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.;

DOCKET NO. 9437

Medco Health Services, Inc.;

Ascent Health Services LLC;

OptumRx, Inc.;

OptumRx Holdings, LLC;

and

Emisar Pharma Services LLC.

ORDER DENYING MOTIONS TO DISQUALIFY COMMISSIONER BEDOYA

On October 8, 2024, Respondents Express Scripts, Inc., Evernorth Health, Inc., Medco Health Services, Inc., Ascent Health Services LLC (collectively "ESI Respondents"), Caremark Rx, LLC ("Caremark") and Zinc Health Services, LLC ("Zinc") (collectively, "Caremark/Zinc Respondents"), Optum Rx, Inc., OptumRx Holdings, LLC (together, "Optum Rx"), and Emisar Pharma Services LLC ("Emisar") (collectively, "Optum/Emisar Respondents") moved to

disqualify Commissioner Bedoya from participating in this proceeding. ¹ For the reasons explained below, we deny the Motions. ²

I. The PBM Study

On June 7, 2022, the Commission unanimously voted to launch under Section 6(b) of the Federal Trade Commission Act ("FTC Act") a study concerning prescription drug middlemen. The study sought to examine the role and impact of pharmacy benefit managers ("PBMs") in the U.S. pharmaceutical system and to shed light on several practices that had drawn scrutiny in recent years.³ As part of this inquiry, the Federal Trade Commission ("FTC" or "Commission") required the six largest PBMs, including the PBM Respondents, to provide information and records regarding their business practices. All of the then-Commissioners issued statements in support of the study.

On January 22, 2024, Senator Charles E. Grassley and thirteen other Senators sent FTC Chair Lina Khan a letter urging that the Commission expedite its Section 6(b) study or issue an interim progress report. Given congressional interest in the timely release of study results, and staff's concerns about the timing of responses from several recipients of the Section 6(b) orders, the Commission authorized the release of an Interim Staff Report detailing staff's initial findings on July 9, 2024. The Interim Staff Report stated that documents and data obtained to date, as well as publicly available information, supported the following preliminary findings: (1) The market for pharmacy benefit management services has become highly concentrated, and the

The Caremark/Zinc Respondents requested leave to exceed the 2,500-word limit in Commission Rule 3.22(c). See Caremark/Zinc Motion 3 n.5. Respondents' Motion may exceed 2,500 words. The ESI and Caremark/Zinc Respondents also requested oral argument regarding their Motions. See ESI Motion 1; Caremark/Zinc Motion 1. The Commission finds that oral argument is not needed for appropriate consideration of the Motions.

¹ See Respondents Express Scripts, Inc., Evernorth Health, Inc., Medco Health Services, Inc., and Ascent Health Services LLC's Motion to Disqualify Commissioner Alvaro M. Bedoya ("ESI Motion"); Respondents Caremark Rx, LLC and Zinc Health Services, LLC's Motion for Disqualification ("Caremark/Zinc Motion"); Optum Rx, Inc.'s; OptumRx Holdings, LLC's; and Emisar Pharma Services LLC's Motion for Disqualification ("Optum/Emisar Motion"). For ease of reference, we will refer to these parties collectively as "Respondents" and their motions collectively as "Motions."

² Respondents' parallel requests to disqualify Chair Khan and Commissioner Slaughter are addressed in separate orders. Commissioners Holyoak and Ferguson are recused from this matter.

³ Press Release, Fed. Trade Comm'n, FTC Launches Inquiry Into Prescription Drug Middlemen Industry (June 7, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry.

⁴ Letter from Sen. Grassley et al. to Chair Khan (Jan. 22, 2024), https://www.grassley.senate.gov/imo/media/doc/grassley_cantwell_colleagues_to_ftc - pbm_investigation.pdf.

⁵ Fed. Trade Comm'n, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies, Interim Staff Report (July 2024), https://www.ftc.gov/system/files/ftc gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

largest PBMs are now also vertically integrated with the nation's largest health insurers and specialty and retail pharmacies; (2) As a result of this high degree of consolidation and vertical integration, the leading PBMs can now exercise significant power over Americans' access to drugs and the prices they pay; (3) Vertically integrated PBMs may have the ability and incentive to prefer their own affiliated businesses, which in turn can disadvantage unaffiliated pharmacies and increase prescription drug costs; (4) Evidence suggests that increased concentration may give the leading PBMs the leverage to enter into complex and opaque contractual relationships that may disadvantage smaller, unaffiliated pharmacies and the patients they serve; and (5) PBMs and brand drug manufacturers sometimes negotiate prescription drug rebates that are expressly conditioned on limiting access to potentially lower cost generic alternatives.⁶

II. The Complaint

On September 20, 2024, the Commission issued an administrative complaint that charged the three largest PBMs—Caremark Rx, Express Scripts, and Optum Rx—and their affiliated group purchasing organizations ("GPOs") with allegedly engaging in anticompetitive and unfair rebating practices that, *inter alia*, artificially inflated the list price of insulin drugs, impaired patients' access to lower list price insulin products, and shifted the cost of high insulin list prices from healthy to chronically-ill or otherwise vulnerable patients. *See, e.g.*, Compl. ¶¶ 9–10, 92–95, 113, 119–25, 185–92, 214–33.

