PUBLIC

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of: **Caremark Rx, LLC;** **Zinc Health Services LLC;** **Express Scripts, Inc.;** **Evernorth Health, Inc.;** **Medco Health Services, Inc.;** **Ascent Health Services LLC;** **OptumRx, Inc.;** **OptumRx Holdings LLC; and** **Emisar Pharma Services LLC,** **Respondents.**	**Docket No. 9437**

NOTICE OF FILING OF COLLATERAL COMPLAINT AND MOTION FOR PRELIMINARY INJUNCTION

Respondents Express Scripts, Inc., Evernorth Health, Inc., Medco Health Services, Inc., and Ascent Health Services LLC, file this Notice to apprise the Court of their recent filings in the United States District Court for the Eastern District of Missouri. On November 19, 2024, the three Respondent groups filed a complaint alleging that this administrative proceeding violates the Constitution of the United States, and a Motion for A Preliminary Injunction to enjoin this unconstitutional proceeding. *See Express Scripts, Inc., et al. v. Fed. Trade Comm'n, et al.*, 4:24-cv-1549, ECF Nos. 1, 7, 8 (E.D. Mo. Nov. 19, 2024). A copy of Respondents' collateral complaint and Motion are attached to this Notice as Exhibits A and B.

Dated: November 19, 2024

Respectfully submitted,

/s/ Charles F. Rule

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CERTIFICATE OF SERVICE

I hereby certify that on November 19, 2024, I caused the foregoing document to be filed electronically using the FTC's E-Filing system which will send notification of such filing to:

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I further certify that on November 19, 2024, I caused the foregoing document to be served via email to:

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Dated: November 19, 2024

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Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR EASTERN DISTRICT OF MISSOURI

EXPRESS SCRIPTS, INC.,

EVERNORTH HEALTH, INC.,

ASCENT HEALTH SERVICES LLC

MEDCO HEALTH SERVICES, INC.

CAREMARK RX, L.L.C.;

ZINC HEALTH SERVICES, LLC;

OPTUMRX, INC.;

OPTUMRX HOLDINGS, LLC;

– and –

EMISAR PHARMA SERVICES LLC,

Plaintiffs,

v.

FEDERAL TRADE COMMISSION,

LINA M. KHAN, in her official capacity as Commissioner and Chair of the United States Federal Trade Commission,

REBECCA KELLY SLAUGHTER, in her official capacity as Commissioner of the United States Federal Trade Commission,

ALVARO M. BEDOYA, in His official capacity as Commissioner of the United States Federal Trade Commission,

D. MICHAEL CHAPPELL, in his official capacity as Federal Trade Commission Chief Administrative Law Judge,

Defendants.

Case No._____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs Express Scripts, Inc. ("ESI"), Evernorth Health, Inc. ("Evernorth"), Ascent Health Services LLC ("Ascent"), and Medco Health Services, Inc. ("Medco") (together referred to as "Express Scripts"[1]); Caremark Rx, L.L.C. and Zinc Health Services, LLC (together referred to as "Caremark"[2]); and OptumRx, Inc., OptumRx Holdings, LLC, and Emisar Pharma Services LLC (together referred to as "Optum"[3]) bring this Complaint for declaratory and injunctive relief against the Federal Trade Commission ("FTC" or "Commission"); Lina M. Khan in her official capacity as Commissioner and Chair of the FTC; Rebecca Kelly Slaughter and Alvaro M. Bedoya in their official capacities as Commissioners of the FTC; and the Honorable D. Michael Chappell, in his official capacity as Federal Trade Commission Chief Administrative Law Judge. Express Scripts, Caremark, and Optum allege as follows:

INTRODUCTION

1. Express Scripts, Caremark, and Optum bring this Complaint to enjoin the Federal Trade Commission's unconstitutional administrative proceeding against Plaintiffs. On September 20, 2024, three Commissioners (with two recused) initiated a complaint before the Commission's in-house administrative forum that would subvert bedrock constitutional principles of accountability and fairness in an attempt to transform significant aspects of an entire industry by regulatory fiat.

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[1] "Express Scripts" is used herein for convenience to refer collectively to four of the entities named as respondents in the Commission's Complaint: ESI, Evernorth, Medco, and Ascent. It is not intended to be an admission or statement of the corporate form or relationship of these entities.

[2] "Caremark" is used herein for convenience to refer collectively to two of the entities named as respondents in the Commission's Complaint: Caremark Rx, L.L.C. and Zinc Health Services, LLC. It is not intended to be an admission or statement of the corporate form or relationship of these entities.

[3] "Optum" is used herein for convenience to refer collectively to three of the entities named as respondents in the Commission's Complaint: OptumRx, Inc., OptumRx Holdings, LLC, and Emisar Pharma Services LLC. It is not intended to be an admission or statement of the corporate form or relationship of these entities.

2. Plaintiffs Express Scripts, Caremark, and Optum are three competing pharmacy-benefit managers ("PBMs"). PBMs work with health plan sponsors, such as employers and unions, to manage prescription-drug benefits. PBMs negotiate with drug-manufacturers about the costs health plan sponsors will pay for drugs, and the amount those plans and employers will pay to fill prescriptions. In doing so, PBMs secure discounts and other savings for health plan sponsors—which in turn allows those health plan sponsors to reduce plan premiums and out-of-pocket costs for patients.

3. The Commission's administrative proceeding, however, seeks to restrict Plaintiff PBMs' ability to negotiate lower drug costs for their plan sponsor clients. The Commission's complaint accuses competing PBMs of nebulous unfair trade practices in negotiating drug costs, all based on a novel theory that Section 5 of the Federal Trade Commission Act—which prohibits "unfair methods of competition" and "unfair ... acts or practices"—gives the Commission roving license to define practices as unfair based on its own subjective policy preferences. The complaint proposes equally novel remedies: The Commission would upend present-day drug rebate contracts, forcing PBMs to revamp their entire contracting framework and countless contracts with drug manufacturers, health plan sponsors, and other private parties. Nor would the Commission stop there: The Commission reserves for itself the right to order "any other relief appropriate" without elaboration. FTC Compl., at 45, ¶ 4 (Notice of Contemplated Relief).

4. This sweeping attempt to reshape an entire industry via law enforcement would never pass muster in a U.S. District Court. It is therefore unsurprising that the Commission brought this action in its own captive tribunal, where the Commission decides the allegations and the claims, sets the rules, does the fact-finding, chooses what the law is, and determines the outcome. Indeed, in the past thirty years, the Commission has found a violation in *every* action brought

before it in its administrative proceeding, even as it notches many high-profile losses when it litigates in federal courts.

5. This type of stacked-deck administrative proceeding is fundamentally unfair. It also violates the U.S. Constitution in at least three ways.

6. First, the Commission's in-house proceeding violates Article III, which requires the type of claims at issue here—those involving private rights that traditionally would have been considered actions at law or equity—to be brought in federal court before an independent Article III judge. Here, the Commission is alleging classic common-law claims about purportedly unfair contracts and transactions among private market participants. And the Commission's requested relief would substantially and adversely affect private rights, including interfering with the PBMs' ability to contract with manufacturers and plan sponsors. The Constitution thus permits the FTC to bring these claims and seek this relief only in an Article III court.

7. Second, the FTC channeled its claims into its own in-house forum before Commissioners and an administrative law judge ("ALJ") that are unconstitutionally insulated from removal by the President and thus are insulated from democratic accountability. Specifically, the FTC Act restricts the President's authority to remove FTC Commissioners in violation of Article II of the Constitution, which reserves the power to execute the laws to the President alone. The FTC Commissioners clearly exercise executive power, and the Constitution prohibits statutory restrictions on the President's authority to remove FTC Commissioners. Relatedly, the ALJ presiding over the Commission's in-house proceeding is also unconstitutionally insulated from presidential accountability and supervision. The FTC's ALJs enjoy multiple layers of tenure protection, which the Supreme Court has already ruled unconstitutional in similar circumstances; indeed, one current FTC Commissioner—who is recused from participating in the administrative

proceeding—has stated explicitly his belief that the limitations on removal of the FTC's ALJs violate the Constitution.

8. Third, the Commission is depriving Plaintiffs of a fair and impartial tribunal in violation of the Due Process Clause of the Fifth Amendment. The same FTC Commissioners who voted to prosecute Plaintiffs for the conduct of others will now also serve as judge and jury empowered to find facts and reach conclusions of law. Giving the Commission the final word on the outcome of its own enforcement action violates due process. And these structural concerns are particularly pronounced here because the Commission's proceeding in this case is wholly partisan and biased, contrary to what Congress intended. Only the three Democratic Commissioners are participating in this matter, as the two Republican Commissioners have been recused for undisclosed reasons. And Chair Khan and the other non-recused Commissioners have already irrevocably made up their minds as to the allegations against Plaintiffs. A proceeding before the Commission with a foreordained outcome—like the one looming over Express Scripts, Caremark, and Optum—fails to provide the due process required and guaranteed by the Constitution.

9. The protections afforded by all of these constitutional rights—politically accountable agency officials and an independent, unbiased, Article III forum to adjudicate disputes—are particularly important here. The Commission's 45-page administrative complaint consists mostly of vague group pleading, underscoring that the Commission is unfairly bringing a single, consolidated action against competitors over their wholly *separate* alleged individual conduct. And the substance of that administrative complaint raises novel theories that historically have drawn skepticism from federal courts. The Commission alleges a "broken system" in which drug manufacturers "preserve the manufacturers' own profits" by increasing their list prices. According to the Commission, this harms certain patients who, as a result of plan design decisions

by plan sponsors, have out-of-pocket costs (copayments) tied to list prices. The Commission's Complaint seeks to fix this purported "broken system" by holding Express Scripts, Caremark, and Optum, which allegedly "administer approximately 80% of all prescriptions in the United States," liable for drug prices they do not set. The Commission also seeks to interfere with Plaintiffs' ability to offer programs and tools to plan sponsors to lower drug costs, even though plan sponsors ultimately decide whether to adopt them. In targeting purported "middlemen," the Commission is attacking the one critical element of the drug distribution and benefit process that *lowers* net drug costs for employers, labor unions, and the government itself. This turns the antitrust and consumer protection laws—which promote, not punish, conduct that spurs competition among manufacturers and lowers prices—on their heads. And if left unchecked, the action will have wide-ranging implications for the American economy.

10. But this Court ultimately need not decide the merits of these contentions. Instead, it need only conclude that the Commission's claims cannot proceed in administrative proceedings that violate multiple constitutional safeguards. Moreover, forcing Plaintiffs to defend themselves in an unconstitutional, illegal, and misguided proceeding would cause irreparable injury that could not be remedied on appeal. The Commission's administrative proceeding must be enjoined.

PARTIES

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

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

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

14. Plaintiff Ascent Health Services LLC is a Delaware limited liability company with its principal place of business at Muhlentalstrasse 36, 8200 Schaffhausen, Switzerland.

15. Plaintiff Caremark Rx, L.L.C. is a Delaware limited liability company with its principal place of business at One CVS Drive, Woonsocket, RI. Caremark Rx, L.L.C. is a wholly owned indirect subsidiary of CVS Health Corporation.

16. Plaintiff Zinc Health Services, LLC is a Delaware limited liability company with its principal place of business at 8300 Norman Center Drive, Suite 850, Bloomington, MN. Zinc Health Services, LLC is a majority owned indirect subsidiary of CVS Health Corporation.

17. Plaintiff OptumRx, Inc. is a California corporation, with its principal place of business at 1 Optum Circle, Eden Prairie, MN. OptumRx, Inc. is a wholly owned indirect subsidiary of UnitedHealth Group Inc.

18. Plaintiff OptumRx Holdings, LLC is a California corporation, with its principal place of business at 1 Optum Circle, Eden Prairie, MN. OptumRx Holdings, LLC is a wholly owned indirect subsidiary of UnitedHealth Group Inc. and the direct parent company of OptumRx, Inc.

19. Plaintiff Emisar Pharma Services LLC is a Delaware limited liability company. Emisar is a wholly owned indirect subsidiary of UnitedHealth Group Inc.

20. Defendant Federal Trade Commission is an agency of the United States government whose principal place of business is at 600 Pennsylvania Avenue, NW, Washington, DC 20580.

21. Defendant Lina M. Khan is a Commissioner and the Chair of the FTC. Plaintiffs sue Chair Khan in her official capacity.

22. Defendant Rebecca Kelly Slaughter is a Commissioner of the FTC. Plaintiffs sue Commissioner Slaughter in her official capacity.

23. Defendant Alvaro M. Bedoya is a Commissioner of the FTC. Plaintiffs sue Commissioner Bedoya in his official capacity.

24. Defendant the Honorable D. Michael Chappell is the FTC Chief ALJ. Plaintiffs sue Chief ALJ Chappell in his official capacity.

JURISDICTION AND VENUE

25. 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. *See Axon Enter., Inc. v. FTC*, 598 U.S. 175 (2023).

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

27. 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 Federal Trade Commission's Unconstitutional Structure and Process

28. 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."[4] The FTC's ALJs, in turn, are removable only for "good cause"[5] as determined by the Merit Systems Protection Board, a separate federal agency that adjudicates

[4] 15 U.S.C. § 41.
[5] 5 U.S.C. § 7521(a), (b)(1).

personnel matters. Members of the Merit Systems Protection Board cannot be removed by the President except for "inefficiency, neglect of duty, or malfeasance in office."[6] Even "dual layer[s] of protection" from removal have been held to be unconstitutional with respect to SEC ALJs and other agency officials.[7] And the Commission's ALJs are further removed from democratic accountability.

29. The Commission is intended to be bipartisan. By statute, no more than three of the Commissioners can be members of the same political party.[8] The Commission currently has three Democratic members (Chair Khan, Commissioner Slaughter, and Commissioner Bedoya) and two Republican members (Commission Holyoak and Commissioner Ferguson).

30. The Commission has statutory authority to exercise a host of executive functions. In particular, the Commission has broad investigative powers to support its "law enforcement" efforts.[9] The Commission can bring administrative proceedings against a person or corporation subject to its jurisdiction for allegedly engaging in unfair methods of competition or unfair or deceptive acts or practices.[10] The Commission also enforces myriad other laws and trade regulations. The Commission itself touts that "in total the Commission has enforcement or administrative responsibilities under more than 70 laws."[11] In the 1970s, Congress amended the FTC Act by giving the Commission substantial additional enforcement authority—authority that

[6] 5 U.S.C.§ 1202(d).

[7] *Jarkesy v. SEC*, 34 F.4th 446, 463-465 (5th Cir. 2022); *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, at 514 (2010).

[8] 15 U.S.C. § 41.

[9] 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.

[10] 15 U.S.C. § 45.

[11] FTC, *Enforcement* (last visited Nov. 17, 2024), https://www.ftc.gov/enforcement.

the Supreme Court has recently characterized as "quintessentially executive power."[12] The Commission has discretion to bring actions in an in-house administrative process or in a federal district court.[13]

31. Administrative enforcement actions are initiated by a vote of the Commission to issue a complaint. The actions are heard in the first instance by an ALJ.[14] The FTC Commissioners do not observe witnesses or scrutinize other evidence but only review the written record post-hearing. Nevertheless, when deciding whether to adopt or modify an ALJ's recommended decision, the Commission owes no deference whatsoever to an ALJ's factual findings.[15]

B. The Commission's Insulin Investigation and Administrative Action

32. In 2022, the Commission launched an investigation into insulin pricing. In June 2022 the Commission issued Civil Investigative Demands to Express Scripts, Caremark, and Optum seeking documents and data. Although the Commission now seeks relief that sweeps more broadly and implicates *all* drugs, the Commission's investigation was focused on insulin costs.

