UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

COMMISSIONERS: Lina M. Khan, Chair

Rebecca Kelly Slaughter

Alvaro M. Bedoya Melissa Holyoak Andrew Ferguson

IN THE MATTER OF INSULIN: CAREMARK RX, ET AL.

ORAL ARGUMENT REQUESTED Docket No. 9437

RESPONDENTS CAREMARK RX, LLC AND ZINC HEALTH SERVICES, LLC'S MOTION FOR DISQUALIFICATION

Chair Khan, Commissioner Slaughter, and Commissioner Bedoya ("the Three Commissioners") all have demonstrated through extensive public comments that they have prejudged this matter and their participation in this proceeding violates the due process rights of Respondents Caremark Rx, L.L.C. ("Caremark") and Zinc Health Services, LLC ("Zinc"). "An administrative hearing . . . must be attended . . . with the [] appearance of complete fairness. Only thus can the tribunal conducting a quasi-adjudicatory proceeding meet the basic requirement of due process." *Texaco, Inc. v. Fed. Trade Comm'n*, 336 F.2d 754, 760 (D.C. Cir. 1964), *vacated and remanded on other grounds*, 381 U.S. 739 (1965). If the opposite of "complete fairness" is "blatant bias," the Three Commissioners would easily satisfy even that standard.

The Three Commissioners have made repeated incorrect prejudgments about Caremark and Zinc and their conduct, including the mistaken assertion, critical to the merits of this case, that "dominant" pharmacy benefit managers ("PBMs") "control" drug pricing and patient access to

drugs, including insulin. The Three Commissioners have maligned PBMs as "price gouge[rs]" who create "disturbing[]," "unacceptable," and "rotten" market "distortions," the effects of which can be "horrific" and "frankly, keep [them] up at night." During the investigation, they even attended closed events to help fundraise for an anti-PBM lobbying group where organizers vilified PBMs as "bloodsuckers" and vampires. Any "disinterested observer [would] conclude that [the Three Commissioners] ha[ve] in some measure" prejudged this case. *Cinderella Career & Finishing Sch., Inc. v. Fed. Trade Comm'n*, 425 F.2d 583, 591 (D.C. Cir. 1970) (internal quotation marks omitted).

Caremark and Zinc would prove before any objective tribunal that the Three Commissioners' prior statements about PBMs are false. But the Three Commissioners are no objective tribunal. Due process requires their disqualification. Commission Rule 4.17, 16 C.F.R. § 4.17 requires that each of the Three Commissioners address this motion in the first instance and

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¹ Lina Khan, Chair, Fed. Trade Comm'n, Remarks at the White House Roundtable on PBMs, at 1 (Mar. 4, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/2024.03.04-chair-khan-remarks-at-the-white-house-roundtable-on-pbms.pdf.

² Rebecca Slaughter, Comm'r, Fed. Trade Comm'n, Statement Regarding the Use of Compulsory Process and Issuance of 6(b) Orders to Study Contracting Practices of Pharmacy Benefit Managers, at 1 (June 7, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/P221200PBMSlaughterStatement.pdf.

³ The Capitol Forum, Fireside Chat with Commissioner Alvaro Bedoya (June 15, 2023), https://thecapitolforum.com/resources/transcript-of-interview-with-ftc-commissioner-alvaro-bedoya/.

⁴ See Ex. 1, 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-overalleged-bias-against-pharmacy-benefit-managers/("During the conference, Khan appeared alongside NCPA executives who wore shirts depicting PBMs as vampires and labeling them as 'bloodsuckers' as the chairwoman spoke about her work."); Lina Khan, X (Oct. 3, 2022), https://x.com/linakhanFTC/status/1577004971664384000; NCPAVids, 2022 NCPA Annual Convention with Federal Trade Commission Chair Lina Khan, YouTube (Jan. 17, 2023) https://www.youtube.com/watch?v=GuAKnpI_X78.

disqualify themselves. If they fail to do so, Rule 4.17 requires that the full Commission act and disqualify each of the Three Commissioners.⁵

BACKGROUND

The Three Commissioners have a lengthy track record of making public statements that indicate serious bias against Caremark, Zinc, and other PBMs. These statements demonstrate that the Three Commissioners have prejudged the Respondent PBMs' liability in this matter.