According to the Complaint, PBMs administer prescription benefits on behalf of insurance companies, unions, and various types of employers, sometimes collectively referred to as "payers." *Id.* ¶ 28. PBMs assertedly perform several roles for payers, including, *inter alia*, developing drug formularies, ⁷ creating and managing networks of pharmacies, processing prescription drug claims, and negotiating with pharmaceutical manufacturers for rebates on behalf of their clients. *Id.* ⁸

The Complaint alleges that, beginning in approximately 2012, the PBM Respondents began to misuse their influence over drug formularies to demand higher and higher rebates from insulin manufacturers in return for priority placement on formularies or for including the manufacturer on the formulary at all. *Id.* ¶¶ 9, 100–18, 215. Although intuitively one might assume that higher rebates would reduce prices for patients, the Complaint alleges that the opposite is true in pharmaceutical pricing because of the role of list prices. *Id.* ¶¶ 6, 216–17. According to the Complaint, PBMs' strategy of seeking high rebates has influenced insulin

⁶ *Id.* at 2–4.

 $^{^{7}}$ A "formulary" is a list of drugs covered by a health plan. Compl. ¶ 32. According to the Complaint, a formulary may have multiple tiers that make drugs on "preferred" tiers cheaper for patients. *Id.* The Complaint alleges that a formulary may be more "open," meaning that it covers nearly all medications, or it may be relatively "closed," meaning that it includes only certain drugs, and excludes others, used to treat a certain condition. *Id.* ¶ 33.

⁸ For the function of negotiating rebates, the Complaint alleges that each named PBM Respondent has created and now utilizes the services of a GPO with which the PBM is affiliated. Compl. ¶¶ 42–43.

manufacturers to dramatically increase their list prices in order to offset the increased rebate payments. *Id.* ¶¶ 119, 216. The Complaint alleges that the higher list prices harm consumers whose out-of-pocket costs are based on the list price (not the net price), including, most especially, uninsured and commercially-insured patients. *Id.* ¶¶ 95, 222.

According to the Complaint, the PBM Respondents also allegedly took steps to exclude lower-cost insulin offerings from their formularies. Beginning allegedly in 2017, in response to public criticism, insulin manufacturers explored ways to reduce insulin list prices, including by launching lower list-price, unbranded versions of their products. *Id.* ¶ 132. According to the Complaint, the PBM Respondents systemically disfavored these products on their formularies in favor of high list price, highly rebated insulin products. *E.g.*, *id.* ¶¶ 144, 148, 218–19. This allegedly had various harmful effects, including preventing the expansion of access to insulin for certain classes of patients and impeding entry of new insulin products. *Id.* ¶¶ 148, 151, 222.

Count I of the Complaint alleges that Respondents' conduct in systematically preferring high list price insulin products, with high rebates and fees, while obscuring actual net cost, is an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a). *Id.* ¶¶ 255–61. Count II alleges that the PBM Respondents' systematic exclusion of low list price insulin products from their most-utilized formularies, in favor of identical high list price insulin products, is an unfair act or practice in violation of Sections 5(a) and (n) of the FTC Act, 15 U.S.C. § 45(a), (n). *Id.* ¶¶ 262–67. Count III alleges that the PBM Respondents have created and implemented a system that shifts the cost of high insulin prices to certain patients, a dynamic of which the PBM Respondents are aware. *Id.* ¶¶ 268–74. Count III further alleges that the PBM Respondents' practices cause and are likely to cause substantial injury to consumers by increasing the price of insulin to certain patients. *Id.* ¶ 271. The Complaint alleges that this conduct is an unfair act or practice in violation of Sections 5(a) and (n) of the FTC Act, 15 U.S.C. § 45(a), (n). *Id.* ¶ 274.