33. On September 20, 2024, the Commission voted to issue an administrative complaint naming as respondents Express Scripts, Caremark, and Optum. Only the Commission's three Democratic Commissioners voted to issue the administrative complaint; the two Republican Commissioners are recused from the Commission's proceedings for reasons not disclosed to the public or to Express Scripts, Caremark, and Optum.

34. The Complaint alleges that Express Scripts, Caremark, and Optum work with clients, often referred to as "plan sponsors," which include employers (including federal

[12] *Seila Law LLC v. Consumer Fin. Prot. Bureau*, 591 U.S. 197, 219 (2020).
[13] 15 U.S.C. §§ 45, 53(b)(2), 57b.
[14] 16 C.F.R. § 3.41.
[15] Revisions to Rules of Practice, 88 Fed. Reg. 42,872 (July 5, 2023), *available at* https://www.ftc.gov/system/files/ftc_gov/pdf/p072104-amendments-to-part-3-rules-frn.pdf.

government agencies offering prescription drug benefits to their employees), health insurance plans, labor unions, government programs, and other groups that offer prescription drug benefits.[16] According to the Complaint, Express Scripts, Caremark, and Optum collectively "administer approximately 80% of all prescriptions in the United States," and effectively represent the lion's share of the industry.[17]

35. As the Commission repeatedly admits, Express Scripts, Caremark, and Optum do not set the prices of prescription drugs. Rather, drug manufacturers set the list price for prescription drugs, called the wholesale acquisition cost ("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.[18]

36. The Complaint recognizes that Express Scripts, Caremark, and Optum each "[n]egotiate with pharmaceutical manufacturers for rebates [from manufacturers' list prices] on behalf of their clients."[19] PBMs like Express Scripts, Caremark, and Optum and their clients use drug formulary design to drive competition between manufacturers of clinically equivalent drugs, such as insulin drugs, in order to "extract price concessions from drug manufacturers."[20] (A drug formulary is a list of prescription drugs covered by a health plan, which often uses separate tiers to "prefer" drugs that are lower cost to the plan sponsor and its members.[21]) One way that PBMs secure cost savings for health plan sponsors is by seeking conditional rebates (i.e., discounts) from

[16] *Id.*
[17] Complaint ¶ 3, *In re Caremark Rx, L.L.C., et al.*, Docket No. 9437 (F.T.C. Sept. 20, 2024) (hereinafter "Complaint") https://www.ftc.gov/system/files/ftc_gov/pdf/d9437_caremark_rx_zinc_health_services_et_al_part_3_complaint_corrected_public.pdf.
[18] *Id.* ¶¶ 2, 6, 9, 40, 119, 135, 236-241.
[19] *Id.* ¶ 28.
[20] *Id.* ¶ 38.
[21] *Id.* ¶ 32.

a drug's list price that the manufacturer must pay after a health plan sponsor prefers the manufacturer's drug on the plan sponsor's formulary.

37. The Complaint concedes that plan sponsors, not Express Scripts, Caremark, and Optum, determine which formularies to adopt and how manufacturer rebates are distributed.[22] Express Scripts, Caremark, and Optum offer standard formularies that include preferences for low net-cost drugs (which account for rebates off of list price) as well as open formularies that do not include preferences. Plan sponsors decide what type of formulary fits with their plan design, or design their own.[23] Plan sponsors may choose to allocate some or all of the rebates they receive to members at the point-of-sale as a way to reduce out-of-pocket costs for members who buy rebated drugs.[24] As another option, a plan sponsor may require Express Scripts, Caremark, and Optum to transfer all of the rebates to the plan sponsor to be used as it sees fit—for example, to reduce premiums, reduce out-of-pocket member costs, and/or improve benefits.[25] The Complaint admits that plan sponsors typically design their prescription benefit plans so that 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.[26]

38. As the Complaint further admits, through competition among manufacturers of clinically equivalent drugs for formulary placement, PBMs Express Scripts, Caremark, and Optum negotiate substantial rebates off the list price of insulin drugs during the relevant time period.[27]

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[22] *Id.* ¶¶ 4, 50, 55, 60, 66, 184, 196-197.
[23] *Id.* ¶ 50.
[24] *Id.* ¶¶ 55, 66, 184, 196-197.
[25] *Id.*
[26] *Id.* ¶ 4.
[27] *See*, *e.g.*, *id.* ¶¶ 44, 117.

These discounts, in turn, reduce insulin costs for plan sponsors, the PBMs' clients.[28] PBMs compete with one another to provide the greatest savings to plan sponsors.[29]

39. Remarkably, the Complaint alleges that competition among Express Scripts, Caremark, and Optum to offer the largest drug cost savings to their plan sponsor clients is an "unfair method of competition" and an "unfair practice" that violates Section 5 of the Federal Trade Commission Act. That is so, the Complaint alleges, because plan sponsors often choose "closed" formularies, where manufacturers have to compete on price for a position on the formulary, over "open" formularies, which offer multiple manufacturers the opportunity to be listed. Express Scripts, Caremark, and Optum offer both types of formularies to their clients.[30] The Complaint alleges that insulin manufacturers then raise their list prices in order to "compensate" themselves "for the very high rebates" and to "preserve the manufacturers' own profits."[31] Finally, according to the Complaint, certain diabetic patients may pay the higher list price for insulin drugs at the pharmacy either because they are uninsured (in which case Express Scripts, Caremark, and Optum are not providing services relating to their prescription at all) or because the plan sponsor has decided to structure the drug benefit to include cost sharing based on list prices (also not a decision made by Express Scripts, Caremark, or Optum).[32]

40. In addition to alleging that generating competition between drug manufacturers is somehow "unfair," the Complaint's allegations also overwhelmingly lump together the "big three" respondent PBMs (Plaintiffs in this case), and often the entire PBM industry. In paragraph after paragraph—nearly 140 times in the Complaint—the Commission refers to the "PBM

[28] *Id.* ¶ 55.
[29] *Id.* ¶ 106.
[30] *Id.* ¶¶ 34-37, 174
[31] *Id.* ¶¶ 6, 123.
[32] *Id.* ¶¶ 60-61, 66-67.

Respondents," assuming that they act in lockstep, attributing the conduct of other PBMs to the individual PBMs. In many other places, the Complaint refers to the practices of PBMs generically, suggesting that the Commission is attacking the same practices employed by the whole industry. Indeed, allegations about Express Scripts' individual conduct are only addressed in 24 paragraphs throughout the 274-paragraph Complaint.[33] Allegations about Caremark's individual conduct are only addressed in 31 paragraphs throughout the Complaint.[34] Allegations about Optum's individual conduct are only addressed in 28 paragraphs throughout the Complaint.[35]

41. Although it names multiple PBMs as respondents, the Complaint contains no allegations that respondents engaged in any collusive conduct in violation of the antitrust laws. Nor does it accuse Express Scripts, Caremark, or Optum of engaging in any common scheme or other coordinated effort with the other respondent PBMs. In its scant individualized allegations, the Complaint is clear that Express Scripts, Caremark, and Optum act individually and in competition with one another—not in coordination. For example:

- The PBMs did not introduce "exclusive" formularies at the same time. Caremark allegedly first introduced one in 2012, Express Scripts in 2014, and Optum in 2016.[36]
- Those formularies vary widely in how narrow or "exclusive" they are across plan sponsors and PBMs.[37]
- Express Scripts, Caremark, and Optum negotiated different rebates with the same insulin manufacturers.[38]

[33] *See id.* ¶¶ 102, 104, 110, 111, 114, 117, 145, 149, 154, 157, 168, 170, 171, 174, 178, 181, 188, 199, 200, 211, 228, 232, 246, 250.
[34] *See id.* ¶¶ 103, 110, 111, 114, 116, 137, 146, 150, 165, 168, 172, 173, 176, 178, 179, 184, 185, 186, 187, 188, 189, 192, 196, 198, 200, 208, 211, 212, 217, 228, 245.
[35] *See id.* ¶¶ 44, 46, 54, 105, 108, 111, 118, 124, 145, 147, 155, 169, 173, 174, 180, 182, 190, 191, 196, 200, 209, 223, 228, 229, 232, 247, 250.
[36] *Id.* ¶¶ 103-105.
[37] *Id.* ¶ 114.
[38] *Id.* ¶ 44.

- Express Scripts, Caremark, and Optum entered into rebate arrangements with different manufacturers, preferring different drugs than each other. For example, "in 2023, Optum preferred Sanofi's long-acting insulins (Lantus and Toujeo) and excluded both Novo's long-acting insulins (Levemir and Tresiba) and Lilly's long-acting insulin (Basaglar) from its flagship Premium Formulary. In the same year, though, Caremark and ESI both preferred Novo's Levemir and Tresiba and excluded Sanofi's Lantus from their flagship formularies."[39]

- Express Scripts, Caremark, and Optum independently negotiate with drug manufacturers to determine appropriate administrative, data, and WAC-based fees.[40] The fees vary for different drug manufacturers.

42. Although the facts alleged in the Complaint relate overwhelmingly to insulin prices and formulary placements, the relief the Commission seeks is strikingly broad and would extend to *all* drugs. Specifically, the Complaint seeks to "prohibit Respondents from excluding or disadvantaging low WAC versions of high WAC drugs made by the same manufacturers whenever the Respondent covers the high WAC drug on a formulary," and to "prohibit Respondents from accepting compensation based on a drug's list price or a related benchmark."[41]

43. The Commission also expressly seeks to regulate Plaintiffs' clients, *i.e.*, the sponsors of prescription drug benefits. The Commission would "prohibit [Plaintiffs] from designing—or assisting with designing—a benefit plan that bases patients' deductibles or coinsurance on the list price, rather than the net cost after rebates."[42] Such relief, if applied to plan sponsors' plan designs choices, would completely reshape how plan sponsors design prescription drug coverage in the United States.

44. Express Scripts, Caremark, and Optum accepted service of the Commission's Complaint on September 25, 2024. The respondents' answers to the Commission's voluminous

[39] *Id.* ¶ 111.
[40] *Id.* ¶¶ 46, 48-49.
[41] *Id.* at 44, ¶¶ 1-2 (Notice of Contemplated Relief).
[42] *Id.* at 44-45, ¶ 3 (Notice of Contemplated Relief).

Complaint were due just 14 days later, on October 9. The Commission has ordered the hearing on its Complaint to commence before an ALJ 11 months later starting on August 27, 2025.

ALLEGATIONS

A. Article III Prohibits the FTC From Adjudicating Private Rights and Restructuring Private Parties' Contracts.

45. The Commission is constitutionally barred from adjudicating in-house the claims or granting the remedies it seeks in this administrative proceeding.

46. Under Article III of the Constitution, the "judicial Power … extend[s] to all Cases, in Law and Equity, arising under th[e] Constitution, the Laws of the United States, …. [and] to Controversies to which the United States shall be a Party."[43] Under "the basic concept of separation of powers," the "judicial Power ... can no more be shared with another branch" than legislative or executive powers can be shared with other branches.[44] Applying this principle, the Supreme Court has explained that cases involving a "private right" must be adjudicated by Article III courts.[45] Thus, Article III prohibits Congress from "withdraw[ing] from judicial cognizance any matter which, from its nature, is the subject of a suit at the common law, or in equity, or admiralty" and assigning it to administrative agencies.[46] Suits involving "private rights," i.e., "the stuff of the traditional actions at common law tried by the courts at Westminster in 1789," are the quintessential suits that Congress "may not … remove[] from Article III courts."[47]

47. Allowing the Commission to adjudicate its complaint via in-house administrative proceedings vitiates the Article III guarantee to a federal judicial forum for multiple reasons.

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[43] U.S. Const. art. III, § 2.
[44] *Stern v. Marshall*, 564 U.S. 462, 483 (2011).
[45] *Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 56 (1989).
[46] *SEC v. Jarkesy*, 144 S. Ct. 2117, 2134 (2024) (citing *Murray's Lessee v. Hoboken Land & Improvement Co.*, 59 U.S. 272, 284 (1855)).
[47] *Jarkesy*, 144 S. Ct. at 2132 (internal quotations omitted).

48. As an initial matter, the Commission's claims are in the nature of an action at common law. The Commission accuses PBMs of committing "unfair method[s] of competition" and "unfair act or practice[s]" in contracting with other private parties, in violation of § 5 of the FTC Act.[48] Common law actions have long existed for unlawful restraints of trade and unfair or unconscionable business practices, predating federal statutory antitrust and consumer protection laws. For example, the common law recognized a remedy for lack of fairness and honesty in the sale of goods between private parties.[49] "Unfair competition" was a "common law" remedy originally "relat[ing] to "palming off of one's goods as those of a rival trader," but "expanded" to include "acts which lie outside the ordinary course of business and are tainted by fraud or coercion or conduct otherwise prohibited by law."[50] The FTC itself looks to the common law as the first factor to determine if a practice is "unfair."[51]

49. While federal law has expanded the scope of unfair competition, that action retains its common-law origins. Congress intended that the FTC and courts to draw from the "idea of unfair trade at common law" and apply the "same principles and tests that have been applied under the common law" to new situations.[52] Because the cause of action FTC invokes "close[ly]

[48] *E.g.*, Complaint ¶¶ 261, 267, 274.

[49] *E.g.*, 3 William Blackstone, Commentaries *164 ("If any one cheats me with fal[s]e cars or dice, or by "fal[s]e weights and mea[s]ures, or by [s]elling one commodity for another, an action on the ca[s]e al[s]o lies again[s]t him for damages, upon the contract which the law always implies, that every tran[s]action is fair and hone[s]t.").

[50] *See A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 531-532 (1935) (citations omitted).

[51] See FTC, Statement of Basis and Purpose of Trade Regulation Rule 408, Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking, 29 Fed. Reg. 8325, 8355 (July 2, 1964) (noting as first factor for discerning "unfair acts or practices" includes whether the practice was considered "unfair" under the common law).

[52] *See Sears, Roebuck & Co. v. FTC*, 258 F. 307, 310-11 (7th Cir. 1919).

relate[s]" to a historical common-law action, only federal courts—not agencies—can adjudicate the action.[53]

50. The Commission's claims also implicate the PBM Plaintiffs' contract rights, which are the paradigmatic private rights that must be adjudicated in Article III courts.[54] The FTC seeks to impose sweeping cease and desist orders that would abrogate, and force the PBM Plaintiffs to restructure, hundreds, if not thousands, of contracts with private market participants and prohibit similar contracts in the future, change how Plaintiffs negotiate discounts off list prices with drug manufacturers, and limit benefit design options for plan sponsors and their members.[55] By seeking relief in this proceeding that will overturn the PBM Plaintiffs' settled economic expectations, as well those of numerous private third parties, the FTC's Complaint clearly concerns Plaintiffs' property rights in their contractual agreements and, therefore, concerns Plaintiffs' private rights.[56] Going forward, Plaintiffs' freedom to contract with manufacturers and plan sponsors in these areas would be permanently and substantially restricted if the Commission were to obtain the expansive cease-and-desist order it requests in its Complaint.

