows:

i. A declaratory judgment that the Report and Press Release defame Express Scripts under Missouri law;

ii. A declaratory judgment that the Report violates Express Scripts' due process rights under the Fifth Amendment to the U.S. Constitution;

iii. A declaratory judgment that the Commission's Report is arbitrary and capricious in violation of 5 U.S.C. § 706(2)(A);

iv. A declaratory judgment that the Commission's Report is not in the public interest in violation of 15 U.S.C. § 46(f) and 5 U.S.C. § 706(2)(C);

v. A declaratory judgment that the Commission's Report is unlawful because the Commission's structure violates Article II of the U.S. Constitution;

vi. An order vacating and setting aside the Report;

vii. An order requiring the Commission to remove the Report from all Commission websites;

viii. An injunction requiring FTC Chair Lina M. Khan's recusal from all Commission actions pertaining to Express Scripts.

ix. An order awarding Express Scripts its reasonable costs, including attorneys' fees, incurred in bringing this action; and

x. Any other relief as the Court deems just and equitable.

Dated: September 17, 2024

Respectfully Submitted,

By: /s/ *Christopher A. Smith*

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