III. The Motions

On October 8, 2024, Respondents filed the instant Motions to disqualify Commissioner Bedoya. Respondents allege that he has prejudged their conduct and demonstrated actual and apparent bias in violation of due process. Caremark/Zinc Motion 6–9, 10–13; Optum/Emisar Motion 6–10; ESI Motion 1–4. In addition, the ESI Respondents assert that Commissioner Bedoya's continued participation in this proceeding would violate standards of ethics applicable to federal employees and federal judges, respectively.⁹

The Respondents' Motions challenge statements of Commissioner Bedoya along with his appearances at certain events and his vote to authorize the release of the Section 6(b) study Interim Staff Report. Respondents assert that Commissioner Bedoya has shown prejudgment

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⁹ ESI Motion 7–8 & nn.9 (citing 5 C.F.R. § 2635.501(a) and Mem. to Designated Agency Ethics Officials Regarding Recusal Obligation and Screening Arrangements, OGE Informal Advisory Mem. 99 X 8, 1999 WL 33308429, at *2 (Apr. 26, 1999)) & 14 (citing U.S. Courts, Guide to Judiciary Policy – Vol. 2: Ethics and Judicial Conduct, Ch. 2: Code of Conduct for U.S. Judges (rev. March 2019), https://www.uscourts.gov/sites/default/files/code of conduct for united states judges effective march 12 2019.pdf).

against the PBMs, or an unacceptable appearance thereof, based on his actions and statements he made before the Commission instituted this proceeding. *See, e.g.*, ESI Motion 2–3; Caremark/Zinc Motion 2, 4, 6–8. Respondents further assert that Commissioner Bedoya's alleged prejudgment extends both to the proceeding as a whole and to certain issues the resolution of which will affect the adjudication of particular counts of the Complaint. Caremark/Zinc Motion 3, 5–9; Optum/Emisar Motion 4–7; ESI Motion 2–4.

IV. Procedure Governing Requests for Disqualification

Requests for disqualification are governed by Commission Rule 4.17, 16 C.F.R. § 4.17, which provides that a participant in a proceeding may seek to disqualify a Commissioner by motion setting forth with particularity the alleged grounds for disqualification, filed at the earliest practicable time after the participant learns, or could reasonably have learned, of the alleged grounds for disqualification. *See* 16 C.F.R. § 4.17(b)(1), (2). The motion must be addressed in the first instance by the Commissioner whose disqualification is sought. *See id.* § 4.17(b)(3)(i). If the Commissioner declines to recuse himself or herself from further participation in the proceeding, the Commission must determine the motion without the participation of such Commissioner. *See id.* § 4.17(b)(3)(ii). Pursuant to this procedure, Commissioner Bedoya declined to recuse himself from participation in the matter. ¹⁰ The Commission, without the participation of Commissioner Bedoya, and with Commissioners Holyoak and Ferguson recused, now assesses the Motions.

V. Legal and Evidentiary Standards for Disqualification

The disqualification of an administrative official acting in a judicial or quasi-judicial capacity is governed by the requirements of due process. *Schweiker v. McClure*, 456 U.S. 188, 195 (1982). An administrative adjudicator must be disqualified if "a disinterested observer may conclude that [the adjudicator] has in some measure adjudged the facts as well as the law of a particular case in advance of hearing it." *Cinderella Career & Finishing Schs., Inc. v. FTC* (*Cinderella II*), 425 F.2d 583, 591 (D.C. Cir. 1970) (quotation omitted); *Texaco, Inc. v. FTC*, 336 F.2d 754 (D.C. Cir. 1964), *vacated on other grounds*, 381 U.S. 739 (1965); *see also Fast Food Workers Comm. v. NLRB*, 31 F.4th 807, 815 (D.C. Cir. 2022) (dictum). Both unfairness and the appearance of unfairness must be avoided. *See Cinderella II*, 425 F.2d at 591.

Administrative adjudicators are presumed to be unbiased. See Schweiker, 456 U.S. at 195. A party seeking disqualification of an agency adjudicator based on a public statement has the burden of overcoming that presumption by showing that the adjudicator "is not capable of judging a particular controversy fairly on the basis of its own circumstances." Hortonville Joint Sch. Dist. No. 1 v. Hortonville Educ. Ass'n, 426 U.S. 482, 493 (1976) (quotation omitted); see also Withrow v. Larkin, 421 U.S. 35, 47 (1975) (The contention of bias or prejudgment in an administrative adjudication "must overcome a presumption of honesty and integrity in those serving as adjudicators."); Aetna Life Ins. Co. v. Lavoie, 475 U.S. 813, 821 (1986) ("[O]nly in the most extreme of cases would disqualification on [a bias or prejudice] basis be constitutionally

¹⁰ Commissioner Bedoya's statement ("Bedoya Statement") is hereby placed on the public record as Attachment A to this Order.