51. This putative remedy is also fundamentally equitable, which Article III requires federal courts, not agencies, to impose.[57] Here, the FTC seeks a broad cease-and-desist order rescinding private parties' contracts that the FTC deems unlawful and prohibiting those same private parties from entering into similar contracts in the future.[58] Cease-and-desist orders are

[53] *See Jarkesy*, 144 S. Ct. at 2129, 2131.
[54] *Career Colls. & Schs. of Tex. v. Dep't of Educ.*, 98 F.4th 220, 248 (5th Cir. 2024).
[55] Compl Notice of Contemplated Relief, ¶¶ 1-3; Compl. ¶¶ 234-254.
[56] *Axon*, 598 U.S. at 197 (Thomas, J., concurring) ("Disposition of private rights to life, liberty, and property' was understood to 'fal[l] within the core of the judicial power, whereas disposition of public rights [was] not.'").
[57] *Jarkesy*, 144 S. Ct. at 2134 (citation omitted).
[58] *See* Complaint, ¶¶ 234-254; *id.* at 44-45, ¶¶ 1-3 (Notice of Contemplated Relief).

nothing more than injunctions by another name, and injunctions are inherently equitable remedies. Likewise, remedies rescinding current contracts and enjoining the entering into of similar contracts on a going-forward basis have been adjudicated by courts of equity for centuries. Because Article III courts cannot adjudicate traditional equitable remedies for claims involving private rights, the Commission's in-house proceeding is unlawful.

52. The FTC cannot invoke the so-called public rights exception to operate free from Article III strictures. The "public rights" exception is "narrow" and encompasses only a limited "class of cases concerning ... matters [that] historically could have been determined exclusively by the executive and legislative branches, even when they were presented in such form that the judicial power was capable of acting on them."[59] Here, courts and juries traditionally resolved analogous unfair-competition claims.[60] For example, common law actions have long existed for unlawful restraints of trade and unfair or unconscionable business practices, predating federal antitrust and consumer protection law.

B. FTC Commissioners Are Unconstitutionally Insulated from Presidential Removal.

53. Article II of the Constitution vests "the executive Power" entirely in the President,[61] who must "take Care that the Laws be faithfully executed."[62] By vesting all of the Nation's executive power in a single, elected official, the Constitution ensures that the people have the ultimate say in how the laws are executed. Yet the FTC's Commissioners are immune from presidential oversight, even "as they exercise[] power in the people's name."[63]

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[59] *Jarkesy*, 144 S. Ct. at 2127, 2132 (cleaned up).
[60] *Supra*, ¶¶ 48-49.
[61] U.S. Const. art. II, § 1, cl. 1.
[62] *Id.* § 3.
[63] *Free Enter. Fund*, 561 U.S. at 497.

54. The Commission has broad authority to "investigate" people and corporations engaging in "commerce" for allegedly committing "unfair or deceptive acts or practices" or engaging in "[u]nfair methods of competition."[64] FTC Commissioners "set enforcement priorities" and "initiate prosecutions" against people and corporations for alleged violations, and once administrative proceedings are instituted, FTC Commissioners "oversee [those] adjudications."[65] FTC Commissioners also can issue final decisions in the administrative adjudications, order people and corporations to cease and desist from engaging in business activities the Commissioners believe to be unlawful, and "seek daunting monetary penalties against private parties on behalf of the United States in federal court."[66]

55. Yet under the Federal Trade Commission Act, Commissioners of the FTC may only be removed by the President for "inefficiency, neglect of duty, or malfeasance in office."[67] The FTC Commissioners thereby enjoy a layer of statutory protection from removal, allowing them to act with less concern that they may be removed by the President. This constitutional problem is particularly troubling at the present moment because Chair Khan's term expired on September 25, 2024, but the newly-elected President, who did not appoint her, will be unable to remove her from the Commission upon taking office. Nor will the newly elected President be able to remove the other two Democratic Commissioners—the only other Commissioners who voted to issue the Complaint against Plaintiffs, if he wished to.

56. The Commission's law enforcement actions, including those directed against Express Scripts, Caremark, and Optum, are a substantial exercise of executive authority. FTC

[64] 15 U.S.C. §§ 45(a)(1), 46(a); *see Collins v. Yellen*, 594 U.S. 220, 230 (2021).
[65] *See Seila Law*, 591 U.S. at 200, 225; 15 U.S.C. §§ 45(m), 53; 16 C.F.R. §§ 3.11, 3.23, 3.52-.54.
[66] *See Seila Law*, 591 U.S. at 218-219; 15 U.S.C. § 45(b), 45(m); 16 C.F.R. § 3.54.
[67] 15 U.S.C. § 41.

Commissioners must therefore be subject to unqualified removal by the President. Because the FTC Commissioners are insulated from presidential removal by a statutory for-cause removal provision, the Commission's structure contravenes constitutional principles, and its law enforcement actions are invalid.

57. That the FTC has five Commissioners, not one, does not immunize it from constitutional scrutiny or presidential accountability. The Supreme Court endorsed for-cause removal protection for the FTC's Commissioners in *Humphrey's Executor v. United States*, 295 U.S. 602 (1935). But that limited exception to the rule that agency heads must be fully accountable to the President turned upon the Commission "as it existed in 1935." At that juncture, the Supreme Court viewed the circa-1935 FTC "as exercising 'no part of the executive power'" and functioning as "'an administrative body' that performed 'specified duties as a legislative or judicial aid.'"[68] In the Court's view at the time, the Commission in 1935 made only "'investigations and reports' to Congress" and "recommendations to courts as a master in chancery."[69]

58. The Commission exercises significantly more executive power today. And the Supreme Court has emphasized that even speaking of the Commission's powers in 1935, the "Court's conclusion that the FTC did not exercise executive power has not withstood the test of time."[70] "[I]t is hard to dispute that the powers of the FTC at the time of *Humphrey's Executor* would at the present time be considered executive, at least to some degree."[71] Under modern

[68] *Seila Law*, 591 U.S. at 215 (quoting *Humphrey's Executor*, 295 U.S. at 628).
[69] *Id.*
[70] *Id.* at 216 n.2.
[71] *Morrison v. Olson*, 487 U.S. 654, 689 n.28 (1988); *accord Seila Law*, 591 U.S. at 216 n.2.

precedent, the FTC's modern powers require that its Commissioners must be fully accountable to presidential supervision and removable at will. [72]

C. FTC ALJs are Executive Officers Who Are Unconstitutionally Insulated from Presidential Removal.

59. FTC ALJs are "inferior" officers within the Executive Branch. They serve indefinitely and exercise significant discretion and administrative authority in conducting adversarial hearings in the Commission's in-house proceedings. The Commission "delegates the initial performance of statutory fact-finding functions and initial rulings on conclusions of law" to ALJs.[73] The ALJs conduct hearings, control discovery, issue subpoenas, make decisions on the admissibility of evidence, and issue orders to keep proceedings moving.[74] At the end of administrative proceedings, the ALJs must file "a recommend decision" that is "based on a consideration of the whole record relevant to the issues decided" and "include[s] a statement of recommended findings of fact … and recommended conclusions of law," as well as a "proposed rule or order."[75] Accordingly, ALJs "determine, on a case-by-case basis, the policy of an executive branch agency," "fill[ing] statutory and regulatory interstices comprehensively with [their] own policy judgments."[76] The FTC then reviews ALJ decisions and may "adopt, modify or set aside the recommended findings, recommended conclusions, and proposed rule or order."[77]

60. Despite the significant executive power FTC's ALJs exercise in administrative proceedings, the FTC can only remove the ALJs "for good cause established and determined by

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[72] To the extent the Court concludes that *Humphrey's Executor* is controlling, Express Scripts, Caremark, and Optum reserve all rights to argue the Supreme Court should overrule *Humphrey's Executor*.

[73] 16 C.F.R. § 0.14.

[74] *Id.* §§ 3.42(c), 3.43.

[75] *Id.* § 3.51(a), (c)(1).

[76] *Sec'y of Educ. Review of ALJ Decisions*, 15 Op. O.L.C. 8, 14-15 (1991).

[77] 16 C.F.R. §§ 3.53, 3.54(a).

the Merits Systems Protection Board," and only "on the record after opportunity for [a] hearing" before that Board.[78] And the FTC Commissioners who can initiate removal proceedings for the ALJs are themselves removable by the President only for-cause.[79]

61. As a result, FTC ALJs serve under multiple layers of for-cause removal protection from Presidential supervision, conflicting with the requirement that, under Article II, the President must have "the ability to remove executive officials"[80]—including FTC ALJs—at will, given that "[t]he entire 'executive Power' belongs to the President alone."[81]

D. The Commission's Adjudicative Process Violates Plaintiffs' Due Process Rights.

1. *The Administrative Process Unconstitutionally Permits the FTC to Play the Role of Prosecutor, Judge, and Jury in a Fundamentally Unfair Proceeding*

62. "[A] fair trial in a fair tribunal is a basic requirement of due process."[82] "[W]hen the same person serves as both accuser and adjudicator in a case," an "unconstitutional potential for bias exists."[83] Yet here, rather than go to federal court, the FTC chose to pursue its claims against Plaintiffs through its in-house adjudicatory system that "combine[s] the functions of investigator, prosecutor, and judge under one roof."[84]

63. The FTC Commissioners decide the cases in which cases the Commission brings a complaint, which factual allegations to make against each respondent, and which legal claims to assert.[85] Then, Commission staff adjudicate the case in front of an FTC ALJ in a proceeding

[78] 5 U.S.C. § 7521(a), (b)(1).
[79] 15 U.S.C. § 41.
[80] *Seila Law*, 591 U.S. at 213.
[81] *Id.* (quoting Art. II, § 1).
[82] *Caperton v. A.T. Massey Coal Co.*, 566 U.S. 868, 876 (2009) (internal quotations omitted).
[83] *Williams v. Pennsylvania*, 579 U.S. 1, 8 (2016).
[84] *Axon*, 598 U.S. at 215 (Gorsuch, J., concurring).
[85] 16 C.F.R. § 3.11(a).

governed by "relaxed rules of procedure and evidence—rules [the FTC] make[s] for [itself]."[86] The Federal Rules of Civil Procedure and Federal Rules of Evidence that apply in federal courts do not apply in FTC proceedings. Then, even if the FTC loses before the ALJ despite all the procedural advantages, the FTC Commissioners review the ALJ's decision *de novo*—including the ALJ's factual findings and credibility determinations.[87] Thus, the ultimate decision whether to find liability is up to the very Commissioners who voted to issue a complaint bring the case in the first place.

64. Compounding the unfairness to Plaintiffs, the proceeding's timeline is highly compressed. In this case, while the Commission has spent more than two years conducting an investigation, Plaintiffs have to be trial-ready in a matter of months.

65. Since Chair Khan began her tenure at the Commission, the Commission has further stacked the deck to weaken due process for respondents and give the Commission even more pronounced procedural advantages in in-house proceedings. Under Chair Khan, the Commission voted in June 2023 to alter the Commission's rules of practice by converting an ALJ's ruling from an "initial decision"—which would automatically become the Commission's decision absent challenge—to a purely "recommended decision" that the Commission must vote to adopt.

66. Unsurprisingly, the "odds [are] stacked against" anyone against whom the FTC brings administrative proceedings.[88] For example, as the Ninth Circuit stated in its 2021 opinion in the *Axon* case, "Axon claims—and FTC does not appear to dispute—that FTC has not lost a single case in the past quarter-century. Even the 1972 Miami Dolphins would envy that type of

[86] *Axon*, 598 U.S. at 215 (Gorsuch, J., concurring); *see* 16 C.F.R. §§ 3.1, 3.43, 3.51.
[87] 16 C.F.R. § 3.54.
[88] *See Jarkesy*, 144 S. Ct. at 2141 (Gorsuch, J., concurring).

record."[89] Attached to this Complaint is a chart identifying all FTC administrative proceedings under Part 3 of the FTC's rules updated by the Commission between January 1, 2015, and November 18, 2024, in which there was a ruling on liability by an ALJ and/or the Commission. *See* Ex. 1. The chart was compiled from the FTC's website listing adjudicative proceedings. As the chart illustrates, the Commission prevailed in each relevant instance. *See id.* The FTC's win-loss record during in-house proceedings raises serious due process concerns, especially when combined with the procedural advantages the FTC has granted to itself.

67. Compounding the problem, the FTC's statutory scheme deprives courts of *de novo* review at the back end. Federal courts must treat FTC factual findings as "conclusive" "if supported by evidence," a highly deferential standard of review.[90] "The reviewing court also cannot take its own evidence—it can only remand the case to the agency for further proceedings."[91] Thus, even on appellate review, courts are required to "put a thumb (or perhaps two forearms) on the agency's side of the scale."[92] "That is the very opposite of the separation of powers that the Constitution demands."[93]

68. Given that the FTC Commissioners owe no deference to an ALJ decision, and the FTC contends that federal court of appeals *must* affirm the Commission's factual findings if they meet the deferential "substantial evidence" standard (a more lenient standard than the one applied

[89] *See Axon Enter., Inc. v. FTC*, 986 F.3d 1173, 1187 (9th Cir. 2021), *rev'd and remanded*, 598 U.S. 175 (2023); *see also* David Balto, *Can the FTC be a Fair Umpire?*, THE HILL (Aug. 14, 2013), https://thehill.com/blogs/congress-blog/economy-a-budget/159122-can-the-ftc-be-a-fair-umpire; A. Douglas Melamed, *Comments to FTC Workshop Concerning Section 5 of the FTC Act* (Oct. 14, 2008), https://www.ftc.gov/sites/default/files/documents/public_comments/section-5-workshop-537633-00004/537633-00004.pdf.

[90] 15 U.S.C. § 45(c).

[91] *Axon*, 598 U.S. at 197 (Thomas, J., concurring) (citing 15 U.S.C. § 45(c)).

[92] *Id.* at 203 (citation omitted).

[93] *Jarkesy*, 144 S. Ct. at 2139.

to a district court's findings of fact), Plaintiffs will forever be denied a fair opportunity to have the factual record considered by a neutral factfinder and decisionmaker. These profound deficiencies in process deny Plaintiffs their constitutional rights to due process because "a 'fair trial in a fair tribunal is a basic requirement of due process.'"[94]

69. Ultimately, the Commission may be entitled to serve as prosecutor *or* as judge. But the Constitution forbids the Commission from doing both in the same matter. "Due process guarantees 'an absence of actual bias' on the part of a judge," and "an unconstitutional potential for bias exists when the same person serves as both accuser and adjudicator in a case."[95] Here, the Commission endeavors to inhabit both roles simultaneously in clear violation of the Constitution. As a result, "the odds [are] stacked against" Plaintiffs in a manner that violates their due process rights.[96]

2. *The Commission Has Prejudged the Facts and Law as to the PBM Plaintiffs, Rendering this Enforcement Action Fundamentally Unfair*

70. The structural unfairness of the Commission's proceedings is especially problematic here, because the Commission has demonstrated that it has already prejudged the case against Express Scripts, Caremark, and Optum, and there is no opportunity for a fair proceeding. The current FTC is led by a Chair who came to the agency with an agenda to target PBMs. The Democratic Commissioners' public statements make clear that the outcome in this case is already foreordained, regardless of what the proceedings before the ALJ reveal and irrespective of whether the ALJ's recommended decision concludes that Express Scripts, Caremark, and Optum did not violate the law.

