PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Lina M. Khan, Chair**
Rebecca Kelly Slaughter
Alvaro M. Bedoya
Melissa Holyoak
Andrew Ferguson

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.**	**Docket No. 9437**

OPTUM RX, INC.'S; OPTUMRX HOLDINGS, LLC'S; AND EMISAR PHARMA SERVICES LLC'S MOTION FOR DISQUALIFICATION

INTRODUCTION

"Rotten." "Horrific." "Violates the fundamental bargain at the center of the American prescription drug system." Any judge who made these remarks about a litigant at the outset of a lawsuit would immediately need to recuse for blatant bias. Yet these are just a few of the many disparaging remarks that the three Commissioners presiding over this case have made about the industry of pharmacy benefit managers ("PBMs"), including the three specific Respondent PBMs. Chair Khan, Commissioner Slaughter, and Commissioner Bedoya ("the Commissioners") all have an extensive public record of statements and actions exhibiting serious bias against Respondents OptumRx, Inc.; OptumRx Holdings, LLC (collectively, "Optum Rx"); and Emisar Pharma Services LLC ("Emisar"), and other PBMs. Each Commissioner has also made clear that they have prejudged this case and made up their minds that Optum Rx's well-established rebate practices are unfair and illegal. To any objective observer, these facts render this administrative proceeding a sham in which Optum Rx cannot possibly persuade the Commissioners by evidence.

The Constitution, federal ethics law, and the Commission's own regulations do not tolerate this actual and apparent bias in adjudicators. Just like prior cases in which other Commissioners improperly "prejudge[d] cases" or "ma[d]e speeches which give the appearance that the case has been prejudged," the Commissioners must be disqualified to provide these proceedings "'not only with every element of fairness but with the very appearance of complete fairness.'" *Cinderella Career & Finishing Schs., Inc. v. FTC*, 425 F.2d 583, 590-91 (D.C. Cir. 1970). The law and fundamental fairness require no less.

Pursuant to Commission Rule 4.17, 16 C.F.R. § 4.17, Optum Rx and Emisar respectfully move for the disqualification of the Commissioners from participation in this case.

BACKGROUND

Each of the Commissioners has a long and well-established record of inflammatory public remarks evincing bias against PBMs including Optum Rx. These remarks have come in official statements, at conferences or interviews hosted by vociferous critics of PBMs, and at other highly partisan events. Additionally, the Commissioners' official actions indicate a willingness to disregard objective data and procedural rules to reach their predetermined conclusion: that the PBMs' rebate practices are unfair and illegal under FTC Act Section 5.

For example, Chair Khan has publicly singled out "PBMs" as "powerful corporate middleman" who supposedly "engage in tactics that hike the price of drugs, deprive patients of access to certain medicines," and "price gouge[]" customers.[1] Commissioner Slaughter has accused PBMs of creating "disturbing[]," "unacceptable," and "rotten" market "distortions,"[2] and publicly declared that "[f]airness in drug pricing is undermined" by rebates, concluding that "[t]his is not the way competition is supposed to work" and branding PBMs by association with "illegal anticompetitive practices."[3] And Commissioner Bedoya has already adjudged it "pretty clear" that rebates improperly "drive up the list price" for consumers,[4] while declaring that rebates' effects can be "horrific" and "frankly, keep [him] up at night."[5]

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[1] https://tinyurl.com/awnhntdr, at 1.

[2] https://tinyurl.com/y98jtfcm, at 1.

[3] https://tinyurl.com/2ak2ju3r, at 1.

[4] https://tinyurl.com/4wjrknaz, at 2.

[5] https://tinyurl.com/2ur3f72p.