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required."). The test for disqualification may be stated in terms of whether the adjudicator's mind is "irrevocably closed' on the issues as they arise in the context of the specific case." *S. Pac. Commc'ns Co. v. Am. Tel. & Tel. Co.*, 740 F.2d 980, 991 (D.C. Cir. 1984) (quoting *FTC v. Cement Inst.*, 333 U.S. 683, 701 (1948)); *see also Metro. Council of NAACP Branches v. FCC*, 46 F.3d 1154, 1165 (D.C. Cir. 1995) (A Commissioner's decision not to recuse himself is set aside "only where he has demonstrably made up his mind about important and specific factual questions and is impervious to contrary evidence." (cleaned up)). A "comment is disqualifying only if it connotes a fixed opinion—'a closed mind on the merits of the case." *United States v. Haldeman*, 559 F.2d 31, 136 (D.C. Cir. 1976) (en banc) (per curiam) (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 583 (1966)). ¹¹

VI. Analysis

Respondents' asserted bases for disqualification may be aggregated into several categories, discussed herein. None provides a basis for disqualification.

a. Statement Explaining Commission Scrutiny of PBM Practices

On June 7, 2022, Commissioner Bedoya issued a statement about the Commission's vote to authorize the Section 6(b) study of PBMs. ¹² Respondents argue that the statement demonstrates bias and prejudgment. They point to his remark that "nearly everyone is affected by PBM business practices. For most Americans, pharmacy middlemen control what medicines you get, how you get it, when you get it, and how much you pay for it." ESI Motion 2; Caremark/Zinc Motion 7 n.26. Respondents omit the remainder of the paragraph, where Commissioner Bedoya explains that, despite this influence, PBM practices are "cloaked in secrecy, opacity, and almost impenetrable complexity," and "[t]his is why the 6(b) study issued today is so critical." As discussed below, Commissioner Bedoya's statement does not show a closed mind on the merits of this case and does not warrant disqualification.

First, highlighting PBMs' influential role in the American prescription drug system does not indicate prejudgment concerning whether PBMs have violated Section 5 with respect to insulin. The statement does not even mention insulin. Nothing in the statement suggests that Commissioner Bedoya had already "demonstrably made up his mind about important and specific factual questions and [was] impervious to contrary evidence." *Metro. Council of NAACP Branches*, 46 F.3d at 1165 (quotation and original brackets omitted). His statement merely reflects broad, preliminary observations about the significance of PBMs in the pharmaceutical industry and is part of his explanation about why he supported the FTC using its scarce resources to examine PBMs under its Section 6(b) authority.

¹¹ Although *Haldeman* discusses the disqualification standard for federal judges, comments that will not disqualify a federal judge would not disqualify an administrative adjudicator. *See infra* Section VI.g.

¹² Alvaro Bedoya, Comm'r, Fed. Trade Comm'n, Statement Regarding 6(b) Order to Study Contracting Practices of Pharmacy Benefit Managers (June 7, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Bedoya Statement re PBM Study %28FINAL%29 6-7-2022.pdf.

To the extent the statement expresses a view on market functioning or economics or may be characterized as an expression of Commissioner Bedoya's initial assessment about the role of PBMs, based on his experience with the Commission or complaints received or preliminary investigative findings, that would also not disqualify him. [A] dvance views on important economic matters in issue" are not a basis for disqualification. Skelly Oil Co. v. Fed. Power Comm'n, 375 F.2d 6, 18 (10th Cir. 1967), rev'd in part on unrelated grounds sub nom. In re Permian Basin Area Rate Cases, 390 U.S. 747 (1968)). As the Supreme Court has explained, "the fact that the Commission had entertained [certain] views as the result of its prior ex parte investigations did not necessarily mean that the minds of its members were irrevocably closed on the subject of respondents' . . . practices." Cement Inst., 333 U.S. at 701. In any ensuing administrative adjudication, respondents may participate in hearings and "point out to the Commission by testimony, by cross-examination of witnesses, and by arguments, conditions of the trade practices under attack which they th[ink] kept these practices within the range of legally permissible business activities." Id.

By issuing a complaint, the Commission necessarily signals that it has found evidence that could support finding a violation, as a complaint may be issued only if the Commission has "reason to believe" that a respondent violated the law. 15 U.S.C. § 45(b). And, it does not offend due process for the Commission to explain why the complaint was filed or to publicize the preliminary considerations that support the filing of charges. *See FTC v. Cinderella Career & Finishing Schs., Inc.* ("*Cinderella P*"), 404 F.2d 1308, 1313 (D.C. Cir. 1968); *cf. Withrow*, 421 U.S. at 56–57. Here, the at-issue statement is even further removed, as it discusses not the reasons the Commission issued its Complaint but the reasons it authorized an earlier, broader PBM study. Commissioner Bedoya's statement explaining the basis for Commission action provides no basis to disqualify him from the case at hand.

Similarly, the Commission's statement to a Senate Judiciary subcommittee, echoing the same points about PBMs' influence on Americans, does not indicate prejudgment by Commissioner Bedoya. ¹⁴ The statement notes that the Section 6(b) study "will shine a light on the opaque operations of these large pharmacy middlemen who can dictate the pricing and access to life-saving drugs for so many Americans." ¹⁵ It explains why the Commission authorized the Section 6(b) study and reflects not a conclusive assessment of the insulin market or the merits of this case but an initial, tentative observation about how PBMs "can" influence drug pricing and access.