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[94] *Withrow v. Larkin*, 421 U.S. 35, 46 (1975).
[95] *Williams*, 579 U.S. at 8.
[96] *Jarkesy*, 144 S. Ct. at 2141 (Gorsuch, J., concurring).

71. The current Commission's dramatic turn against PBMs vividly illustrates the prejudgment exhibited against Express Scripts, Caremark, and Optum in this case. Past Commissions have recognized the benefits of PBMs on a bipartisan basis and across administrations of both political parties. For example, past Commissions have observed that PBMs have the "ability to negotiate lower prices for prescription drugs,"[97] create incentives "for pharmacies to bid aggressively on prescription drug prices,"[98] and that PBM formulary and generic substitution practices "lowers prescription drug costs" and "lower prices for health care"[99] for consumers. Indeed, after its 2012 "comprehensive investigation" of the Express Scripts, Inc. acquisition of Medco Health Solutions (both of which are Respondents in the Commission's administrative action), the Commission concluded that competition among PBMs "is intense, has driven down prices, and has resulted in declining PBM profit margins."[100]

[97] Letter from Susan S. DeSanti, Joseph Farrell & Richard A. Feinstein, FTC to State Rep. Mark Formby, Miss. H.R., at 1 (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.

[98] *Id.* at 4.

[99] Letter from Maureen K. Ohlhausen, Michael A. Salinger & Jeffrey Schmidt, FTC to Terry G. Kilgore, Member, Va. 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.

[100] 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/public_statements/statement-federal-trade-commission-concerning-proposed-acquisition-medco-health-solutions-express./120402expressscripts.pdf.

72. The current Commission has decided to cast those findings aside in single-minded pursuit of its anti-PBM agenda.[101] For example, in September 2022 testimony before a Subcommittee of the Senate Judiciary Committee, Chair Khan prejudged PBMs for having "opaque operations" and an ostensible ability to "dictate the pricing and access to life-saving drugs for so many Americans."[102] Separately, she has disparaged PBMs as "obscure players" and "these middlemen" who "determine who gets access to what medicines and at what price."[103] She has publicly singled out "PBMs" as "powerful corporate middlemen" who supposedly "engage in tactics that hike the price of drugs, deprive patients of access to certain medicines," and "price gouge[]" customers.[104] She has referred to rebating on drugs as a form of "kickback" to PBMs,[105] which supposedly ensure that the "medicines that are made available at the pharmacy are not the

[101] In July 2023, the Commission suddenly 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. The decision to disavow these letters and reports was made only by Chair Khan and the two other Democratic Commissioners—Commissioners Slaughter and Bedoya. 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." 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.

[102] Lina M. Khan, Chair, FTC, *Oversight of the Enforcement of the Antitrust Laws*, Prepared Statement of the FTC Before the United States Senate Committee on the Judiciary Subcomm. on Antitrust, Competition Policy and Consumer Rights, at 14 (Sept. 20, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/P210100SenateAntitrustTestimony09202022.pdf.

[103] Senator Bernie Sanders, *LIVE with FTC Chair Lina Khan* at 9:26–9:34, YOUTUBE (Apr. 15, 2024), https://www.youtube.com/watch?v=-C99FUnGnJU.

[104] Lina M. Khan, Chair, FTC, *Remarks as Prepared for Delivery 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.

[105] 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.

most affordable medicines for Americans"[106]—echoing precisely the allegation later made later in the Commission's instant Complaint against Express Scripts, Caremark, and Optum. Chair Khan has also claimed that PBMs "are sitting right in the middle and controlling the types of practices that independent pharmacies are facing, the medicines that consumers are or have not been able to access, so we are looking at magnitude of harm [and] who are the most significant players in the supply chain."[107] And Chair Khan has declared that these "practices violate the fundamental bargain at the center of the American prescription drug system."[108]

73. The Commission's Complaint echoes or repeats nearly verbatim many of Chair Khan's favored jabs against PBMs. For example, it alleges that PBMs "are central actors in pharmaceutical transactions, influencing drug pricing, rebates, and sales"[109] and that PBMs "have created an opaque drug pricing and reimbursement system."[110] It claims that the "PBM Respondents have a significant role in controlling consumers' affordable access to prescription medications."[111] And it alleges that "[b]ecause of Respondents' conduct, many diabetics have been denied access to more affordable lower list price insulin products."[112] Chair Khan has explicitly prejudged the facts and legal claims alleged in the Complaint.

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[106] Senator Bernie Sanders, *LIVE with FTC Chair Lina Khan*, at 9:48–10:17, YOUTUBE (Apr. 15, 2024), https://www.youtube.com/watch?v=-C99FUnGnJU.

[107] Economic Liberties, *2023 Anti-Monopoly Summit*, at 1:22:40, YOUTUBE (May 4, 2023), https://www.youtube.com/watch?v=_MUdBWApI9k&t=3928s.

[108] Lina M. Khan, Chair, FTC, *Remarks Regarding Policy Statement on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products*, at 2, Commission File No. P221201 (June 16, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Remarks-Chair-Lina-Khan-Regarding-Policy-Statement-Rebates-Fees.pdf.

[109] Complaint at 5 (Background).

[110] *Id.* ¶ 7; *see also* ¶ 4.

[111] *Id.* at ¶ 263; *see also* ¶ 4.

[112] *Id.* at ¶ 218.

74. The two other Democratic Commissioners have also demonstrated that they, too, have already prejudged the issues central to the Commission's administrative action. Commissioner Slaughter has publicly declared that "[f]airness in drug pricing is undermined" by PBM rebates, concluding that "[t]his is not the way competition is supposed to work" and branding PBMs by association with "illegal anticompetitive practices."[113] She has also attributed increases in "patients' out-of-pocket costs" to "mushroom[ing]" "PBM rebates and fees."[114] And she has accused PBMs of creating "disturbing[]," "unacceptable," and "rotten" market "distortions."[115]

75. Commissioner Bedoya has concluded that it is "pretty clear" that rebates improperly "drive up the list price" for consumers, while declaring that rebates' effects can be "horrific" and "frankly, keep [him] up at night."[116] Commissioner Bedoya has suggested that "[w]e all know" that PBM pricing is "not what fair markets look like."[117] He has also disparaged

[113] Rebecca Kelly Slaughter, Acting Chair, FTC, *Statement Regarding the Federal Trade Commission's Report to Congress on Rebate Walls*, at 1 (May 28, 2021), https://www.ftc.gov/system/files/documents/public_statements/1590532/statement_of_acting_chairwoman_slaughter_regarding_the_ftc_rebate_wall_report_to_congress.pdf.

[114] Rebecca Kelly Slaughter, Comm'r, FTC, *Statement Regarding the Commission Statement on Reliance on Prior PBM-Related Advocacy Statements and Reports that No Longer Reflect Current Market Realities*, at 2 (July 20, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/finalbksremarksonftcstatementagainstrelianceonpriorpbmadvocacy7202023.pdf.

[115] Rebecca Kelly Slaughter, Comm'r, FTC, *Statement Regarding the Use of Compulsory Process and Issuance of 6(b) Orders to Study Contracting Practices of Pharmacy Benefit Managers*, at 1 https://www.ftc.gov/system/files/ftc_gov/pdf/P221200PBMSlaughterStatement.pdf.

[116] Capital Forum, *Fireside Chat with FTC Commissioner Alvaro Bedoya*, at 4:30, YOUTUBE (Nov. 13, 2023), https://youtu.be/VkQCHB1IVrY; Capital Forum, Transcript of Interview with FTC Commissioner Alvaro Bedoya (June 15, 2023), https://thecapitolforum.com/resources/transcript-of-interview-with-ftc-commissioner-alvaro-bedoya.

[117] Alvaro M. Bedoya, Comm'r FTC, *Returning to Fairness*, Prepared Remarks Before the Midwest Forum on Fair Markets, at 8 (Sept. 22, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/returning_to_fairness_prepared_remarks_commissioner_alvaro_bedoya.pdf.

PBMs as "the middlemen who control our access to insulin" and "make billions off it" by means of "placements on formularies."[118]

76. These are among the key issues the Commission will confront in adjudicating its Complaint and are vigorously disputed by Plaintiffs. Yet as with Chair Khan, the Complaint echoes Commissioners Slaughter and Bedoya's prior statements. It alleges PBMs have created a "broken drug pricing system,"[119] which is "a pattern of anticompetitive and unfair conduct."[120] It claims that PBMs' supposed "high rebates and fees" result in "higher out-of-pocket costs,"[121] and this "mode of competition []is detrimental to patients."[122]

77. The Commissioners' attacks on PBMs have often come at one-sided events hosted and funded by notoriously anti-PBM groups. For example, the Commissioners have spoken numerous times before a trade association and lobbying group that is openly hostile to PBMs.[123] Khan even headlined the group's 2022 convention, where executives described PBMs as "bloodsuckers," wore shirts depicting PBMs as vampires, and distributed "F*** PBM" pins.[124]

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[118] Alvaro M. Bedoya, Comm'r, FTC, *Statement Regarding Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products*, at 1, 3 (June 16, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/P214501BedoyaStatementRebatePolicy.pdf.

[119] Complaint ¶ 8.

[120] *Id.* ¶ 214.

[121] *Id.* ¶ 259.

[122] *Id.* ¶ 193.

[123] *See*, *e.g.*, Celine Castronuovo, *FTC Intends to 'Not Rush' Probe into Pharmacy Benefit Mangers*, Bloomberg Law (Apr. 27, 2023), https://news.bloomberglaw.com/health-law-and-business/ftc-intends-to-not-rush-probe-into-pharmacy-benefit-managers.

[124] 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/; CVS Health, *Independent Pharmacies: Myths versus Reality*, at 9 https://www.cvshealth.com/content/dam/enterprise/cvs-enterprise/pdfs/2024/drug-costs/2024-08-10-FTC-White-Paper-on-Independent-Pharmacies.pdf.

78. Chair Khan's Commission has also made similar statements about insulin specifically. In June 2022, the Commission issued a policy statement asserting that rebates from PBMs are a reason insulin prices increased in the past.[125] The Commissioners also issued a press release demonizing PBMs' "illegal rebate schemes" as "bribes."[126] Without waiting for the study's results, the Commissioners took the unusual step of releasing an interim report, marred by a politicized process and lack of evidence, that in its very title accuses PBMs of "inflating drug costs."[127] The Complaint essentially repeats those same conclusions as allegations in the instant administrative action, showing that the fix is in. The Commission will ultimately decide Plaintiffs have violated the law and will enter its own industry-altering remedies, regardless of the evidence or the ALJ's findings or credibility determinations. This is not, as the Constitution requires, a process without an appearance of bias.

79. Worse still, the only votes authorizing the action against Plaintiffs were cast by the Democratic Commissioners due to the recusal of both Republican Commissioners. The rationale for these recusal decisions was not made public, and Express Scripts, Caremark, and Optum have

[125] FTC, *Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products* (June 16, 2022), https://www.ftc.gov/legal-library/browse/policy-statement-federal-trade-commission-rebates-fees-exchange-excluding-lower-cost-drug-products.

[126] FTC, *FTC to Ramp Up Enforcement Against Any Illegal Rebate Schemes, Bribes to Prescription Drug Middleman That Block Cheaper Drugs* (June 16, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-ramp-up-enforcement-against-illegal-rebate-schemes.

[127] FTC, Office of Policy Planning, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf. On September 17, 2024, Express Scripts filed a lawsuit in the Eastern District of Missouri concerning the PBM report against the FTC and Chair Khan in her official capacity alleging claims for defamation and violations of due process, Article II of the Constitution, the FTC Act, and the Administrative Procedure Act. *See Express Scripts, Inc. v. FTC et al.*, No. 4:24-cv-01263-SRC (E.D. Mo. Sept. 17, 2024).

no meaningful opportunity to challenge them with the Commission. The partisan origin of this high-stakes enforcement action raises further due process problems with the Commission's action because it circumvented one of the key procedural protections that Congress included in the FTC's structure: that the Commissioners would convene a *bipartisan* group that would make enforcement decisions jointly.

80. The bias against Express Scripts, Caremark, and Optum as to both the law and facts that pervades the Commission's administrative process makes it fundamentally unfair. The Commission's public position is so firmly entrenched—given the prejudgment reflected in numerous speeches, statements, and other issuances—that it makes it "difficult, if not impossible" for the Commission to "reach a different conclusion" in this adjudication against Express Scripts, Caremark, and Optum.[128] Chair Khan and her Democratic Commissioner colleagues came to the FTC with an agenda to reverse the FTC's multi-decade and bipartisan conclusion that PBMs promote competition in the prescription drug industry and to sue the PBMs. The Democratic Commissioners' minds are irrevocably closed to the possibility that PBMs' conduct is procompetitive and pro-consumer, not anticompetitive and anti-consumer. Judicial intervention is therefore warranted to enjoin this unfair proceeding that runs roughshod over the PBMs' due process rights and falls short of embodying the "appearance of justice," given that "justice must satisfy the appearance of justice."[129]

81. For the above reasons, Plaintiffs cannot realistically or fairly be expected to receive a fair hearing on these or other challenges to the Commission's constitutionally deficient

[128] *Cinderella Career & Finishing Schools, Inc. v. FTC*, 425 F.2d 583, 590 (D.C. Cir. 1970).

[129] *Antoniu v. SEC*, 877 F.2d 721, 724 (8th Cir. 1989) (quoting *In re Murchison*, 349 U.S. 133, 136 (1955)).

proceedings in the administrative process itself. Having decided to initiate this improper proceeding, there is no reason to believe that the Commission would change its mind now and respect the U.S. Constitution. Moreover, the Commission, which has no special expertise in analyzing and interpreting the Constitution, has consistently rejected such arguments when raised in the past.[130]

E. Express Scripts, Caremark, and Optum Will Suffer Irreparable Harm Unless the Administrative Proceeding is Enjoined.

82. Multiple serious defects in the structure of the Commission and in the administrative proceeding, combined with the Commission's prejudgment of the facts and bias against Express Scripts, Caremark, and Optum, as outlined above, render the administrative proceeding unconstitutional.

83. Unless the proceeding is enjoined, Express Scripts, Caremark, and Optum will suffer an immediate constitutional injury by being subjected to an illegitimate proceeding. The harm from such illegitimate proceedings cannot be undone. The Supreme Court has recognized that the injury of being subjected to an illegitimate proceeding is a "'here-and-now injury.'"[131]

84. Plaintiffs also face the independent irreparable harm of being deprived of fundamental constitutional liberties. Article II and Article III confer and protect individual

[130] *See, e.g.*, Order Denying Motion to Disqualify, *In re Intuit Inc.*, Docket No. 9408 (F.T.C. Oct. 19, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/d09408_2023-10-19_intuit_order_denying_motion_to_disqualify_unsigned.pdf; Statement of Chair Lina M. Khan Regarding the Petition for Recusal from Involvement in Intuit Inc., *In re Intuit Inc.*, Docket No. 9408 (F.T.C. Oct. 19, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/statement_of_chair_lina_m._khan_re_intuit_inc.pdf; Order Denying Respondent's Motion to Disqualify the Administrative Law Judge, *In re Axon Enterprise, Inc. & Safariland, LLC*, Docket No. 9389 (F.T.C. Sept. 3, 2020), https://www.ftc.gov/system/files/documents/cases/d09389_order_denying_motion_to_disqualify_alj.pdf.