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.[6] 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.[7] And just months ago, the nominally "independent" Khan attended a White House event featuring exclusively anti-PBM speakers, including Democratic politicians and Mark Cuban, a prominent Democratic donor and co-founder of a direct competitor to PBMs.[8] Khan also personally hired biased staff including the anti-PBM ideologue David Barclay, who has made public statements calling PBMs "bulls***" and labeling rebates "bribes ... to force patients onto more expensive brand insulins."[9]

The Commissioners' official acts also indicate a preexisting vendetta against PBMs including Optum Rx. In June 2022, the Commission commenced a Rule 6(b) study "concerning the competitive impact of the contracting and business practices of pharmacy benefit managers."[10] 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."[11] Commissioner Holyoak, dissenting, criticized the "politicized

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[6] *See*, *e.g.*, https://tinyurl.com/28hnpk5e.

[7] https://tinyurl.com/j7pzdkrx; https://tinyurl.com/4na7bpta, at 9.

[8] https://tinyurl.com/4k4t3rrk.

[9] https://tinyurl.com/3d67e3n2; *see* https://tinyurl.com/9m5jd4xm, at 15 n.69.

[10] https://tinyurl.com/5n9y6sk2.

[11] https://tinyurl.com/v8fx2xfs.

nature of th[at] process," including "process irregularities and concerns over the substance—or lack thereof—of the original [Rule 6(b)] order."[12] Commissioner Ferguson echoed Commissioner Holyoak's criticisms, labeling the report "especially unusual" because it "relies heavily on public comments" that "are rather beside the point of the 6(b) study."[13] These procedural irregularities evince further, unacceptable hostility to PBMs by the other three Commissioners. Just as they did not bother waiting for the study's results before announcing their conclusions, they will not wait to hear the evidence in this case.

Beyond their general antipathy toward PBMs, the public record also establishes that the Commissioners have prejudged the specific claims raised in this case: *First*, whether Optum Rx's rebate pricing is an unfair method of competition because Optum Rx allegedly improperly promotes "high list price insulin products" and "fees." Compl. ¶ 257. *Second*, whether Optum Rx has illegally and unfairly excluded "low WAC insulin products from their most-utilized commercial formularies and custom client formularies." *Id.* ¶ 263. And *third*, whether Optum Rx illegally exploits consumers through alleged "cost-shifting practices." *Id.* ¶ 271.

Each of these counts is plainly a settled issue for the Commissioners. As to Count I (rebate preferencing), Slaughter evinced prejudgment about rebates as early as 2021, more than a year before the Commission's investigation began: "Fairness in drug pricing is undermined by a complex system of rebates … This is not the way competition is supposed to work."[14] Similarly, to Bedoya, it has long been "pretty clear" that rebates "drive up the list price," which evinces his

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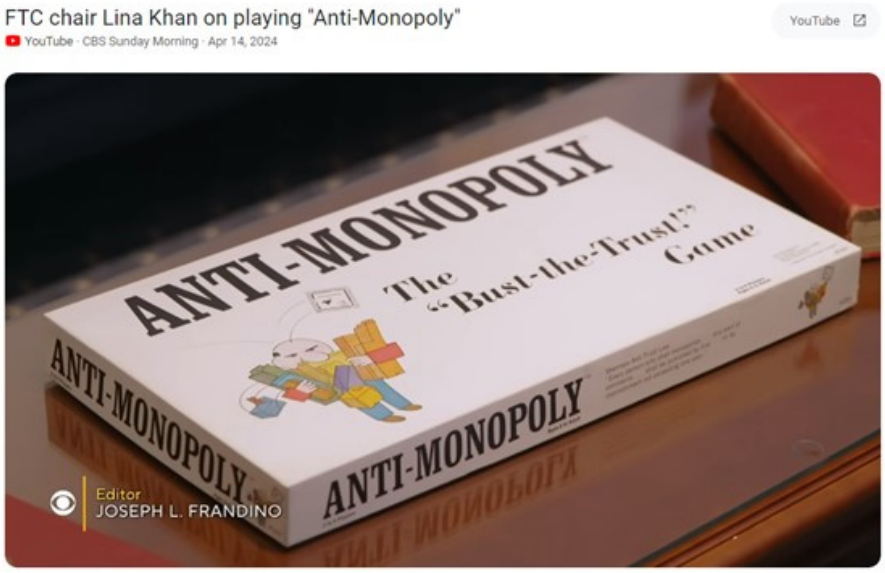
[12] https://tinyurl.com/yc7dv34v, at 2.