¹³ Nor would very similar remarks about the PBMs' influence in other statements. *See, e.g.*, Alvaro Bedoya, Comm'r, Fed. Trade Comm'n, Remarks on "Returning to Fairness" to the Midwest Forum on Fair Markets, at 3 (Sept. 22, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/returning_to_fairness_prepared_remarks_commissioner_alvaro_bedoya.pdf (partially quoted in ESI Motion 2–3).

¹⁴ See 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/P210100 SenateAntitrustTestimony09202022.pdf (partially quoted in Caremark/Zinc Motion 9).

¹⁵ *Id*.

b. Statements Expressing Views on Policy or Market Conditions

Respondents allege that various statements by Commissioner Bedoya expressing views on policy or market conditions require his disqualification. However, in none of the cited instances did Commissioner Bedoya assert that any particular PBM had violated the law, either in the insulin market or otherwise. Nor did he state that the Commission should take enforcement action against any specific PBM or the industry generally. As discussed below, the statements that Respondents point to fail to demonstrate that Commissioner Bedoya has adjudged the facts and law of this particular case. *Cinderella II*, 425 F.2d at 591.

Respondents shift the import of a snippet from Commissioner Bedoya's speech, "Returning to Fairness," in an attempt to support his disqualification. ¹⁶ The theme of the speech is the conceptual tradeoff in antitrust policy between fairness and efficiency. Giving cautionary anonymized examples he heard from several highly concentrated industries including the PBM industry, cattle ranching, and baby formula, Commissioner Bedoya observes as to all three examples that "[w]e all know that that's not what fair markets look like." ¹⁷ The expression of this general opinion does not approach disqualifying Commissioner Bedoya in this proceeding. He does not mention any of the PBM Respondents, or indeed any firm. He does not mention insulin or rebates, nor does he voice a conclusion that any PBM violated the law. At most, Commissioner Bedoya describes an anonymized example of steering patients to a certain pharmacy, a practice that is not the focus of this proceeding. He also makes a policy-based argument that fairness should trump efficiency. Commissioner Bedoya is permitted to make such observations and to advance such policy arguments. See Skelly Oil Co., 375 F.2d at 18; Ass'n of Nat'l Advertisers, Inc. v. FTC, 627 F.2d 1151, 1171 n.51 (D.C. Cir. 1979) (Adjudicators "are free to decide cases involving policy questions on which they previously have expressed a view."); S. Pac. Commc'ns Co., 740 F.2d at 991 ("If a judge approached every case completely free of preconceived views concerning the relevant law and policy, we would be inclined not to applaud his impartiality, but to question his qualification to serve as a judge."). 18

Respondents also assert that Commissioner Bedoya in interviews with the news organization Capitol Forum stated that aggressive use of rebates in the PBM industry drives up

¹⁶ See, e.g., Caremark/Zinc Motion 8 & n.32 (citing 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_alv_aro_bedoya.pdf).

¹⁷ "Returning to Fairness" at 8.

¹⁸ Indeed, it is appropriate and unexceptionable that Commissioner Bedoya should have expressed a view on the functioning of a market. *Cf. FTC v. Facebook, Inc.*, 581 F. Supp. 3d 34, 65 (D.D.C. 2022) (Although Chair Khan expressed views about market functioning prior to her selection as chair, this did not disqualify her from voting to pursue a case; she was presumably chosen because of such views.).

list prices. 19 The statements at issue fail to merit disqualification for several reasons. First, viewing the statements in their context shows that they are far less definitive than Respondents suggest. In the October 26, 2023 interview, Commissioner Bedoya observed that he had a "concern" for uninsured patients because rebates "could cut all sorts of different ways" but that it "seems pretty clear . . . that they seem to drive up the list price[.]" This type of hedged statement does not be peak a mind closed to additional evidence or a change of view. In a similar vein, Commissioner Bedova's general observation that in a vertically integrated industry, a PBM "serves as something of a gatekeeper to [its] population of insured" is an observation, likely uncontroversial, about PBMs' business model: by aggregating covered individuals, a PBM may be able to gain additional bargaining leverage in a negotiation with pharmaceutical manufacturers. Either way, though, Commissioner Bedoya's preliminary, general expression about an economic issue, untethered to any concern about a particular PBM or even the drug at issue—insulin—is not disqualifying. In FTC v. Cement Institute, the Commission had prepared reports concluding that the basing-point pricing system that the cement industry members used was a violation of the Sherman Act. 333 U.S. at 700. The Court refused a request to disqualify the Commission in a matter where that same pricing system was at issue. *Id.* at 701. The existence of the report did not mean that the Commissioners' minds were irrevocably closed, and moreover the respondents would have the opportunity to present their own evidence in the adjudication. Id.