[131] *Axon*, 598 U.S. at 191.

constitutional rights, in addition to vindicating interests in the appropriate separation of powers.[132] The Due Process Clause likewise protects individual rights to a fair and impartial adjudicator. The deprivation of fundamental constitutional rights, even if temporary, is an injury.[133] And because the Commission's ongoing proceeding violates these constitutional rights, Plaintiffs' rights will continue to be lost every day, and their injuries will continue to mount. And these injuries cannot be remedied by judicial review of a final FTC order.

85. Express Scripts, Caremark, and Optum cannot obtain a fair hearing and remedy for this constitutional defect within the confines of the Commission's proceeding. The Federal Rules of Civil Procedure and the Federal Rules of Evidence do not apply there, and the Commission decides all questions of law. Although Express Scripts, Caremark, and Optum can and will make objections to preserve their rights, those objections will be decided ultimately by the three Commissioners participating in the administrative matter—all of whom have already demonstrated bias against Express Scripts, Caremark, and Optum and have prejudged the disputed facts.

86. As previously explained, any appeal from an adverse ALJ decision against Plaintiffs would go directly to the full Commission that voted to investigate and file the Complaint and has already prejudged the outcome, giving Plaintiffs no real recourse and guaranteeing a predetermined outcome. The Commission can rewrite the ALJ's factual conclusions when reviewing the ALJ's non-binding recommendation, meaning that Express Scripts, Caremark, and Optum will be deprived of an opportunity for a neutral decision-maker to make factual findings.

87. Put otherwise, Express Scripts, Caremark, and Optum are being backed into a corner with no fair options. The Commission has effectively already won by bringing this

[132] *See, e.g.*, *Bond v. United States*, 564 U.S. 211, 222 (2011) (explaining that "structural principles secured by the separation of powers" also "protect the individual").

[133] *See Elrod v. Burns*, 427 U.S. 347, 373 (1976).

proceeding in its home court. It will certainly win the administrative action, no matter what the evidence shows, because even if the ALJ rules in Plaintiffs' favor, the Commission, having prejudged the facts and law, will decline to accept the recommendation. Meanwhile, review in the Court of Appeals of any Commission decision—after millions of dollars in attorney's fees and countless hours of employee time and distraction—will be under a highly deferential standard with respect to the Commission's factual findings. Only this action can prevent the harms to Plaintiffs stemming from the Commission's unconstitutional proceeding.

COUNT ONE

Violation of Article III of the U.S. Constitution

88. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein. Article III requires the judicial power of the United States to be vested in Article III courts, and prohibits administrative agencies from adjudicating claims understood as part of that power at the Founding.

89. The Commissions' in-house proceeding under Section 5 of the FTC Act seeks to adjudicate unfair methods of competition and unfair or deceptive practices claims that are analogous to claims at common law that traditionally would have been litigated between private parties—claims involving private rights that must be tried in an Article III court.

90. The "public rights" exception does not permit the FTC to adjudicate unfair methods of competition and unfair or deceptive practices claims outside of an Article III court.

91. The FTC's adjudication of private rights in an in-house FTC proceeding violates Article III of the Constitution.

COUNT TWO

Violation of Article II of the U.S. Constitution Because the FTC Commissioners Are Unlawfully Insulated from Removal

92. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

93. Article II of the Constitution vests the executive Power entirely in the President, who must "take Care that the Laws be faithfully executed."

94. Restrictions on the President's ability to remove subordinate officials who exercise significant executive power unlawfully trammel on presidential supervision of the officials and insulate the officials from political accountability in violation of Article II.

95. The for-cause removal restrictions enjoyed by FTC Commissioners flout these principles. The FTC exercises significant executive power and its Commissioners direct and control the work of the agency, yet the politically-accountable President is restricted in the ability to exercise the President's removal power over FTC Commissioners.

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

COUNT THREE

Violation of Article II of the U.S. Constitution Because the FTC's ALJ Is Unlawfully Insulated from Removal

97. Plaintiffs incorporate and reallege each allegation contained above, as though fully set forth herein.

98. Article II of the Constitution vests "the executive Power" entirely in the President, art. II, § 1, cl. 1, and thus the President must have the ability to remove subordinate officers whom exercise part of the executive power on the President's behalf.

99. The Supreme Court has thus held that the general rule is that the President must have the ability to remove his subordinates without restrictions. Specifically, the Supreme Court has held that two layers of for-cause removal protection unconstitutionally strip the President of the ability to supervise subordinate officers.

100. The FTC's ALJ in the underlying administrative proceeding exercising significant executive power in the administrative proceeding and is unconstitutionally insulated from presidential control by multiple layers of for-cause removal protection.

101. Because of the multiple levels of removal protection enjoyed by the FTC's ALJ, the President cannot remove the ALJ even if the President determines the ALJ is not properly exercising his duties or is discharging them improperly. Moreover, the ALJ is insulated from political accountability as a result of his multiple levels of removal protection.

102. The FTC ALJ's multiple for-cause removal protections violate Article II, and thus the proceeding before the unconstitutionally appointed ALJ is unlawful and violates the PBMs' rights.

COUNT FOUR

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

103. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

104. Under the FTC Act, the FTC, as prosecutor, initiates or reopens an administrative proceeding in its discretion, and as judge, decides the matter, including through factual findings and legal determinations.

105. In the administrative action against Express Scripts, Caremark, and Optum, the FTC will act as both a prosecutor and judge. This dual role violates the PBMs' right to due process because it cannot receive a fair and unbiased hearing.

106. The Commissioners, including Chair Khan and the other Democratic Commissioners, have made statements suggesting that they have already made a decision on the merits against the PBMs and their minds are irrevocably closed to a different outcome. The other two Commissioners are recused.

107. After the administrative hearing, an Article III court cannot, according to the FTC, meaningfully review the FTC's decision, as the order will be subject to a highly deferential standard of review.

108. The FTC's unfettered authority to act as prosecutor and judge violates Plaintiffs' Fifth Amendment Due Process rights, including because the Commission has already decided the outcome of this proceeding.

PRAYER FOR RELIEF

Wherefore, Plaintiffs respectfully request that this Court enter judgment in their favor and against Defendants as follows:

i. A declaratory judgment that the FTC's administrative action against Express Scripts, Caremark, and Optum violates Article III of the U.S. Constitution;

ii. A declaratory judgment that the FTC Commissioners are unconstitutionally insulated from removal in violation of Article II of the U.S. Constitution, and thus the proceeding is unlawful;

iii. A declaratory judgment that the that the FTC's ALJ is unconstitutionally insulated from removal in violation of Article II of the U.S. Constitution, and thus the proceeding is unlawful;

iv. A declaratory judgment that the FTC's proceeding violates the Due Process Clause of the Fifth Amendment;

v. An order preliminarily and permanently enjoining the FTC's unlawful administrative proceeding against Express Scripts, Caremark, and Optum;

vi. Grant Plaintiffs such additional or other relief as it deems just and proper, including an award of reasonable attorneys' fees and the costs of this action.

Dated: November 19, 2024

Respectfully Submitted,

By: /s/ *Sarah C. Hellmann*

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Exhibit 1

Federal Trade Commission Adjudicative Proceedings Updated from January 1, 2015 – November 18, 2024

Includes proceedings in which Part 3 Complaint was filed and there was a decision on liability by the ALJ and/or Commission.
The chart excludes cases filed exclusively in Federal Court.
Source: FTC Website, https://www.ftc.gov/legal-library/browse/cases-proceedings/adjudicative-proceedings

	A	B	C	D	E	F	G
	TITLE	**DOCKET NUMBER**	**STATUS**	**LAST UPDATED[1]**	**ALJ Liability Decision**	**Commission Liability Decision**	**Commission WIN or LOSS**
1	Illumina, Inc., and GRAIL, Inc., In the Matter of	9401	Closed[2]	August 15, 2024	No Liability	Liability (Reversed ALJ)	WIN
2	Intuit Inc., In the Matter of (TurboTax)	9408	Pending	June 14, 2024	Liability	Liability (Upheld ALJ)	WIN
3	Altria Group/JUUL Labs, In the Matter of	9393	Closed	July 3, 2023	No Liability	ALJ decision of no liability vacated and complaint dismissed following the voluntary unwinding of the investment that triggered the complaint.	N/A
4	Traffic Jam Events, LLC, In the Matter of	9395	Closed[3]	January 28, 2022	N/A	Liability (Summary Decision)	WIN
5	Otto Bock HealthCare North America, Inc., In the Matter of	9378	Closed	December 1, 2020	Liability	Liability (Upheld ALJ)	WIN
6	Benco/Schein/Patterson, In the Matter of	9379	Closed	July 31, 2020	Partial Liability	No Appeal to Commission	WIN
7	1-800 Contacts, Inc, In the Matter of	9372	Closed	August 6, 2021	Liability	Liability (Upheld ALJ)	WIN
8	Impax Laboratories, Inc., In the Matter of	9373	Closed	April 13, 2021	No Liability	Liability (Reversed ALJ)	WIN

[1] This column refers to the date on which the FTC docket was last updated, and does not reflect associated federal court dockets.
[2] This case, although listed as "pending" on the FTC's website as of November 18, 2024, appears to be closed.
[3] This case, although listed as "pending" on the FTC's website as of November 18, 2024, appears to be closed.

	A	B	C	D	E	F	G
	TITLE	**DOCKET NUMBER**	**STATUS**	**LAST UPDATED[1]**	**ALJ Liability Decision**	**Commission Liability Decision**	**Commission WIN or LOSS**
9	Jerk, LLC, d/b/a Jerk.com, In the Matter of	9361	Closed	January 8, 2018	N/A	Liability (Summary Decision)	WIN
10	ProMedica Health System, Inc., a corporation, In the Matter of	9346	Closed	October 16, 2017	Liability	Liability (Upheld ALJ)	WIN
11	ECM BioFilms, Inc., also d/b/a Enviroplastics International, In the Matter of	9358	Closed	March 16, 2017	Partial Liability	Liability (Upheld ALJ in part and reversed ALJ in part)	WIN
12	California Naturel, In the Matter of	9370	Closed	December 12, 2016	N/A	Liability (Summary Decision)	WIN
13	LabMD, Inc., In the Matter of	9357	Closed	September 29, 2016	No Liability	Liability (Reversed ALJ)	WIN
14	McWane, Inc., and Star Pipe Products, Ltd., In the Matter of	9351	Closed	April 17, 2015	Partial Liability	Partial Liability (Upheld ALJ in part and reversed ALJ in part)	WIN

Exhibit B

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

EXPRESS SCRIPTS, INC., et al., Plaintiffs, v. FEDERAL TRADE COMMISSION, et al., Defendants.	Case No. 4:24-cv-01549-MTS

PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

Pursuant to Rule 65 of the Federal Rules of Civil Procedure, Plaintiffs move to preliminarily enjoin Defendants from pursuing further administrative proceedings against Plaintiffs before the Federal Trade Commission ("FTC" or "Commission") in *In the Matter of (Insulin)*, Dkt. No. 9437, and from initiating any other administrative action(s) against Plaintiffs. As explained in Plaintiffs' accompanying Memorandum of Law, a preliminary injunction is necessary to prevent the Commission from subverting bedrock constitutional principles, violating Plaintiffs' constitutional rights, and inflicting irreparable harm on Plaintiffs.

The FTC's administrative proceeding violates the U.S. Constitution in multiple respects.

First, it violates Article III by improperly seeking to adjudicate Plaintiffs' private rights in an agency forum rather than federal court because the FTC's claims have roots in the common law, and its remedy seeks to interfere with Plaintiffs' contracts with other private parties.

Second, it violates Article II because the presiding FTC Administrative Law Judge, as well as FTC Commissioners, are improperly insulated by statutory for-cause protections from presidential accountability.

Third, it violates the Fifth Amendment's Due Process Clause because the Commissioners are impermissibly acting as the prosecutor, judge, and jury, and the three non-recused Democratic Commissioners who voted to bring this case have prejudged its outcome.

Absent preliminary injunctive relief, Plaintiffs are being, and will continue to be, irreparably harmed by being subjected to an unconstitutional administrative proceeding before an unconstitutionally structured agency. By contrast, a preliminary injunction will not harm the FTC because the FTC has no legitimate interest in violating the Constitution, and it is in the public interest to prohibit unconstitutional conduct by federal agencies and officials.

Pursuant to Local Rule 4.02(B), Plaintiffs respectfully request that the Court hold oral argument on their Motion. Disposition of the Motion involves numerous complex and significant questions of constitutional law, and Plaintiffs believe that oral argument would assist the Court in assessing Plaintiffs' request for a preliminary injunction.

For the foregoing reasons, and as set forth in the accompanying Memorandum of Law, Plaintiffs respectfully request that their Motion for a Preliminary Injunction be granted.

Dated: November 19, 2024

Respectfully Submitted,

By: /s/ *Sarah C. Hellmann*

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Exhibit A

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

EXPRESS SCRIPTS, INC., et al., Plaintiffs, v. FEDERAL TRADE COMMISSION, et al., Defendants.	Case No. 4:24-cv-01549-MTS

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION

Preliminary injunctive relief is essential to prevent the Federal Trade Commission from subverting bedrock constitutional principles of accountability and fairness.

On September 20, 2024, the FTC's three Democratic Commissioners (with the two Republicans recused) initiated a complaint before the FTC's in-house administrative forum in an attempt to transform significant aspects of the pharmacy-benefit management industry by regulatory fiat.[1] Pharmacy-benefit managers ("PBMs") work with health plan sponsors, such as employers and unions, to manage prescription-drug benefits. PBMs negotiate with drug manufacturers over the costs that their clients pay for a drug. By negotiating, PBMs secure discounts and other savings for clients—which in turn helps health plan sponsors to improve benefits and reduce plan premiums and out-of-pocket costs for their members. Plaintiffs Caremark Rx, L.L.C., Express Scripts, Inc., and OptumRx, Inc., are the three largest PBMs.

The FTC's complaint accuses these Plaintiffs (along with related entities known as group purchasing organizations) of nebulous unfair trade practices in negotiating drug costs, all based on the novel theory that Section 5 of the Federal Trade Commission Act—which prohibits "unfair methods of competition" and "unfair ... acts or practices"—gives the FTC unbounded license to define practices as unfair based on its own subjective policy preferences. The complaint proposes equally novel remedies: the FTC would upend present-day drug pricing contracts, forcing PBMs to restructure countless contracts with drug manufacturers, health plan sponsors, and other private parties. Nor would the FTC stop there: the FTC reserves for itself the right to order "any other relief appropriate" without elaboration. FTC Compl., Notice of Contemplated Relief ¶ 4.

[1] *In re Caremark Rx, L.L.C. et al.*, Dkt. No. 9437 (F.T.C. Sept. 20, 2024) ("FTC Compl."), https://www.ftc.gov/system/files/ftc_gov/pdf/d9437_caremark_rx_zinc_health_services_et_al_part_3_complaint_corrected_public.pdf.