[13] https://tinyurl.com/5ajk8f23, at 2.

[14] https://tinyurl.com/2ak2ju3r, at 1.

inability to fairly evaluate Optum Rx's forthcoming presentation of evidence that rebates do *not* in fact drive up list price.[15] *Cf.* Compl. ¶ 259 (alleging that rebates "force[]" consumers to "pay higher out-of-pocket costs"). And Khan has publicly branded "the three major PBMs'" rebate practices with the inflammatory label "kickback,"[16] as part of a televised interview with a politician who called the industry "insane" and attributed its problems to "the manipulations of PBMs"—without rebuttal from Khan, who ended the interview by "thank[ing him] so much for all [his] terrific leadership."[17] This interview came as part of a media blitz in which Khan proudly displayed, in her office, an "Anti-Monopoly" board game with a graphic depicting "Optum Rx" on a "Monopoly" card:[18]

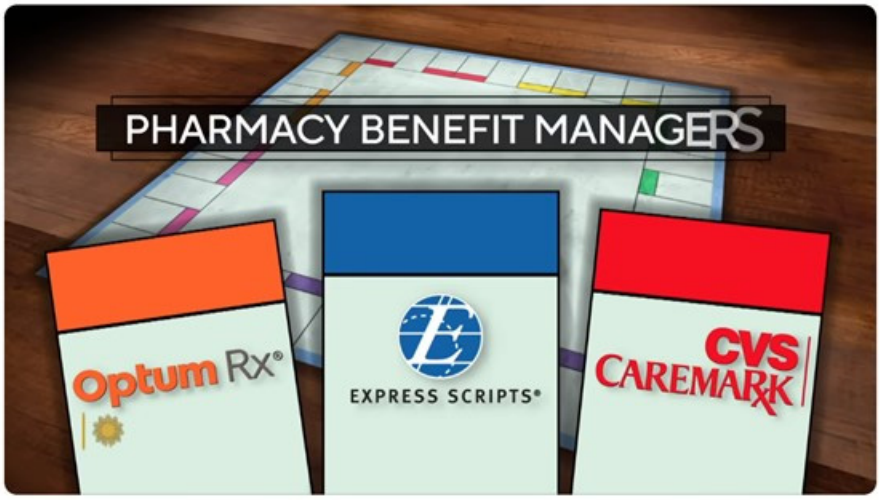


[15] https://tinyurl.com/4wjrknaz, at 2.

[16] https://tinyurl.com/5n8yrd3w, at 9:50-10:24, 11:26-31.

[17] *Id.* at 12:32-53, 31:57-32:00.

[18] https://tinyurl.com/vvza3jz7, at 0:41, 4:22.



The Commissioners also issued a press release demonizing PBMs' "illegal rebate schemes" as "bribes."[19] This evidence of prejudgment leaves no doubt the Commissioners will find Optum Rx's alleged "high rebates" are "unfair" in violation of Section 5. Compl. ¶¶ 256, 261.

As to Count II (formulary exclusion), the Commissioners have plainly telegraphed their prejudgment of the allegations against Optum Rx. Before the FTC's Rule 6(b) study even began, Khan prominently endorsed concerns that "PBMs and other middlemen may exclude the lowest-cost generic and biosimilar drugs from patients' formularies entirely to maximize rebates and fees,"[20] and declared that these "practices violate the fundamental bargain at the center of the American prescription drug system."[21] Slaughter likewise has already concluded that formulary exclusion has "grave consequences," causes "apparent distortions in insulin markets," and "subject[s] patients to insulin rationing."[22] And Bedoya has disparaged PBMs as "the middlemen

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[19] https://tinyurl.com/w3tkkdk9.

[20] https://tinyurl.com/yn5mep3k, at 2.