Respondents challenge Commissioner Bedoya's statements about rebates in a June 7, 2023 interview with Capitol Forum, including that:

- "[T]here's been a lot of assumptions about the economic benefits of rebates and the ostensible and alleged good they do"; and
- "That said, if you're focused on the people struggling in this country . . . people who are uninsured, people who don't have government payors, people who aren't on Medicare, Medicaid, people who fall into that donut hole. What ends up happening with rebates is they get stuck with what's called the usual and customary price at the pharmacy counter. And that's a fancy term for full freight."

Commissioner Bedoya's opinions about the functioning of the pharmaceutical market are not disqualifying. "It is well established that the mere fact that [an adjudicator] holds views on law or policy relevant to the decision of a case does not disqualify him from hearing the case." S. Pac. Commc'ns, 740 F.2d at 990; see also Nuclear Info. & Res. Serv. v. NRC, 509 F.3d 562, 571 (D.C. Cir. 2007) ("[A] mere showing that an official has taken a public position, or has expressed strong views, or holds an underlying philosophy with respect to an issue in dispute" is not a basis for disqualification.) (quotation and quotation marks omitted). In any event, Respondents overlook key passages of the interview in which Commissioner Bedoya qualified his expressions of opinion about rebates and espoused an openminded desire to learn more ("And certainly, in

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¹⁹ See, e.g., Caremark/Zinc Motion 2 & n.3, 6–7 & n.22 (partially quoting The Capitol Forum, Fireside Chat with Commissioner Alvaro Bedoya (published June 15, 2023), https://thecapitolforum.com/resources/transcript-of-interview-with-ftc-commissioner-alvaro-bedoya/ and The Capitol Forum, Fireside Chat with Commissioner Alvaro Bedoya, at 4:28 (Oct. 26, 2023) https://library.thecapitolforum.com/docs/768k6m9a1tv1); Optum/Emisar Motion 2 & n.4; ESI Motion 3 & n.6.

some circumstances, I can see a world where rebates are good. And so I don't think the rebates as a whole are a bad idea."); ("And so I think we need to *question* this rationale around rebates and *kick the tires* on that.") (emphasis added). The Optum/Emisar and Caremark/Zinc Respondents claim that Commissioner Bedoya portrayed rebates' effects as potentially "horrific" and stated that they "frankly, keep [him] up at night," but as Commissioner Bedoya stated clearly, he was describing "some of the stories you hear" and "some of the allegations you hear," not his own views, and he used the word "allegation" or "allegations" no fewer than five times to emphasize that he did not view those stories as written in stone. *Id.* 21 Recounting complaints that the Commission receives does not disqualify Commissioner Bedoya from adjudicating this matter. The Commission is "specifically authorized to make public information acquired by it" and, "acting in the public interest, to alert the public to suspected violations of the law." *Cinderella I*, 404 F.2d at 1314.

c. Statement Regarding the Commission Policy Statement on Rebates and Fees in Exchange for Excluding Lower-Cost Drugs

Respondents claim Commissioner Bedoya's Statement Regarding the Commission's Policy Statement on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products. demonstrates prejudgment and bias. Respondents misleadingly quote excerpts from the Statement out of context. Respondents ESI and Caremark/Zinc contend Commissioner Bedoya attributed "a significant part of the blame" for insulin price increases to rebates and fees demanded by PBMs. ESI Motion 2; Caremark/Zinc Motion 6. Yet, Commissioner Bedoya couched his views in the limiting phrase "[i]t appears that . . ." and, importantly, Respondents omit that Commissioner Bedoya is describing a Congressional study. Bedoya Statement Regarding Policy Statement on Drug Rebates and Fees at 1 ("It appears that in the insulin market, companies compete to *raise* [prices]. At least that is the conclusion of a recent yearslong investigation by the Senate Finance Committee That study laid a significant part of the blame on rebates demanded by pharmacy benefit managers"). Similarly, the Optum/Emisar Respondents and Caremark/Zinc Respondents claim Commissioner Bedoya "disparaged" PBMs as "the middlemen who control our access to insulin" and "make billions off of it," but omit that

²⁰ See, e.g., Optum/Emisar Motion 2 & Caremark/Zinc Motion 4 (quoting The Capitol Forum, Fireside Chat with Commissioner Alvaro Bedoya (published June 15, 2023), *supra* note 19).

²¹ Moreover, the adjective "horrific" referred to a "story" that Commissioner Bedoya stated he had read on an insurance commissioner's website that involved "some of the allegations around steering" as they affected a cancer patient. The alleged incident had nothing to do with insulin, price, or rebates.

²² 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 (June 16, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/P214501BedoyaStatementRebatePolicy.pdf ("Bedoya Statement Regarding Policy Statement on Drug Rebates and Fees").