The FTC's attempted industry-wide shakeup would be startling enough had the FTC sought to enjoin clearly identified conduct in federal-court proceedings, as Congress authorized in 15 U.S.C. § 53(b). Instead, the FTC seeks to litigate its complaint in the FTC's in-house administrative forum, where the agency acts as prosecutor, judge, jury, and executioner. Unsurprisingly, the FTC "has not lost a single case in the past quarter-century," a win rate that "[e]ven the 1972 Miami Dolphins would envy." *Axon Enter., Inc. v. FTC*, 986 F.3d 1173, 1187 (9th Cir. 2021), *rev'd and remanded*, 598 U.S. 175 (2023); *see also* Plaintiffs' Compl., ECF No. 1, ¶ 66; Ex. 1.

By proceeding in-house instead of in federal court, the FTC obtains immense home-field advantages. The FTC's lawyers prosecute the FTC's complaint before an FTC administrative law judge (ALJ). Then the same Commissioners who greenlit the complaint ultimately decide its merit. Along the way, the FTC's ALJ "decides discovery disputes" and "determines the scope and form of permissible evidence," including relying on "hearsay and other testimony that would be inadmissible in federal court." *See SEC v. Jarkesy*, 144 S. Ct. 2117, 2126 (2024) (discussing materially similar SEC procedures). Defending against the entire administrative process often costs millions of dollars. Yet the outcome is all but foreordained, since the Commission never second-guesses its own decision to initiate a complaint and controls how evidence comes in. And, while the Commission's ultimate decision is subject to judicial review in federal appellate courts, that review is limited and "deferential." *Id.*

The Commission's choice to ram its complaint through stacked-deck FTC administrative proceedings—rather than testing its allegations in federal courts, which have historically been skeptical of the FTC's novel theories—contravenes multiple constitutional guarantees.

First, Article III guarantees that federal courts must resolve the very types of claims and remedies that the FTC now seeks to adjudicate via in-house administrative proceedings. Article III of the Constitution requires courts—not agencies—to adjudicate suits involving "private rights." *Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 56 (1989). If, as here, the agency is pursuing claims or remedies that traditionally would have been litigated between private parties at law or equity, the case involves private rights and the agency must proceed in federal court. *See Jarkesy*, 144 S. Ct. at 2129, 2132. Applying those rules, the Supreme Court just held that the SEC acted unconstitutionally by administratively adjudicating private-law claims for securities fraud and extracting civil penalties. *Id.* at 2129, 2136, 2139.

Yet, months after the Supreme Court's *Jarkesy* decision, the FTC deliberately bypassed federal court and now seeks to bring analogous private-rights claims in administrative proceedings. The FTC is pressing claims about allegedly unfair contracts and transactions among private market participants—claims with common-law antecedents that federal courts must decide. Further, the FTC avowedly seeks to compel PBMs to restructure contracts with sophisticated market participants and change how it negotiates with drug manufacturers—the kind of equitable remedy federal courts must impose. And the FTC seeks to impose remedies that would force PBMs to upend their contracting, impairing their private rights.

Second, Article II of the Constitution guarantees democratic accountability in agency decision-making by requiring that the President be able to remove agency heads at will and exercise adequate supervision of agency adjudicators. The "general rule" is that the President enjoys "unrestricted removal power." *Seila Law LLC v. CFPB*, 591 U.S. 197, 215 (2020). On that basis, the Supreme Court has invalidated a range of removal restrictions in recent years.

The FTC's convoluted adjudicative machinery defies that constitutionally required accountability and control at every turn. FTC Commissioners are agency heads who exercise vast executive powers, ranging from rulemaking to adjudication, with massive consequences for the U.S. economy. Yet the President can remove Commissioners only "for inefficiency, neglect of duty, or malfeasance in office." 15 U.S.C. § 41. That restriction unconstitutionally constrains the President from reining in agency heads. Here, this limitation on presidential accountability is especially acute. On the eve of a change in administration, a politically one-sided subset of agency heads appointed by the prior President is rushing headlong into uncharted waters beyond the agency's statutory purview.

The ALJ presiding over the FTC's in-house proceeding is also unconstitutionally insulated from presidential accountability and supervision. FTC ALJs are "inferior" officers—officials who exercise continued, significant authority under the laws of the United States. These ALJs have authority "much like a regular trial judge, to resolve motions, hold a hearing, and then issue a decision." *Axon Enter., Inc. v. FTC*, 598 U.S. 175, 181 (citing 16 C.F.R. §§ 3.21-.56 (2021)). Yet the President has no direct way to hold these important officials accountable through removal because they are shielded by multiple layers of tenure protection—a result the Supreme Court has held unconstitutional for similar types of officers. *See Free Enter. Fund v. PCAOB*, 561 U.S. 477, 484 (2010). The Fifth Circuit has thus held that similar restrictions governing SEC ALJs are unconstitutional. *Jarkesy v. SEC*, 34 F.4th 446, 463-65 (5th Cir. 2022); *aff'd on other grounds by SEC v. Jarkesy*, 144 S. Ct. 2117 (2024).

Third, the FTC's proceedings violate the Fifth Amendment's Due Process Clause because the FTC acts as prosecutor, judge, jury, and executioner in its own administrative proceedings. Like prosecutors, FTC Commissioners vote to issue a complaint. Like judges and juries, FTC

ALJs adjudicate complaints in an adversarial proceeding between FTC prosecutors and the private party. Then, on the back end, FTC Commissioners act as the final judge of whether a party has violated any laws, decide what penalties to impose, and seek enforcement. That structure violates Plaintiffs' due process right to a fair tribunal. Compounding the due-process problems from that structural bias, the Commissioners have plainly prejudged the outcome here, calling PBMs "rotten" and "horrific" before the administrative hearing has even begun.

Only a preliminary injunction can avert the irreparable harm of forcing Plaintiffs to defend themselves in these unconstitutional proceedings. Plaintiffs face the irreparable loss of their constitutional right to a federal forum. That is textbook irreparable harm no matter the outcome in an alternative forum—let alone here, where the FTC virtually always wins in-house. *See In re Simons*, 247 U.S. 231, 239 (1918). And the Supreme Court recently held that being subjected to unconstitutional agency proceedings—including because agency officials are unconstitutionally insulated from removal—itself imposes a "here-and-now injury" that "cannot be undone" after proceedings conclude. *Axon*, 598 U.S. at 191 (citation omitted).

This Court should intervene now, before the Plaintiffs lose their rights to a neutral and constitutional process and to prevent the irreparable harm of being further subjected to an unlawful administrative proceeding. The public interest strongly favors holding the FTC to basic constitutional precepts. The FTC can still pursue its novel claims—it simply must do so in compliance with the Constitution's demands.

FACTUAL BACKGROUND

PBMs administer and manage prescription-drug benefits, working with their clients, who include employers, government entities, and other groups offering prescription-drug benefits through health plans they sponsor. FTC Compl. ¶¶ 3, 28. To do so, PBMs and their clients develop and maintain drug formularies, which are lists of prescription drugs that a given health plan covers.

Id. ¶¶ 28, 32-38, 50. Plan sponsors decide what formularies to adopt. *Id.* PBMs also negotiate discounts with drug manufacturers who independently set the "list price" for their drugs. *Id.* ¶ 40. Like a car's sticker price, a drug's list price does not reflect discounts or rebates. *Id.* ¶¶ 2, 6, 9, 40, 119, 135, 236-41.

One way that PBMs "extract price concessions" from drug manufacturers is by seeking conditional rebates (i.e., discounts) from a drug's list price that the manufacturer must pay after a health plan sponsor prefers the manufacturer's drug on the plan sponsor's formulary. *Id.* ¶¶ 38-39. Generally, "manufacturers are willing to pay higher rebates for more preferential treatment of their drugs on formularies" because preferential placement can boost the drug's sales volume and market share. *Id.* ¶ 44. "[C]ommercial rebate contract[s]" between PBMs and drug manufacturers memorialize those discounts. *Id.* ¶¶ 42, 54, 112, 116. Plan sponsors then decide whether to share those rebates directly with their members at the point of sale, or to put those rebates to other uses, such as reducing plan premiums, reducing out-of-pocket costs for members, or otherwise improving drug benefit plans. *Id.* ¶¶ 55, 66, 184, 196-97.

PBMs have used formulary placement to substantially lower the net costs of insulin drugs by driving competition among manufacturers of clinically equivalent drugs. *Id.* ¶¶ 44, 117. Previous FTC Commissioners have accordingly recognized that PBMs have the "ability to negotiate lower prices for prescription drugs." ECF No. 1 ¶ 71.

In spite of these past findings, the FTC is now pressing a novel legal theory to recast these rebates and Plaintiffs' formulary design decisions as anticompetitive and anti-consumer evils. On September 20, 2024, the FTC's three Democratic Commissioners voted to issue an administrative complaint naming as respondents the industry's three largest PBMs and related entities. The FTC's two Republican Commissioners were recused for undisclosed reasons.

The Complaint alleges that, in negotiating rebate contracts with prescription-drug manufacturers, Plaintiff PBMs engaged in "unfair methods of competition" and "unfair trade practices" that have caused those manufacturers to raise the price of insulin, thereby harming "competitive conditions" and consumers. FTC Compl. ¶¶ 3-5, 14, 259, 261, 264, 267, 273-74. The Complaint asserts there is vigorous competition among drug manufacturers and among PBMs. *See e.g.*, *id.* ¶¶ 38, 44, 215, 233. Yet the Complaint alleges that, by negotiating cost discounts with insulin manufacturers, PBMs allegedly prompted insulin manufacturers to raise their drugs' list price to "compensate" themselves "for the very high rebates" and to "preserve the manufacturers' own profits." *Id.* ¶¶ 6, 123, 261, 267, 274. The Complaint posits that increased list prices for insulin may prompt certain diabetic patients without insurance or with insurance plans that require copays to pay the higher list price for insulin at the pharmacy. *Id.* ¶¶ 60-61, 66-67, 264.

As relief, the FTC seeks extraordinarily broad remedies that would upend virtually every contract between PBMs and health plan sponsors, drug manufacturers, and other private market participants. Though the Complaint overwhelmingly focuses on insulin prices and formulary placements, the FTC's proposed remedies would encompass *all* drugs and would:

- Change which drugs PBMs place on their formularies by "prohibit[ing]" them "from excluding or disadvantaging low [list-price] versions of high [list-price] drugs made by the same manufacturers whenever the [PBM] covers the high [list-price] drug on a formulary." FTC Compl., Notice of Contemplated Relief, ¶ 1.
- Prohibit PBMs "from accepting compensation based on a drug's list price or a related benchmark." *Id.* ¶ 2.

- Prohibit PBMs "from designing—or assisting with designing—a benefit plan that bases patients' deductibles or coinsurance on the list price, rather than the net cost after rebates." *Id.* ¶ 3.

Put simply, this relief would force Plaintiffs to restructure their entire contracting framework with other private market participants.

In an unusual move, the FTC also has joined all three Plaintiff PBMs in the same proceeding, forcing a joint defense against sprawling allegations and limiting individual defenses—even though the Complaint lacks any allegations that the respondents are acting in concert. The Complaint refers to the "PBM Respondents" nearly 140 times, treating PBMs as interchangeable cogs. This unusual joinder threatens to force each PBM to have to defend against all admitted evidence, without isolating its own particular practices.

The FTC has also leveraged its internal rules to force Plaintiffs to identify witnesses and produce discovery at warp speed. Plaintiffs' answers to the Complaint were due on October 9, a mere fourteen days after service. *See* 16 C.F.R. § 3.12(a). On October 23, the ALJ entered a scheduling order that (among other things) requires Plaintiffs to disclose lay and expert witness lists in fewer than three months, with fact discovery set to close by June 6, 2025. The FTC's three non-recused Commissioners also ordered the hearing before the ALJ to commence fewer than ten months from now, on August 27, 2025. On November 14, the ALJ denied Plaintiffs' motions for separate hearings on each Plaintiffs' individual conduct.

LEGAL STANDARD

A party seeking a preliminary injunction "must establish: (1) it is likely to succeed on the merits; (2) it is likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in its favor; and (4) an injunction is in the public interest." *Dakotans for Health v. Noem*, 52 F.4th 381, 388 (8th Cir. 2022) (cleaned up). Those factors are readily satisfied here.

ARGUMENT

I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS

Plaintiffs are likely to succeed on the merits of their three structural constitutional challenges to the FTC's administrative proceeding. The FTC seeks to deprive Plaintiffs of federal court adjudication of their private rights; the FTC's Commissioners and ALJs are unlawfully restricted from removal by the President; and the FTC's adjudicatory process where it acts as prosecutor, judge, jury, and executioner violates Plaintiffs' due process rights.

A. The FTC Cannot Constitutionally Adjudicate Private Rights and Restructure Private Parties' Contracts Through an Agency Proceeding

The FTC seeks to proscribe transactions between private parties in the marketplace, force significant changes to a private industry, and overhaul contracts across that industry on the theory that existing contracts are unfair. But, as longstanding Supreme Court precedent holds, the FTC can only bring its unfair competition claims in federal courts. FTC's decision to force Plaintiffs to adjudicate these claims via in-house administrative proceedings is plainly unconstitutional.

Under Article III of the Constitution, the "judicial Power … extend[s] to all Cases, in Law and Equity, arising under th[e] Constitution, the Laws of the United States, …. [and] to Controversies to which the United States shall be a Party." U.S. Const. art. III, § 2. By definition, the "judicial Power ... can no more be shared with another branch" than legislative or executive powers can be shared with other branches. *Stern v. Marshall*, 564 U.S. 462, 483 (2011) (citation omitted).

Applying these principles, the Supreme Court has explained that only Article III courts can adjudicate cases involving a "private right." *Granfinanciera*, 492 U.S. at 56. As the Supreme Court recently held in the related Seventh Amendment context, suits involving "the stuff of the traditional actions at common law tried by the courts at Westminster in 1789" are the quintessential

private-right suits that Congress "may not … remove[] from Article III courts." *Jarkesy*, 144 S. Ct. at 2132 (citation omitted). Article III prohibits Congress from assigning "any matter which, from its nature, is the subject of a suit at the common law, or in equity, or admiralty" to administrative agencies. *Id.* at 2134 (quoting *Murray's Lessee v. Hoboken Land & Improvement Co.*, 59 U.S. 272, 284 (1855)).[2] Only cases involving "public rights" can be tried in administrative proceedings—and that narrow category encompasses only a limited "class of cases concerning ... matters [that] historically could have been determined exclusively by the executive and legislative branches, even when they were presented in such form that the judicial power was capable of acting on them." *Id.* at 2132 (cleaned up). "[E]ven with respect to matters that arguably" involve "public rights," however, "the presumption is in favor of Article III courts." *Id.* at 2134 (citation omitted).

Allowing the FTC to adjudicate its Complaint via an in-house administrative proceeding vitiates those constitutional guarantees for several reasons.

First, the FTC's suit "is in the nature of an action at common law," and thus "presumptively concerns private rights," making "adjudication by an Article III court … mandatory." *Id.* at 2132. For example, Article III courts must hear statutory fraudulent conveyance claims and antifraud claims under the federal securities laws, because those types of claims were adjudicated by common-law courts in 1789. *See id.* at 2134-36; *Granfinanciera*, 492 U.S. at 52-58.