[21] *Id.*

[22] https://tinyurl.com/mzywffe3, at 1.

who control our access to insulin" and "make billions off it" via "placements on formularies."[23] Yet these Commissioners will now be asked to impartially adjudicate whether Optum Rx's "formulary exclusion practices" are "unfair." Compl. ¶¶ 263, 265.

As to Count III (cost-shifting), Khan has falsely claimed that "PBMs practically determine … the amount patients will pay at the pharmacy counter,"[24] that PBMs "dictate the pricing and access to life-saving drugs for so many Americans,"[25] and that Americans are "[t]oo often … price gouged for [life-saving] medications."[26] Similarly, Slaughter has attributed increases in "patients' out-of-pocket costs" to "mushroom[ing]" "PBM rebates and fees."[27] And Bedoya has blamed PBMs as "middlemen who control our access to insulin,"[28] which he suggests "[w]e all know" is "not what fair markets look like."[29] These statements have prejudged the dispute in this case whether Optum Rx's rebate and formulary-exclusion practices unfairly "shift[] the cost of high insulin prices of drugs onto certain insulin patients." Compl. ¶ 269.

The Commissioners' official actions further show they have already prejudged the issues. Under majorities of both parties across administrations, the Commission has previously recognized that PBMs benefit consumers because PBMs "negotiate lower prices for prescription drugs."[30]

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[23] https://tinyurl.com/bdme9wxa, at 1, 3.

[24] https://tinyurl.com/wtcr4fpp, at 1.

[25] https://tinyurl.com/z92wdyzn, at 14.

[26] https://tinyurl.com/awnhntdr, at 1.

[27] https://tinyurl.com/2fcwdauc, at 2.

[28] https://tinyurl.com/bdme9wxa, at 1.

[29] https://tinyurl.com/ab8carc3, at 8.

[30] https://tinyurl.com/manvv7my, at 1.

But in July 2023 (while the latest 6(b) study of PBMs was pending), the Commissioners abruptly voted to withdraw much of the Commission's bipartisan prior research and reports on the PBM industry, with an apparent eye toward this litigation. These Commissioners "warn[ed] against rely[ing]" on "eleven advocacy letters and reports" because "the PBM industry has changed significantly"[31]—even though, as dissenting Commissioner Holyoak objected, this action came "*prior to* FTC staff conducting any new market analysis."[32] And by releasing the 2024 Interim Report concluding (before the FTC's study even concluded) that PBMs "exercise significant power over Americans' access to drugs and the prices they pay," "increase prescription drug costs," and negotiate rebates that "may cut off patient access to lower-cost medicines,"[33] the Commissioners have already adjudged Optum Rx guilty of the charges. *See* Compl. ¶¶ 270-72.

ARGUMENT

The Fifth Amendment's Due Process Clause guarantees "'[a] fair trial in a fair tribunal,'" free of any "serious, objective risk of actual bias." *Caperton v. A.T. Massey Coal Co.*, 556 U.S. 868, 876, 886 (2009). That protection applies with special force in the context of an administrative agency that, like the Commission, combines adjudicative and prosecutorial functions in the same hands, which raises "substantial" constitutional concerns. *Withrow v. Larkin*, 421 U.S. 35, 51 (1975). Under decades of precedent, therefore, 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.

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[31] https://tinyurl.com/y6mr6898, at 1.

[32] https://tinyurl.com/yc7dv34v, at 4.

[33] https://tinyurl.com/v8fx2xfs, at 3-4.

Similarly, federal regulations require disqualification if an official's participation "would raise a question in the mind of a reasonable person about the employee's impartiality." 5 C.F.R. § 2635.502(e). Commissioners have accordingly been disqualified when their prior public statements have created a "reasonable suspicion of unfairness." *Am. Cyanamid Co. v. FTC*, 363 F.2d 757, 767 (6th Cir. 1966). That is because negative public statements about parties in a proceeding before the Commission can "give the appearance" that some the Commissioners have "already prejudged the case and that the ultimate determination of the merits will move in predestined grooves." *Cinderella*, 425 F.2d at 590.