Chair Khan has vilified PBMs for the entirety of her professional career,⁶ calling PBMs "powerful intermediaries at the center of the U.S. prescription drug system . . . [that] practically determine which medicines are prescribed, which pharmacies patients can use, and the amount patients will pay at the pharmacy counter." And she has consistently blamed PBMs for issues across the healthcare system, asserting that "Pharmacy Benefit Managers . . . control[] the types of practices that independent pharmacies are facing [and] the medicines consumers are or are not been able to access." Similarly, Commissioner Slaughter has called PBMs' rebating practices "disturbing[]," "unacceptable," and "rotten," and has accused PBMs of creating "competitive

⁵ To the extent the word limit of § 3.22(c) applies to motions under § 4.17, Caremark and Zinc request leave to exceed the 2,500-word limit to allow this motion addressing Three Commissioners, rather than three separate, shorter motions.

⁶ As a law student, Chair Khan published an article claiming that vertical integration of PBMs creates a "conflict of interest" that "keep[s] drug prices high" and (incorrectly) suggested that "PBMs joined to pharmacies tend to steer plan members away from independent entities." Lina Khan, How to Reboot the FTC, Politico (Apr. 13, 2016), https://www.politico.com/agenda/story/2016/04/ftc-antitrust-economy-monopolies-000090/.

⁷ Lina Khan, Chair, Fed. Trade Comm'n, Statement Regarding 6(b) Study of Pharmacy Benefit Managers, No. P221200, at 1 (June 8, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Statement-Khan-6b-Study-Pharmacy-Benefit-Managers.pdf.

⁸ Economic Liberties, 2023 Anti-Monopoly Summit, at 1:22:41, YouTube (May 4, 2023), https://www.youtube.com/watch?v=_MUdBWApI9k&t=3928s.

distortions in pharmaceutical markets." For his part, Commissioner Bedoya has declared that the effect of PBMs' rebates can be "horrific, and frankly, keep [him] up at night." ¹⁰

The Three Commissioners often make such disparaging statements at one-sided events hosted by anti-PBM special interest groups. For example, the Three Commissioners have frequently spoken at events hosted by the National Community Pharmacists Association ("NCPA"), a self-described anti-PBM lobbying organization funded by PBM counterparties that stand to profit at the expense of employers and patients from policies that impair PBMs, such as the instant attempted regulatory change masquerading as litigation. For instance, in June 2022—after the FTC commenced its "inquiry" into PBMs¹¹ and the insulin investigation—Chair Khan spoke at an event cohosted by NCPA lobbyists at which she asserted that PBMs' "decisions help to determine which medicines are prescribed, which pharmacies patients can use, and the prices that patients ultimately pay at the pharmacy counter." And in October 2022, Chair Khan headlined the NCPA's annual convention and commended the NCPA's work opposing PBMs.¹³

⁹ Slaughter, Statement Regarding the Use of Compulsory Process, *supra* note 2, at 1.

¹⁰ The Capitol Forum, Fireside Chat with Commissioner Alvaro Bedoya, *supra* note 3.

¹¹ See FTC Order to File Special Report, No. P221200 (June 6, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/P221200PBMModelOrder.pdf; see also FTC Launches Inquiry Into Prescription Drug Middlemen Industry, Fed. Trade Comm'n (June 7, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry.

¹² Lina Khan, Chair, Fed. Trade Comm'n, Remarks at American Economic Liberties Project and the National Community Pharmacists Association: How Pharmacy Benefit Managers Impact Drug Prices, Communities, and Patients, at 1 (June 22, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Remarks-Lina-Khan-Economic-Liberties-National-Community-Pharmacists-Association.pdf.

¹³ See supra note 4.

Event participants wore anti-PBM paraphernalia, including pins that vilified PBMs as "bloodsuckers" and shirts depicting PBMs as vampires. 14

But the Three Commissioners' conduct goes beyond a general hostility to PBMs; the Three Commissioners have prejudged the *specific issues* raised in this action by making repeated, incorrect assertions throughout the course of the insulin investigation.

Count I. Under Count I, the FTC alleges that the Respondent PBMs have committed unfair trade practices by promoting "high list price insulin products, with high rebates and fees." Compl. ¶ 257.