Here, the FTC accuses PBMs of violating § 5 of the FTC Act by committing "unfair method[s] of competition" and "unfair act[s] or practice[s]" in contracting with other private parties. *E.g.*, FTC Compl. ¶¶ 261, 267, 274. The statutory causes of action the FTC invokes

[2] The Seventh Amendment specifically enshrines a right to a jury trial "[i]n Suits at common law." U.S. Const. amend. VII.

"close[ly] relat[e]" to historical common-law actions for unfair competition, fraud, and deceit. *See Jarkesy*, 144 S. Ct. at 2130. The common law long ago recognized a remedy for lack of fairness and honesty in the sale of goods between private parties. *E.g.*, 3 William Blackstone, Commentaries *164 ("If any one cheats me with false cars or dice, or by false weights and measures, or by selling me one commodity for another, an action on the case also lies against him for damages, upon the contract which the law always implies, that every transaction is fair and honest." (cleaned up)). And "unfair competition" was a "common law" remedy originally "relat[ing] to the palming off of one's goods as those of a rival trader," but "extended" to include "acts which lie outside the ordinary course of business and are tainted by fraud or coercion or conduct otherwise prohibited by law." *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 531-32 (1935).

Unfair competition claims thus retain their common-law origins even though federal law has expanded their scope. Congress intended the FTC and courts to draw from the "idea of unfair trade at common law" and apply the "same principles and tests that have been applied under the common law" to new situations. *Sears, Roebuck & Co. v. FTC*, 258 F. 307, 310-11 (7th Cir. 1919). The FTC has traditionally looked in part to the "common law" to determine if a practice is "unfair." *E.g.*, FTC, *Statement of Basis and Purpose of Trade Regulation Rule 408, Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking*, 29 Fed. Reg. 8325, 8355 (July 2, 1964). Because the cause of action the FTC invokes "close[ly] relate[s]" to a historical common-law action, the FTC's claims involve private rights and only federal courts—not agencies—can adjudicate them. *Jarkesy*, 144 S. Ct. at 2129-31.

Second, not only do unfair-competition claims involve private rights; their object—Plaintiffs' "contract rights"—involves "the very paradigm of private rights." *Career Colls. &*

Schs. of Tex. v. Dep't of Educ., 98 F.4th 220, 248 (5th Cir. 2024). The FTC seeks to impose sweeping cease and desist orders that would abrogate and force Plaintiffs to restructure hundreds, if not thousands, of contracts with private market participants and prohibit similar contracts in the future, change how Plaintiffs negotiate discounts off list prices with drug manufacturers, and limit benefit design options for plan sponsors and their members. FTC Compl., Notice of Contemplated Relief, ¶¶ 1-3; FTC Compl. ¶¶ 234-54. The "object of this [FTC] action is to regulate transactions between private individuals interacting in a pre-existing market." *See Jarkesy*, 144 S. Ct. at 2136. But, "[h]istorically, common-law courts possessed broad power to adjudicate suits involving the alleged violation of private rights," including "contract rights." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 344 (2016) (Thomas, J., concurring). Thus, "disposition of private rights to life, liberty, and property was understood to fall within the core of the judicial power." *Axon*, 598 U.S. at 197 (Thomas, J., concurring) (cleaned up). By contrast, non-Article III courts could only adjudicate "public rights," historically understood as "forms of adjudication that did not deprive any people of their private rights to life, liberty, or property." William Baude, *Adjudication Outside Article III*, 133 Harv. L. Rev. 1511, 1542 (2020).

Third, even in the Complaint's telling, the FTC seeks equitable remedies, which Article III requires federal courts, not agencies, to impose. Article III prohibits Congress from assigning "any matter which, from its nature, is the subject of a suit … in equity" in 1789 to administrative agencies. *Jarkesy*, 144 S. Ct. at 2134 (citation omitted). Yet here, the FTC seeks to impose in administrative proceedings a broad cease-and-desist order rescinding private parties' contracts and a prohibition on entering into similar contracts in the future. *See* FTC Compl., Notice of Contemplated Relief, ¶¶ 1-3. Cease-and-desist orders are "analogous to" "injunction[s]." *Regal Knitwear Co. v. NLRB*, 324 U.S. 9, 14 (1945). And an injunction is an "inherently … equitable

remedy." *Great-West Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 211 n.1 (2002). Remedies rescinding current contracts and enjoining the entering into of similar contracts on a going-forward basis have been adjudicated by courts of equity for centuries. *See Atl. Delaine Co. v. James*, 94 U.S. 207, 214 (1876); 1 Dan B. Dobbs, *Law of Remedies* § 2.6(3). These remedies alone render the FTC's in-house adjudication unconstitutional.

B. FTC Commissioners and ALJs Are Unconstitutionally Insulated from Removal

Article II of the Constitution vests "[t]he executive Power" exclusively in the President, U.S. Const. art. II, § 1, cl. 1, who must "take Care that the Laws be faithfully executed," *id.* § 3. By vesting all executive power in a single, elected official, the Constitution ensures that the people have the ultimate say in how the laws are executed. Yet the FTC's structure instead immunizes its Commissioners and ALJs from presidential oversight, even "as they exercise[] power in the people's name." *Free Enter. Fund*, 561 U.S. at 497.

Of course, the President requires the assistance of subordinate officers to carry out official duties. To ensure that "[t]he buck stops with the President," however, Article II enables "the President to keep [executive] officers accountable," including "by removing them from office." *Id.* at 483, 493. Restrictions on removal insulate subordinates from presidential "control" and "thus from that of the people." *Id.* at 499. Article II's "general rule," therefore, is that the President's "removal power" is "unrestricted." *Seila Law*, 591 U.S. at 215.

The FTC's structure for adjudicating complaints such as the one at issue here violates those constitutional commands with respect to both FTC Commissioners and FTC ALJs.

First, FTC Commissioners are unconstitutionally insulated from presidential removal. The five FTC Commissioners exercise substantial executive power. The FTC has broad authority to "investigate" people and corporations engaging in "commerce" for allegedly committing "unfair

or deceptive acts or practices" or engaging in "[u]nfair methods of competition." 15 U.S.C. §§ 45(a)(1), 46(a); *see Collins v. Yellen*, 594 U.S. 220, 230 (2021). FTC Commissioners "set enforcement priorities," "initiate prosecutions" and, once administrative proceedings are instituted, "oversee [those] adjudications." *Seila Law*, 591 U.S. at 225; 15 U.S.C. §§ 45(m), 53; 16 C.F.R. §§ 3.11, 3.52-3.54. FTC Commissioners also can issue final decisions in the administrative adjudications, order people and corporations to cease and desist from engaging in business activities the Commissioners believe to be unlawful, and "seek daunting monetary penalties against private parties on behalf of the United States in federal court." *See Seila Law*, 591 U.S. at 218-19; 15 U.S.C. § 45(b), (m); 16 C.F.R. § 3.54.

Yet the President can remove Commissioners only "for inefficiency, neglect of duty, or malfeasance in office," thwarting presidential supervision. 15 U.S.C. § 41. Such restrictions "make it impossible for the President … to take care that the laws be faithfully executed." *Seila Law*, 591 U.S. at 214 (quoting *Myers v. United States*, 272 U.S. 52, at 164 (1926)). Such restrictions risk saddling the President with subordinate officers whose policy disagreements or "lack of loyalty to the service" could thwart execution of the laws. *Myers*, 272 U.S. at 131. Restrictions on the President's ability to remove the heads of Executive Branch departments, like FTC Commissioners, are particularly pernicious because those restrictions prevent the President from effectively supervising how agency heads dictate how an entire agency and its personnel will exercise executive power. *See Seila Law*, 591 U.S. at 213-15; *Collins*, 594 U.S. at 251.

To be sure, the Supreme Court endorsed for-cause removal protection for the FTC's Commissioners in *Humphrey's Executor v. United States*, 295 U.S. 602 (1935). But that limited exception to the rule that agency heads must be accountable to the President turned on the FTC's structure "as it existed in 1935." *Seila Law*, 591 U.S. at 215. Back then, the Supreme Court viewed

the circa-1935 FTC "as exercising 'no part of the executive power'" and functioning as "'an administrative body' that performed 'specified duties as a legislative or judicial aid.'" *Id.* (quoting *Humphrey's Executor*, 295 U.S. at 628). The Supreme Court characterized the FTC circa 1935 as making only "'investigations and reports' to Congress" and "recommendations to courts as a master in chancery." *Id.* (quoting *Humphrey's Executor*, 295 U.S. at 628).

The FTC exercises vastly more executive power today. And the Supreme Court has emphasized that the "Court's conclusion that the FTC did not exercise executive power [in 1935] has not withstood the test of time." *Id.* at 216 n.2. The Court has recognized "it is hard to dispute that the powers of the FTC at the time of *Humphrey's Executor* would at the present time be considered executive, at least to some degree." *Morrison v. Olson*, 487 U.S. 654, 689 n.28 (1988). And the Court has identified *Humphrey's Executor* as "'the outermost constitutional limit[]'" and cautioned against extending for-cause removal restrictions beyond the FTC "as it existed in 1935." *Seila Law*, 591 U.S. at 215, 218 & n.4 (cleaned up). Under current precedent, the FTC's Commissioners must be fully accountable to presidential supervision and removable at will.[3]

Second, the FTC's ALJs are unconstitutionally insulated from presidential supervision, including removal. The Fifth Circuit has ruled that materially similar removal protections for ALJs within the Securities and Exchange Commission unduly trammel on presidential authority and thus violate Article II. *Jarkesy*, 34 F.4th at 463-65.

As discussed, Article II requires that the President have the ability to remove subordinate officers who exercise part of the executive power. *Supra* pp. 13-14. The Supreme Court has countenanced removal restrictions on inferior officers only for those with "limited duties and no

[3] To the extent the Court concludes that *Humphrey's Executor* is controlling, Plaintiffs preserve the argument that the Supreme Court should overrule *Humphrey's Executor*.

policymaking or administrative authority." *Seila Law*, 591 U.S. at 218. But the Court has rejected inferior-officer removal protections that exceed those bounds. Most relevant here, the Court has held that two layers of for-cause removal protection unconstitutionally "strip[]" the President of the "ability to execute the laws … by holding his subordinates accountable for their conduct." *Free Enter. Fund*, 561 U.S. at 496. The President cannot be "restricted in his ability to remove a principal officer, who is in turn restricted in his ability to remove an inferior officer." *Id.* at 484.

Under those principles, the three layers of removal protections insulating the FTC's ALJs are plainly unconstitutional. The FTC's ALJs are inferior officers who exercise significant executive authority over FTC administrative proceedings. *See Lucia v. SEC*, 585 U.S. 237, 248-49 (2018). The FTC's ALJs "operate 'much like a regular trial judge.'" Statement of Comm'r Andrew N. Ferguson, Dissenting in Part and Concurring in the Denial of Mot. to Recuse Administrative Law Judge at 2 ("Ferguson Statement"), *In re H&R Block, Inc.*, Dkt. No. 9427 (F.T.C. Oct. 18, 2024) (quoting *Axon*, 598 U.S. at 181), https://www.ftc.gov/system/files/ftc_gov/pdf/hrblock-ferguson-statement-dissenting-in-part-and-concurring-in-denial-of-motion.pdf. The FTC's ALJs "are officials to whom the Commission … delegates the initial performance of statutory fact-finding functions and initial rulings on conclusions of law." 16 C.F.R. § 0.14. They conduct hearings, control discovery, issue subpoenas, make decisions on the admissibility of evidence, and issue orders to keep proceedings moving. *Id.* §§ 3.42(c), 3.43. At the end of administrative proceedings, the ALJ must file "[a] recommended decision" that is "based on a consideration of the whole record relevant to the issues decided" and "include[s] a statement of recommended findings of fact … and recommended conclusions of law," as well as a "proposed rule or order." *Id.* § 3.51(a), (c)(1). The Commission then reviews the ALJ's decision and may "adopt, modify or set aside the recommended findings, recommended conclusions, and proposed

rule or order." *Id.* §§ 3.53, 3.54(a). Just as an "SEC ALJ exercises authority 'comparable to' that of a federal district judge conducting a bench trial," *Lucia*, 585 U.S. at 242 (citation omitted), so too does an FTC ALJ.

Yet the FTC ALJ in this proceeding—like all FTC ALJs—enjoys *three* layers of for-cause removal protection, making him unconstitutionally unaccountable to the President. The FTC can only remove an ALJ "for good cause established and determined by the Merits Systems Protection Board," and only "on the record after opportunity for [a] hearing" before that Board. 5 U.S.C. § 7521(a), (b)(1). And the FTC Commissioners who can initiate removal proceedings for ALJs are themselves removable by the President only for cause. 15 U.S.C. § 41; *supra* pp. 14-15. The President also cannot remove members of the Merit Systems Protection Board, who ultimately adjudicate removal of the ALJs, except for cause. 5 U.S.C. § 1202(d) ("Any member may be removed by the President only for inefficiency, neglect of duty, or malfeasance in office.").

These overlapping layers of statutory insulation contravene Article II. They prevent the President from removing ALJs "even if the President determines that [they are] neglecting [their] duties or discharging them improperly." *See Free Enter. Fund*, 561 U.S. at 484. Those judgments are instead "committed to []other officer[s], who may or may not agree with the President's determination, and whom the President cannot remove simply because th[ose] officer[s] disagree[] with" the President. *Id.*

The FTC has defended insulating its ALJs from removal by asserting that they "perform solely adjudicative functions … and possess purely recommendatory powers." Order Denying Respondents' Mot. to Disqualify the Administrative Law Judge at 4, *In re H&R Block, Inc.*, Dkt. No. 9427 (F.T.C. Oct. 18, 2024). The FTC has also recently required ALJs to produce only "recommended" and not "initial" decisions, and ALJs' decisions no longer become final "unless

and until the Commission approves them." *Id.*; *see* FTC, Rules of Practice, 88 Fed. Reg. 42,872, 42,873-74, 42,876-77 (July 5, 2023). Based on these features, some courts have concluded that FTC ALJs' removal restrictions are likely constitutional because their "duties and powers are quite limited." *H&R Block Inc. v. Himes*, 2024 WL 3742310, at *5 (W.D. Mo. Aug. 1, 2024), *appeal pending*, No. 24-2626 (8th Cir.).[4]

But FTC ALJs still "exercise considerable power" that is the hallmark of federal officers, not mere employees. *Jarkesy*, 34 F.4th at 464. FTC ALJs control discovery, decide on the admissibility of evidence, and issue recommended findings of fact and conclusions of law. *See* 16 C.F.R. §§ 0.14, 3.42(c), 3.43, 3.51(a), (c)(1); *supra* pp. 15-17. And the FTC's recent decision to call its ALJs' decisions "recommended" rather than "initial" decisions is not "constitutionally dispositive," since that terminological change "does not change the power of the ALJ in the hearing room." Ferguson Statement at 12-13, *In re H&R Block, Inc.*, Dkt. No. 9427. Because FTC ALJs undeniably exercise "administrative authority" given their expansive roles and responsibilities, the narrow exception to presidential removal for inferior Officers with "limited duties and no policymaking or administrative authority" is inapplicable here. *Seila Law*, 591 U.S. at 218.