²³ Staff of S. Finance Comm. 116th Cong., Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug (January 14, 2021), *available at* Grassley-Wyden Insulin Report (FINAL 1).pdf (senate.gov).

the excerpts again cite to the Congressional study. ²⁴ *Compare* Optum/Emisar Motion 6–7 & n.23; Caremark/Zinc Motion 7, *with* Bedoya Statement Regarding Policy Statement on Drug Rebates and Fees at 1 n.1 (citing Congressional Study at 18, 23, 7). No reasonable person could conclude that Commissioner Bedoya's qualified comments passing along the findings and conclusions of another branch of government mean that he has an irrevocably closed mind in this proceeding. *S. Pac. Commc'ns Co.*, 740 F.2d at 991.

The Caremark/Zinc Respondents contend that Commissioner Bedoya has prejudged liability for the third count in the complaint (alleging an unfair act or practice) based on excerpts from his statement suggesting that PBMs' rebate negotiations "may create a conflict of interest" and "may also be commercial bribery." Caremark/Zinc Motion 8. This claim is yet another example of Respondents' misuse of excerpted phrases. Firstly, both of these statements consider the possibility of a law violation, not the conclusion that one has occurred. In addition, in this example, Commissioner Bedoya hypothesizes a possible negotiation between a PBM and a drug manufacturer and analyzes this negotiation under the Robinson-Patman Act, which is not a basis for the unfair act or practice charged in this case. ²⁵ Commissioner Bedoya's statement does not even in the hypothetical analyze the negotiation as an unfair act or practice under Section 5 of the FTC Act, the statute at issue here. ²⁶

Contrary to Respondents' claims, the point of Commissioner Bedoya's Statement Regarding the Policy Statement on Drug Rebates and Fees is to explain that the Commission "will use every tool . . . to investigate what's going on with drug manufacturers, pharmacy middlemen, and insulin prices." Bedoya Statement Regarding Policy Statement on Drug Rebates and Fees at 2. Promising to *investigate* PBMs and drug manufacturers does not evidence

²⁴ Commissioner Bedoya's citation for "billions" reinforces the primacy of manufacturers rather than PBMs: he points to net sales figures for Eli Lilly and Sanofi insulin products that total in the billions of dollars (or Euros), but does not identify the profits of any PBM, noting that their revenue statistics are "more difficult to identify." Statement of Commissioner Alvaro M. Bedoya Regarding Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products at 1 n.1.

²⁵ See Bedoya Statement 3.

The Optum/Emisar Motion also claims that the issuance of "a press release demonizing PBMs' 'illegal rebate schemes' as 'bribes'... leaves no doubt the Commissioners will find Optum Rx's alleged 'high rebates' are 'unfair' in violation of Section 5." Optum/Emisar Motion 6. But, here too, the cited discussion of "bribery" in the press release referred to commercial bribery, a potential violation of the Robinson-Patman Act. *See* Press Release, Fed. Trade Comm'n, 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 ("Paying or accepting rebates or fees in exchange for excluding lower cost drugs may constitute commercial bribery under Section 2(c) of the Robinson-Patman Act, which prohibits compensating an intermediary to act against the interests of the party it represents in the transaction."). The FTC press office's general discussion of commercial bribery under the Robinson-Patman Act, unconnected to any specific respondent, drug, or charge here, does not indicate Commissioners' prejudgment of the Section 5 claims in the present matter.

prejudgment. See supra Section VI.a. Instead, it demonstrates an open mind regarding facts and culpability, not an already fixed conviction.

d. Release of Interim Staff Report on the Section 6(b) Study of PBMs

The Optum/Emisar Respondents also allege that disqualification is necessary based on the Interim Staff Report from the Section 6(b) study of PBMs. Optum/Emisar Motion 3–4, 8. They argue that the Commission's release of the interim report, before the conclusion of the study, indicates "unacceptable hostility to PBMs" and a "vendetta." *Id.* at 3–4. They also aver that the Interim Staff Report's preliminary findings, as well as the Commission's decision in July 2023 to withdraw some prior research and reports on PBMs, ²⁷ suggest prejudgment in this case. *Id.* at 8.

Nothing in the Interim Staff Report indicates that Commissioner Bedoya has prejudged this matter. *Cement Institute* is squarely on point. There, the Supreme Court held that the Commission's reports under Section 6(b) condemning the industry-wide use of a basing point pricing system, and individual Commissioners' congressional testimony along the same lines, did not disqualify the Commissioners from an administrative adjudication involving the same practices. 333 U.S. at 700–01. As noted *supra* in Section VI.a, the Court held that the fact that the Commission had entertained certain views as the result of its prior ex parte investigation did not mean that the minds of its members were irrevocably closed on the subject of the respondents' practices. *Id.* at 701. Moreover, disqualifying Commissioners based on an industry study "would to a large extent defeat the congressional purposes which prompted passage of the Trade Commission Act" and would render "experience acquired from their work as commissioners . . . a handicap instead of an advantage." *Id.* at 701–02. Here, too, the Interim Staff Report, which in any case reflected the preliminary findings of *staff*, not the Commission, does not indicate that Commissioner Bedoya has a closed mind on the merits and should be precluded from adjudicating this case. *See* Bedoya Statement 4.