Chair Khan has made her bias on this issue clear. She has publicly asserted that the drugs available at pharmacies "are not the most affordable medicines for Americans," but instead are "the medicines on which the PBMs are getting the biggest kickback from the drug manufacturer." She has declared that PBMs "may be diverting patients to higher cost medicines and branded drugs as opposed to generics and biosimilars." She has further stated that PBMs have "incentives to drive patients to more expensive drugs that come with rebates instead of the most affordable drugs

¹⁴ See Ex. 1, Mondeaux, FTC Chairwoman Lina Khan Faces Ethics Complaint, *supra* note 4. The NCPA has castigated PBMs in similarly derisive ways for years, including depicting PBMs as wolves. *See* Independent Pharmacies: Myths Versus Reality, at 8–9, CVS Health (Aug. 10, 2024), https://www.cvshealth.com/content/dam/enterprise/cvs-enterprise/pdfs/2024/drug-costs/2024-08-10-FTC-White-Paper-on-Independent-Pharmacies.pdf.

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

¹⁶ Institute for Local Self-Reliance, Small Business vs. Monopoly Power, at 35:29, YouTube (Mar. 4, 2024), https://www.youtube.com/watch?v=UOMomXHQIYA.

PUBLIC

available."¹⁷ And she has asserted that "rebates that PBMs demand may function as kickbacks that raise costs and limit access to affordable medicines."¹⁸

Similarly, more than a year before the FTC began its investigation into PBMs, Commissioner Slaughter stated that "[f]airness in drug pricing is undermined by a complex system of rebates" and that "[t]his is not the way competition is supposed to work." Like Chair Khan, Commissioner Slaughter continued to make such statements after the FTC's investigation began, further asserting her belief that PBM rebates are connected to higher drug prices by claiming that "visibility into PBM contracting practices have decreased; and list prices and patients' out-of-pocket costs for prescription drugs have increased as PBM rebates and fees have mushroomed."²⁰

And Commissioner Bedoya has suggested "a significant part of the blame" for insulin price increases rest "on rebates demanded by pharmacy benefit managers, the middlemen between drug manufacturers, insurers, and your pharmacy."²¹ Moreover, he has asserted that it is "pretty clear"

¹⁷ Lina Khan, Chair, Fed. Trade Comm'n, Remarks Regarding the 6(b) Study on Pharmacy Benefit Managers, at 3 (Feb. 17, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/p221200khanstatementrepbms.pdf.

¹⁸ Lina Khan, Chair, Fed. Trade Comm'n, 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.

¹⁹ Rebecca Slaughter, Acting Chair, Fed. Trade Comm'n, 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.

Rebecca Slaughter, Comm'r, Fed. Trade Comm'n, 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/finalbksremarksonftcstatementagainstrelianceonpriorpbma dvocacy7202023.pdf.

²¹ Alvaro Bedoya, Comm'r, Fed. Trade Comm'n, 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.

that rebates "drive up the list price."²² These incorrect assertions, among others, are the exact sorts of factual disputes at issue in Count I of the FTC's complaint.

Count II. The Three Commissioners' public statements also demonstrate that they have prejudged Count II, which alleges that the Respondent PBMs have illegally excluded "low WAC insulin products from their most-utilized commercial formularies and custom client formularies." Compl. ¶ 263. Chair Khan 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" and that "[s]uch practices violate the fundamental bargain at the center of the American prescription drug system." Commissioner Slaughter has asserted: "[C]onsumers with insurance have been forced to pay for branded insulin drugs because lower cost alternatives are not covered under insurance formularies dictated by PBMs. The grave consequences of these apparent distortions in insulin markets subject patients to insulin rationing and can lead to permanent, even fatal consequences." And Commissioner Bedoya has disparaged PBMs as "the middlemen who control our access to insulin" and "make billions off it" through control of placements on formularies. These statements make clear that the Three Commissioners who must decide

The Capitol Forum, Fireside Chat with Commissioner Alvaro Bedoya, at 4:28 (Oct. 26, 2023) https://library.thecapitolforum.com/docs/768k6m9a1tv1.

²³ Lina Khan, Chair, Fed. Trade Comm'n, 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.

²⁴ *Id*.

²⁵ Slaughter, Statement Regarding the Use of Compulsory Process, *supra* note 2, at 1 (internal footnote omitted).

²⁶ Bedoya, Statement Regarding Policy Statement of the Federal Trade Commission on Rebates and Fees, *supra* note 21, at 1; *see also* Alvaro Bedoya, Comm'r, Fed. Trade Comm'n, Statement Regarding 6(b) Orders to Study Contracting Practices of Pharmacy Benefit Managers, at 1 (June 7, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Bedoya_Statement_re_PBM_Study_%28FINAL%29_6-7-2022.pdf ("[N]early everyone is affected by PBM business practices. For most Americans, pharmacy middlemen control what medicine you get, how you get it, when you get it, and how much you pay for it.").

whether Caremark's and Zinc's "formulary exclusion practices" are "unfair" have already made that determination. Compl. ¶ 265.