Finally, an injunction of FTC's proceedings is proper because the removal protections at issue are non-severable from the adjudicatory powers Congress granted. Congress vested the Commissioners and ALJs with "adjudicatory" power only because they were cloaked with removal protection. *See Ramspeck v. Fed. Trial Examiners Conf.*, 345 U.S. 128, 130-32 (1953); *Humphrey's Executor*, 295 U.S. at 629. Courts cannot sever an unconstitutional provision where the remainder of the statute would not function as Congress intended. *See Alaska Airlines, Inc. v.*

[4] In a brief order, the Eighth Circuit denied a motion for an injunction pending appeal. *See* Order, No. 24-2626 (8th Cir. Sept. 13, 2024). The appeal has since been held in abeyance because of settlement discussions. *See* Order, *id.* (8th Cir. Oct. 28, 2024).

Brock, 480 U.S. 678, 685 (1987). By contrast, an injunction ensures the "unconstitutional actions are stopped for [Plaintiffs], and Congress is left with the ability to remedy the problem as it pleases." *Walmart Inc. v. King*, 2024 WL 1258223, at *4 (S.D. Ga. Mar. 25, 2024) (permanently enjoining DOJ ALJ proceedings and finding that "severability [was] not the proper solution"). Accordingly, Plaintiffs are likely to prevail on their claim that the proper remedy for the constitutional violation is to enjoin the proceeding against Plaintiffs.

C. FTC Adjudications Violate Due Process by Empowering the Agency to Act as Prosecutor, Judge, Jury, and Executioner

"[A] fair trial in a fair tribunal is a basic requirement of due process." *Caperton v. A.T. Massey Coal Co.*, 556 U.S. 868, 876 (2009) (citation omitted). "No man is allowed to be a judge in his own cause." Federalist No. 10. Thus, "when the same person serves as both accuser and adjudicator in a case," an "unconstitutional potential for bias exists." *Williams v. Pennsylvania*, 579 U.S. 1, 8 (2016). That constitutional problem describes the FTC's in-house adjudicatory system to a T: it "combine[s] the functions of investigator, prosecutor, and judge under one roof." *Axon*, 598 U.S. at 215 (Gorsuch, J., concurring in judgment).

The FTC Commissioners decide the cases in which the FTC brings a complaint, which factual allegations to make against each respondent, and which legal claims to assert. 16 C.F.R. § 3.11(a). FTC staff then try the case in front of an FTC ALJ in a proceeding governed by "relaxed rules of procedure and evidence—rules [the FTC] make[s] for [itself]." *Axon*, 598 U.S. at 215 (Gorsuch, J., concurring in judgment); *see* 16 C.F.R. §§ 3.1, 3.43, 3.51. The Federal Rules of Civil Procedure and Federal Rules of Evidence, which govern proceedings in federal courts, do not apply in FTC proceedings. And even if the FTC staff loses before an ALJ, in spite of all of their procedural advantages, the FTC Commissioners then review the ALJ's decision de novo—including the ALJ's factual findings and credibility determinations. 16 C.F.R. § 3.54. This is true

even though the Commission reviews a wholly "cold" record and does not observe witnesses' testimony. Unsurprisingly, the "odds [are] stacked against" anyone against whom the FTC brings administrative proceedings. *Jarkesy*, 144 S. Ct. at 2141 (Gorsuch, J., concurring).

For the past quarter century, the FTC has found liability in *every case* where it has ruled on the merits.[5] By contrast, the FTC in federal court has experienced significant losses. For example, in antitrust cases during the first two years of Chair Khan's tenure, "the FTC [] lost every single merger challenge it [] brought through litigation" in federal court.[6]

That unfairness is compounded by limited judicial review of the Commission's findings on the back end. Federal courts must treat FTC factual findings as "conclusive" "if supported by evidence," a highly deferential standard of review. 15 U.S.C. § 45(c). "The reviewing court also cannot take its own evidence—it can only remand the case to the agency for further proceedings." *Axon*, 598 U.S. at 197 (Thomas, J., concurring) (citing 15 U.S.C. § 45(c)). Thus, even in reviewing the FTC's decision-making, courts are required to "put a thumb (or perhaps two forearms) on the agency's side of the scale." *Id.* at 203 (citation omitted). Far from satisfying the baseline principle that "justice must satisfy the appearance of justice," *Antoniu v. SEC*, 877 F.2d 721, 724 (8th Cir. 1989) (citation omitted), the FTC is rife with unconstitutional structural bias.

Those due-process concerns are exacerbated here because the three Commissioners adjudicating the action have publicly prejudged the specific issues at stake. In particular:

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[5] *See Axon*, 986 F.3d at 1187; *accord* David Balto, *Can the FTC be a Fair Umpire?*, The Hill (Aug. 14, 2013), https://bit.ly/3UtLIcY; A. Douglas Melamed, Comments to FTC Workshop Concerning Section 5 of the FTC Act (Oct. 14, 2008), https://bit.ly/4fgunfS; ECF No. 1, Ex. 1.

[6] Jeffrey A. Sonnenfeld & Steven Tian, *The FTC's Antitrust Overreach is Hurting U.S. Competitiveness and Destroying Value*, Yale Insights (Dec. 13, 2023), https://bit.ly/4exXrhS; *see also* Cecilia Kang, *F.T.C.'s Court Loss Raises Fresh Questions About Its Chair's Strategy*, N.Y. Times (July 11, 2023), https://bit.ly/3Cx2rWV; Diane Bartz, *U.S. Keeps Losing Antitrust Court Battles but Few Expect Pullback*, Reuters (Oct. 4, 2022), https://bit.ly/4fQ13wC.

- Chair Khan has claimed that drugs available at pharmacies "are not the most affordable medicines," but instead are "the medicines on which the [PBMs] are getting the biggest kickback from the drug manufacturer."[7] She has asserted that "rebates that [PBMs] demand may function as kickbacks that raise costs and limit access to affordable medicines."[8] And she has asserted that PBMs "and other middlemen may exclude the lowest-cost generic and biosimilar drugs from patients' formularies entirely to maximize rebates and fees."[9]
- Commissioner Rebecca Slaughter has asserted that PBMs' rebates fuel higher drug prices, claiming that "list prices and patients' out-of-pocket costs for prescription drugs have increased as [PBMs'] rebates and fees have mushroomed"[10] and that PBMs' "rebating practices" are an "anticompetitive exploitation of market power."[11]
- Commissioner Alvaro Bedoya has placed "a significant part of the blame" for insulin price increases "on rebates demanded by pharmacy benefit managers" and has disparaged PBMs

[7] Sen. Bernie Sanders, LIVE with FTC Chair Lina Khan, at 9:59-10:17, YouTube (Apr. 15, 2024), https://www.youtube.com/watch?v=-C99FUnGnJU.

[8] Lina Khan, Remarks to 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.

[9] Lina Khan, Remarks Regarding Policy Statement on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products, at 2 (June 16, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Remarks-Chair-Lina-Khan-Regarding-Policy-Statement-Rebates-Fees.pdf.

[10] Rebecca Slaughter, Statement Regarding the Commission Statement on Reliance on Prior PBM-Related Advocacy Statements and Reports, at 2 (July 20, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/finalbksremarksonftcstatementagainstrelianceonpriorpbmadvocacy7202023.pdf.

[11] Rebecca Slaughter, Statement Regarding the Federal Trade Commission's Report to Congress on Rebate Walls, at 1 (May 28, 2021), https://www.ftc.gov/system/files/documents/public_statements/1590532/statement_of_acting_chairwoman_slaughter_regarding_the_ftc_rebate_wall_report_to_congress.pdf.

as "middlemen who control our access to insulin" who supposedly "make billions off it" by controlling formulary placements.[12]

Due process requires adjudicators to "hold the balance [between the parties] nice, clear and true," and such "prejudg[ment]" offends Plaintiffs' due process rights. *See Yamaha Motor Corp., U.S.A. v. Riney*, 21 F.3d 793, 798 (8th Cir. 1994) (citation omitted). Given their public statements and well-known positions, it would be "difficult, if not impossible," for the Commissioners now to "reach a different conclusion" in this adjudication. *Cinderella Career & Finishing Schs., Inc. v. FTC*, 425 F.2d 583, 590 (D.C. Cir. 1970).[13] Plaintiffs can hardly expect a fair trial in the FTC's dice-loading administrative proceedings when the Commissioners who initiated the Complaint have already pre-judged the very facts and key issues at issue in the ensuing adjudication. *Supra* pp. 20-22.

II. EQUITABLE FACTORS FAVOR A PRELIMINARY INJUNCTION

As to the remaining equitable criteria, Plaintiffs will suffer obvious irreparable harm absent a preliminary injunction. Both the balance of equities and public interest favor an injunction. *See Wilbur-Ellis Co., LLC v. Erikson*, 103 F.4th 1352, 1355 (8th Cir. 2024).

A. Plaintiffs Will Be Irreparably Harmed by an Unconstitutional Proceeding Absent a Preliminary Injunction

Without preliminary relief, Plaintiffs will suffer myriad irreparable harms. To start, they will continue to be subjected to an unconstitutional proceeding administered by an unconstitutionally-structured administrative agency. "In most instances, constitutional violations

[12] Alvaro Bedoya, Statement Regarding Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products, at 1 (June 16, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/P214501BedoyaStatementRebatePolicy.pdf.

[13] Each Plaintiff filed a motion to recuse Chair Khan and Commissioners Slaughter and Bedoya on October 8, 2024, on similar grounds. Those motions remain pending.

constitute irreparable harm." *Morehouse Enters., LLC v. ATF*, 78 F.4th 1011, 1017 (8th Cir. 2023); *see also* 11A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure § 2948.1 (3d ed. updated June 2024) (similar). Plaintiffs are incurring these injuries now, and they will be "unable to recover any damages" for these constitutional violations in light of the Commission's "sovereign immunity in federal court in suits requesting money damages." *Baker Elec. Co-op., Inc. v. Chaske*, 28 F.3d 1466, 1473 (8th Cir. 1994).

As the Supreme Court has long recognized, an order denying plaintiffs their right to a particular method of adjudication—such as federal court—"should be dealt with now, before the plaintiff is put to the difficulties … that would be raised" by the improper denial of that right. *Simons*, 247 U.S. at 239; *accord Burgess v. FDIC*, 639 F. Supp. 3d 732, 749 (N.D. Tex. 2022). And requiring Plaintiffs to undergo unlawful proceedings that the Constitution requires adjudicating in federal courts inflicts a clear "here-and-now injury" that "cannot be undone." *Axon*, 598 U.S. at 191. Parties thus routinely challenge the deprivation of the right to proceed in federal court before an agency adjudication runs its course to avoid being deprived of that right without effective recourse at the end of an unlawful proceeding. *E.g., Tull v. United States*, 481 U.S. 412, 417 (1987); *Jarkesy*, 34 F.4th at 450.

Moreover, Plaintiffs also bring claims that the FTC's Commissioners and ALJs are insufficiently accountable to the President, and that the combination of prosecutorial and adjudicatory functions in the FTC violates due process. As the Supreme Court recognized in *Axon*, "subjection to an illegitimate proceeding, led by an illegitimate decisionmaker" itself constitutes a "here-and-now injury" that is irreparable. *Axon*, 598 U.S. at 191.[14] The same is true, moreover,

[14] *Accord ABM Indus. Grps., LLC v. U.S. Dep't. of Lab.*, 2024 WL 4642962, at *6 (S.D. Tex. Oct. 30, 2024) (holding, under *Axon*, that risk of irreparable injury was established based on claim that

when a party "attacks the combination of prosecutorial and adjudicatory functions in a single agency." *Id.* at 180. In sum, under *Axon*'s "explicit language, the nature of the constitutional claims asserted here … suffice to show irreparable harm." *Scottsdale Cap. Advisors Corp. v. FINRA*, 678 F. Supp. 3d 88, 110 (D.D.C. 2023).

B. The Remaining Equitable Factors Favor an Injunction

Finally, both the balance of equities and public interest favor an injunction. These two factors "merge when the Government is the party opposing the preliminary injunction." *Morehouse Enters.*, 78 F.4th at 1018. This Court must weigh the benefits of an injunction to Plaintiffs against any alleged harms to the government and the public if the proceeding is enjoined. *See id.* Here, the FTC will suffer no cognizable harm from an injunction halting "unlawful agency action." *League of Women Voters of the U.S. v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016). "To the contrary, there is a substantial public interest in having governmental agencies abide by the federal laws that govern their existence and operations." *Id.* (citation omitted); *see also, e.g.*, *Sierra Club v. U.S. Army Corps of Eng'rs*, 645 F.3d 978, 997 (8th Cir. 2011) (affirming as "sound" district court's reasoning that "an injunction was in the public interest because it would convey to the public the importance of having its government agencies fulfill 'their obligations and comply with the laws that bind them'"); *State v. Biden*, 10 F.4th 538, 560 (5th Cir. 2021) (same principle). And "it is always in the public interest to protect constitutional rights." *Carson v. Simon*, 978 F.3d 1051, 1061 (8th Cir. 2020) (citation omitted).

ALJs are unconstitutionally insulated from presidential removal); *Seton v. NLRB*, 2024 WL 4678057, at *2 (W.D. Tex. Oct. 18, 2024) (same); *Bertha v. NLRB*, 2024 WL 4202383, at *4 (N.D. Tex. Sept. 16, 2024) (same); *Energy Transfer, LP v. NLRB*, 2024 WL 3571494 (S.D. Tex. July 29, 2024) (same); *Space Expl. Techs. Corp. v. NLRB*, 2024 WL 3512082 (W.D. Tex. July 23, 2024) (same).

Absent an injunction, Plaintiffs will be forced to expend significant resources during the discovery phase, which is moving rapidly and set to close by June 6, 2025. *See* Scheduling Order at 2, *In re Caremark Rx, L.L.C. et al.*, Dkt. No. 9437 (F.T.C. Oct. 23, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/612031.2024.10.23_scheduling_order.pdf. The FTC, on the other hand, will suffer no prejudice if this Court temporarily pauses the FTC's proceeding while it considers the merits of Plaintiffs' constitutional claims. If this Court ultimately rules for Plaintiffs, the FTC will not have expended significant public resources on an unconstitutional proceeding. If this Court ultimately rules for the FTC, the FTC will be able to resume the proceeding at that time. Any inconvenience to the FTC does not outweigh Plaintiffs' irreparable "here-and-now injury" of being "subject[ed] to an illegitimate proceeding[] led by an illegitimate decisionmaker." *Axon*, 598 U.S. at 191.

* * *

The FTC cannot push its agenda through a sweeping and novel complaint against an industry that its non-recused Commissioners routinely disparage in an action adjudicated by the FTC itself. And it cannot simply refuse to go to federal court to avoid federal procedural protections and a neutral federal adjudicator. This Court should not allow the FTC to preserve its house-always-wins advantage within an unconstitutional adjudicatory structure while the Plaintiffs suffer the irreparable consequences.

CONCLUSION

For the foregoing reasons, this Court should grant Plaintiffs' motion for a preliminary injunction staying the FTC proceeding pending resolution of Plaintiffs' constitutional challenges.

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Respectfully Submitted,

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