In this case, disqualification follows *a fortiori* from these precedents. In *Cinderella*, for example, the Commission alleged that a finishing school for women made false statements in advertising. 425 F.2d at 584. While the case was pending before an administrative law judge, the Chairman made a speech suggesting that ads are deceptive if they promise that one can "becom[e] an airline's hostess by attending a charm school." *Id.* at 589-90. The D.C. Circuit agreed with the respondents that the Chairman should have recused from the case because adjudicators have no license to "make speeches which give the appearance that the case has been prejudged." *Id.* at 590. These speeches can "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.* Crucially, *Cinderella* required recusal based on its identification of just one offending remark by the Chairman—a sentence in a single speech that did not mention the respondent finishing school by name. Here, the facts here are far more egregious. Each Commissioner has made many derogatory comments about PBMs, including while the Commission's 6(b) study and investigation was underway, and they have specifically targeted the three major PBMs including Optum Rx.

Texaco, Inc. v. FTC further confirms that disqualification is necessary. 336 F.2d 754 (D.C. Cir. 1964), *vacated on other grounds*, 381 U.S. 739 (1965). The Commission alleged that Texaco illegally entered a contract with Goodrich that, at a high level, functioned similarly to the rebate practices here: Goodrich paid Texaco a commission "to promote the sale of Goodrich tires, batteries and accessories" ("TBA") in its stores. *Id.* at 756. While the case was pending, the Chairman issued a press release assuring consumers that the Commission was "well aware of the practices which plague you and we have challenged their legality in many important cases. You know the practices—price fixing, price discrimination, and overriding commissions on TBA." *Id.* at 759. Although the Chairman did not name Texaco, his speech "plainly reveal[ed] that he had already concluded that Texaco" was "violating the Act." *Id.* at 760. Just as the Chairman gave a speech accusing Texaco of "price discrimination, and overriding commissions on TBA"—the very conduct at issue in the Commission's complaint—the Commissioners here have made public remarks accusing Optum Rx of price discrimination while they are set to adjudicate that very issue. *See* Compl. ¶¶ 256-57. That demands disqualification.

So does the Commissioners' attendance at many anti-PBM events without attending a single event hosted by PBMs or their supporters. Courts have recognized that adjudicators' attendance at even one event tilted "predominantly" to one side creates an appearance of partiality. *In re Sch. Asbestos Litig.*, 977 F.2d 764, 782 (3d Cir. 1992). Moreover, disqualification of these three (Democratic) Commissioners is even more important because the unexplained "recus[als]" of the two other (Republican) Commissioners, Holyoak and Ferguson, from this administrative proceeding, Compl. at 45, raise heightened questions about the impartiality of the one-sided, partisan Commission that will decide this case—contrary to the statutory requirement of a balanced, bipartisan Commission, 15 U.S.C. § 41.

At minimum, the Commissioners should follow Commissioner Brill's example and recuse to further public confidence in these proceedings even if they disagree over the application of the recusal standard. Facing a similar disqualification motion filed by LabMD based on her prior speeches addressing issues to be litigated, Brill deemed that motion "without merit" but nonetheless recused out of "concern[]" that her participation "would likely create an undue distraction from the important issues raised" and "would not serve the public interest."[34]

CONCLUSION

Chair Khan, Commissioner Slaughter, and Commissioner Bedoya should be disqualified from participation in this case.

DATED: October 8, 2024

Respectfully submitted,

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[34] https://tinyurl.com/3eajcxn3, at 1-2.

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PROPOSED ORDER

Upon consideration of Respondents OptumRx, Inc.; OptumRx Holdings, LLC; and Emisar Pharma Services LLC Motion to Disqualify Chair Khan, Commissioner Slaughter, and Commissioner Bedoya, IT IS HEREBY ORDERED that the Motion is GRANTED.

ORDERED: _____

Lina M. Khan
Chair of the Federal Trade Commission

Date: _____

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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