Count III. The Three Commissioners have similarly prejudged liability as to Count III, which alleges that the Respondent PBMs' rebating practices exploit consumers by "shift[ing] the cost of high insulin prices of drugs onto certain insulin patients." Compl. ¶ 269. Chair Khan has claimed that "PBMs practically determine . . . the amount patients will pay at the pharmacy counter," that PBMs "engage in tactics that hike the price of drugs, deprive patients of access to certain medicines," and that Americans are "[t]oo often . . . price gouged for [life-saving] medications." Commissioner Slaughter has attributed alleged increases in "patients' out-of-pocket costs" to "mushroom[ing]" "PBM rebates and fees," and she has called PBMs' "rebating practices" an "anticompetitive exploitation of market power." And Commissioner Bedoya has concluded that "[w]e all know" that PBM rebating "isn't fair" and is "not what fair markets look like." He has further suggested that PBMs' rebate negotiations "may create a conflict of interest" and "may also be commercial bribery." Indeed, in joint testimony to the House and Senate

²⁷ Khan, Statement Regarding 6(b) Study of Pharmacy Benefit Managers, *supra* note 7, at 1.

²⁸ Khan, Remarks at the White House Roundtable on PBMs, *supra* note 1, at 1.

²⁹ *Id*.

³⁰ Slaughter, Statement Regarding the Commission Statement on Reliance on Prior PBM-Related Advocacy Statements and Reports, *supra* note 20, at 2.

³¹ Slaughter, Statement Regarding the Federal Trade Commission's Report to Congress on Rebate Walls, *supra* note 19, at 1.

³² Alvaro Bedoya, Comm'r, Fed. Trade Comm'n, Remarks on "Returning to Fairness" to 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.

³³ Bedoya, Statement Regarding Policy Statement of the Federal Trade Commission on Rebates and Fees, *supra* note 21, at 2.

PUBLIC

Judiciary Committees, the Three Commissioners jointly and inaccurately described PBMs as "middlemen who can dictate the pricing and access to life-saving drugs for so many Americans."³⁴

* * *

Remarkably, these biased public statements continue unabated, even after the instant complaint was filed. As recently as last week, Commissioner Khan continued to publicly malign PBMs and refer to "work that we've done recently with regards to pharmacy benefits managers" in a podcast billed as covering "the recent actions against major PBMs."³⁵ The Three Commissioners' public statements and actions clearly illustrate their bias against Caremark, Zinc, and the other PBMs. The Three Commissioners prejudged the facts and predetermined their opinions concerning this matter long before it was ever initiated and continued their biased statements during the pendency of this investigation and beyond.

LEGAL STANDARD

"The requirement of an unbiased tribunal is fundamental to due process." *Rosen v. N.L.R.B.*, 735 F.2d 564, 571 n.10 (D.C. Cir. 1984). This constitutional requirement has equal "vitality for executive and administrative determinations." *Thompson v. Washington*, 497 F.2d 626, 634–35 (D.C. Cir. 1973) ("Application of due process protection to executive and administrative action has followed from recognition of the basic principle that 'the constitutional right to be heard is a basic aspect of the duty of government to follow a fair process of

³⁴ Prepared Statement of the Federal Trade Comm'n Before the U.S. Sen. Comm. on the Judiciary Subcomm. on Antitrust, Competition Policy and Consumer Rights "Oversight of the Enforcement of the Antitrust Laws," at 14 (Sept. 20, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/P210100SenateAntitrustTestimony09202022.pdf; Lina Khan, Chair, Fed. Trade Comm'n, Opening Statement before the U.S. House Comm. on the Judiciary, Hearing on Oversight of the Fed. Trade Comm'n, at 2 (July, 13, 2023) https://www.ftc.gov/system/files/ftc_gov/pdf/house-judiciary-hearing-chair-khan-oral-testimony_.pdf.

³⁵ The Heart of Healthcare: Competition and Consolidation in Healthcare, Interview of FTC Chair Lina Khan, (Oct. 3, 2024), https://podcasts.apple.com/us/podcast/the-heart-of-healthcare/id1575404727?i=1000671636977 ("these major entities, and especially when they're middlemen, it means that they're getting to pick and choose, you know, who's getting access to certain markets, who's not getting access to certain markets").

decisionmaking." (quoting *Fuentes v. Shevin*, 407 U.S. 67, 80 (1972))). As such, agency officials, like the Three Commissioners, may not adjudicate a case when "a disinterested observer may conclude that (the agency) has in some measure adjudged the facts as well as the law of a particular case in advance of hearing it." *Cinderella*, 425 F.2d at 591 (internal quotation marks omitted); *see also Am. Cyanamid Co. v. Fed. Trade Comm'n*, 363 F.2d 757, 766 (6th Cir. 1966). Accordingly, courts have disqualified agency officials in situations in which the officials have made public statements that "give the appearance that the case has been prejudged." *Cinderella*, 425 F.2d at 590.

DISCUSSION

The Three Commissioners' prior public statements plainly demonstrate that they have prejudged this case. Courts have unequivocally held that Commissioners must recuse themselves when their prior statements and actions convey *even an appearance* that they have prejudged a respondent's liability. That standard is more than met here. Any "disinterested observer" would conclude that the Three Commissioners have "in some measure adjudged the facts as well as the law of [this] case in advance of hearing it." *Id.* (internal quotation marks omitted). It defies credulity to suggest otherwise.

The Three Commissioners' conduct here closely mirrors—and, in fact, surpasses—the actions of former FTC Chair, Paul Rand Dixon. Appellate courts delivered a trio of rulings against Dixon for his failure to recuse. First, in *Texaco, Inc. v. Fed. Trade Comm'n*, the D.C. Circuit vacated an FTC order based on Dixon's public statements. 336 F.2d 754. In that action, the Commission alleged that Texaco used coercive tactics to cause its petroleum dealers to buy tires, batteries, and accessories from a rubber company from which Texaco allegedly received commissions. *Id.* at 757. Dixon gave a speech before a group of petroleum dealers—*i.e.*, those

alleged to have been coerced by Texaco—saying, "[y]our problems are many, and many of them are the problems of the [FTC] too We at the Commission are well aware of the practices which plague you and we have challenged their legality in many important cases." *Id.* at 759. The court held that "a disinterested reader of Chairman Dixon's speech could hardly fail to conclude that he had in some measure decided in advance that Texaco had violated the Act," and so the court set aside the FTC's order due to Chair Dixon's involvement. *Id.* at 760.

Next, in *American Cyanamid*, Dixon refused to recuse himself from a case, even though, as counsel to a Senate Subcommittee, he had "played an 'active role' in an investigation by that Subcommittee of many of the same facts and issues and of the same parties as are involved in this [FTC] proceeding." 363 F.2d at 763. The Sixth Circuit concluded that Dixon's participation in the FTC's case against the same defendants for the same conduct "amounted [] to a denial of due process which invalidated the order under review." *Id.* at 767 (internal quotation marks omitted). The court noted that "[i]t is fundamental that both unfairness and *the appearance of unfairness should be avoided*. Wherever there may be reasonable suspicion of unfairness, it is best to disqualify." *Id.* (emphasis added). The court remanded the case to the commission for a de novo hearing "without the participation of Chairman Dixon." *Id.* at 768.

A few years later, the D.C. Circuit reaffirmed that if a Commissioner's prior statements present the appearance of prejudgment they must not participate in an FTC case. In *Cinderella*, the court vacated another FTC order because Dixon had given a speech "which g[a]ve the appearance that the case has been prejudged." 425 F.2d at 590. The court held that FTC Commissioners may not make such speeches and participate in the FTC's work on the same manner because prior speeches "may have the effect of entrenching a Commissioner in a position which he has publicly stated, making it difficult, if not impossible, for him to reach a different

conclusion in the event he deems it necessary to do so after consideration of the record." *Id.* The court further explained that recusal must follow from statements that "give the appearance that [a Commissioner] has already prejudged the case and that the ultimate determination of the merits will move in predestined grooves." *Id.*

The Three Commissioners here stand on even worse footing than Chair Dixon. In each of his cases, Dixon's conduct ran afoul of due process requirements by giving a single speech or producing a single writing. By contrast, the Three Commissioners here have for years, through numerous public speeches and writings during a live investigation, issued a steady drumbeat of anti-PBM rhetoric that reveals their predetermined positions on the exact issues raised in this case. The Three Commissioners' prior statements do not merely evince an appearance of bias or prejudgment—although that would be sufficient to require disqualification—the statements are proof-positive that Caremark's and Zinc's fates have been determined in the minds and *statements* of those who seek to adjudicate this matter. Nor were the Three Commissioners' statements and beliefs expressed only before the outset of the investigation. See Majority Statement Order Denying Petition for Recusal, In the Matter of Meta Platforms, Inc., et al., No. 9411 (Feb. 1, 2023) (denying recusal based on statements made before FTC appointment); see also Dissenting Statement of Comm'r Christine S. Wilson at 27 ("The Majority Opinion implies that Chair Khan should not be disqualified because the statements and work forming the basis of recusal were made before the President nominated Chair Khan, and before the Senate confirmed her. Chair Dixon's work at issue in American Cyanamid, which took place prior to his becoming a Commissioner, demonstrates that the nomination and confirmation processes do not invalidate due process concerns. . . . The President and Senate did not, and could not, grant Chair Khan a waiver to ignore

due process and federal ethics requirements."). The Three Commissioners' biases were demonstrated even after the investigation began.

As set forth above, each of the Three Commissioners has publicly stated that PBMs allegedly promote "high list price insulin products, with high rebates and fees." Compl. ¶ 257. The Three Commissioners have also publicly asserted that PBMs have illegally excluded "low WAC insulin products from their most-utilized commercial formularies and custom client formularies." Compl. ¶ 263. And they have espoused their belief that the PBMs' alleged "exploitative cost-shifting practices" results in patients "paying more out-of-pocket for their insulin drugs." Compl. ¶¶ 270–71. As in *Cinderella*, 425 F.2d at 590, these public statements against PBMs "may have the effect of entrenching [the Three Commissioners] in a position" regarding PBMs, "making it difficult, if not impossible, for [them] to reach a different conclusion in the event [they] deem[] it necessary to do so after consideration of the record." The Three Commissioners' public condemnations of Caremark, Zinc, and the other Respondents would lead any neutral observer to believe that their minds are—at the outset of this action—irrevocably closed to contrary views of PBMs and their conduct. Their disqualification from this matter is required.

³⁶ See supra notes 15–22 and accompanying text.

³⁷ See supra notes 23–26 and accompanying text.

³⁸ See supra notes 27–34 and accompanying text.

PUBLIC

CONCLUSION

For the foregoing reasons, Caremark and Zinc respectfully request that Chair Khan, Commissioner Slaughter, and Commissioner Bedoya be disqualified from participating in the Commission's enforcement action against Caremark and Zinc.

Dated: October 8, 2024 Respectfully submitted,

/s/ Enu Mainigi

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EXHIBIT 1

FTC Chairwoman Lina Khan faces ethics complaint over alleged bias against pharmacy benefit managers

washingtonexaminer.com/news/2449295/ftc-chairwoman-lina-khan-faces-ethics-complaint-over-alleged-bias-against-pharmacy-benefit-managers/

September 7, 2023

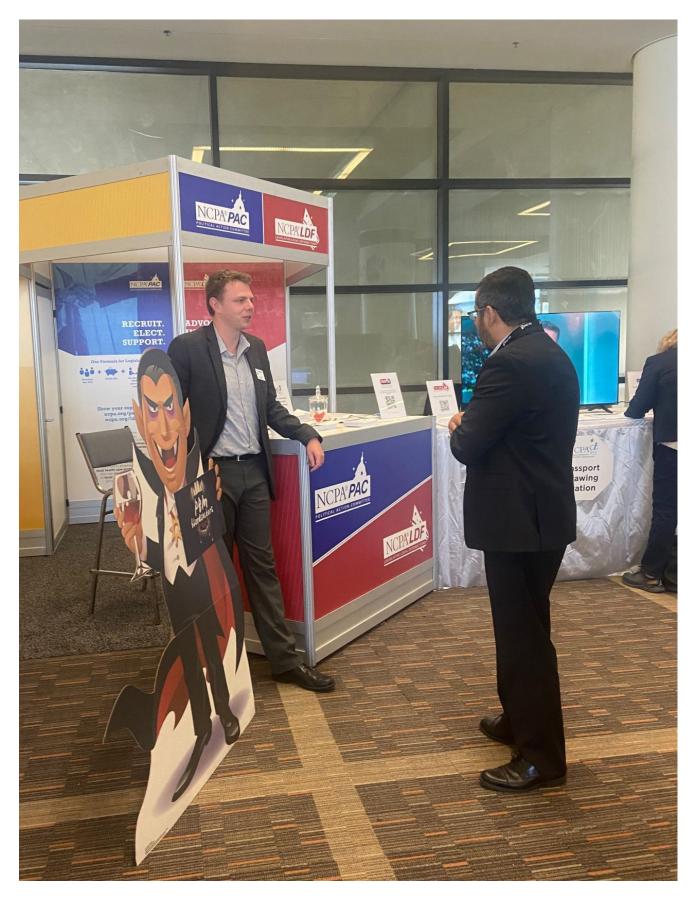
EXCLUSIVE — <u>Federal Trade Commission</u> Chairwoman Lina Khan could face a possible ethics inquiry over <u>allegations she violated the agency's ethics rules</u> by cracking down on pharmaceutical benefit managers while publicly positioning herself against the healthcare companies.

The American Accountability Foundation submitted a <u>Freedom of Information Act request</u> to the FTC on Wednesday, seeking access to all communications between Khan and other agency staff related to PBMs, the National Community Pharmacists Association, and other drug manufacturers, according to a copy of the request obtained by the *Washington Examiner*. The request comes after Khan appeared at an NCPA conference last year, during which she told the group they had "helped shape" her work on benefit managers.

BIDEN FCC NOMINEE ON TRACK FOR CONFIRMATION, OPENING PATH TO NET NEUTRALITY DEBATE

"Commissioner Khan's leadership at the FTC has been marred by a series of ethical lapses. Sadly, this is all too common in the Biden administration," AAF President Tom Jones told the *Washington Examiner.* "Her recent efforts to put her thumb on the scale in the pharmacy benefit managers dispute is sad and problematic. This is the beginning of an investigation by AAF to get to the bottom of Khan's dealings and to hold her to account."

During the conference, Khan <u>appeared alongside NCPA executives</u> who wore shirts depicting PBMs as vampires and labeling them as "bloodsuckers" as the chairwoman spoke about her work. In the months following the event, Khan later announced punitive actions she would be taking against PBMs, raising concerns about possible political motivation.



NCPA event in October 2022 included pictures of PBMs as vampires and labeled as "bloodsuckers" Courtesy American Accountability Foundation

The FTC voted in July to walk back its stance on PBMs, noting its previous guidance to relax oversight no longer reflects current market guidelines. The new stance warns against relying on advocacy letters published between 2004 and 2014 that opposed mandatory transparency policies and regulatory measures for benefit managers.

Instead, Khan <u>announced an inquiry</u> into the PBM industry to investigate whether the former policies adequately oversee the health care companies — prompting an outcry from critics who say such a move ignores ethical guidelines to push forward a "progressive agenda."

Many thanks to <u>@Commpharmacy</u> for the invitation and thoughtful discussion. Addressing unlawful business practices that are depriving Americans of affordable medicines and impeding fair competition is a top priority. https://t.co/ExlqVjpgHe

— Lina Khan (@linakhanFTC) October 3, 2022

"The FTC's overreach isn't just inappropriate. It will raise drug costs for every American," said former Rep. Ryan Costello, who served on the House Oversight Committee from 2017 to 2019.

The FTC requires agency officials to act "impartially" and not give "preferential treatment to any private organization or individual," according to the <u>commission's ethics guidelines</u>. The rules also advise employees to "avoid any actions creating the appearance that they are violating the law or ethical standards," which AAF officials say were violated by Khan.

The most recent ethics complaint follows a similar inquiry by the House Judiciary Committee earlier this year about whether Khan has adhered to ethics advice given by the FTC's Designated Agency Ethics Official.

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The inquiry cited an instance in which Khan failed to recuse herself as a judge in a case against Meta Platforms despite the DAEO recommending she do so, raising concerns among House Republicans "about her commitment to the fair and impartial administration of the FTC's authorities," the committee <u>wrote in June</u>.

It's not clear how quickly the latest complaint will move through the FTC, which told the *Washington Examiner* on Thursday they have no record of a request. A spokesperson for the agency declined to comment further.

CERTIFICATE OF SERVICE

I hereby certify that on October 8, 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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The Honorable D. Michael Chappell Administrative Law Judge 600 Pennsylvania Ave., NW, Rm. H-110 Washington, DC 20580

I further certify that on October 8, 2024, I caused the foregoing document to be served via email to:

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DATED: October 8, 2024 Respectfully submitted,

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