The Optum/Emisar Respondents suggest that there is something improper about the Commission releasing an *interim* report and cautioning against reliance on some older advocacy. Optum/Emisar Motion 3–4, 8. Authorizing release of an Interim Staff Report before conclusion of the study, however, does not show bias or prejudgment. In January of 2024, a bipartisan group of Senators sent Chair Khan a letter urging her to expedite the study and provide an interim progress report. ²⁸ The study had been delayed by the slow pace of document and data production

²⁷ Fed. Trade Comm'n Statement Concerning Reliance on Prior PBM-Related Advocacy Statements and Reports That No Longer Reflect Current Market Realities (July 20, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/CLEANPBMStatement7182023%28OPPFinalRevisionsnoon%29.pdf; see also Press Release, Fed. Trade Comm'n, FTC Votes to Issue Statement Withdrawing Prior Pharmacy Benefit Manager Advocacy (July 20, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/07/ftc-votes-issue-statement-withdrawing-prior-pharmacy-benefit-manager-advocacy.

²⁸ Letter from Sen. Grassley et al. to Chair Khan (Jan. 22, 2024), https://www.grassley.senate.gov/imo/media/doc/grassley_cantwell_colleagues_to_ftc_-pbm_investigation.pdf.

by the companies in response to the Section 6(b) compulsory orders. ²⁹ Notwithstanding those delays, the Commission had enough information to provide the public with a material update on the study, and therefore authorized release of the Interim Staff Report.

Nor is any bias or prejudgment evidenced by the Commission's statement cautioning against reliance on certain earlier advocacy statements and reports that no longer reflected market realities. The Commission issued its statement of caution in light of the ongoing Section 6(b) study and significant changes in the PBM industry over the prior two decades, including increased vertical integration and horizontal concentration; the growth of PBM rebates, list prices, and certain types of fees; and the expiration of prior FTC consent orders. The Commission's statement contains no opinions or conclusions about insulin or the charges against Respondents, and it does not indicate that Commissioner Bedoya's mind is irrevocably closed as to the merits of the case.

e. Attendance at Events

Respondents contend that Commissioner Bedoya must be disqualified because he attended events they believe reflect an anti-PBM viewpoint. Optum/Emisar Motion 3, 10; ESI Motion 7–8; Caremark/Zinc Motion 2, 4. They point to Commissioner Bedoya's attendance at events organized by the National Community Pharmacists Association, including a meeting with independent pharmacy owners. Optum/Emisar Motion 3; ESI Motion 7–8; Caremark/Zinc Motion 4.

To support their argument that attendance at even a single event "predominantly" favoring one side requires disqualification, Respondents point to *In re School Asbestos Litigation*, 977 F.2d 764 (3d Cir. 1992), which involved disqualification of a federal judge. Optum/Emisar Motion 10; ESI Motion 7. However, *School Asbestos Litigation* did not rest simply on the fact that the judge went to an event during a pending litigation, but instead considered the circumstances of and activities at the event. The court noted that:

[The judge] attended a predominantly pro-plaintiff conference *on a key merits issue*; the conference was indirectly sponsored by the plaintiffs, largely with funding that he himself had approved; and his expenses were largely defrayed by the conference sponsors with those same court-approved funds. Moreover, [the judge] was . . . exposed to a Hollywood-style 'pre-screening' of the plaintiffs' case: thirteen of the eighteen expert witnesses the plaintiffs were intending to call gave presentations very similar to what they expected to say at trial.

²⁹ Letter from Chair Khan to Sen. Grassley, at 2 (Feb. 13, 2024), https://www.grassley.senate.gov/imo/media/doc/ftc to grassley - pbm 6b study.pdf.

³⁰ Statement Concerning Reliance on Prior Advocacy, *supra* note 27, at 2–3.

³¹ As discussed below in Section VI.g, the disqualification standard for an administrative adjudicator is more flexible than the standard that applies to a federal judge.

977 F.2d. at 782 (emphasis added). Indeed, the court emphasized that it "need not decide whether any of these facts alone would have required disqualification, for . . . we believe that together they create an appearance of partiality that mandates disqualification." *Id*.

Unlike School Asbestos Litigation, Commissioner Bedoya's participation in the meetings cited by Respondents occurred before this case was filed and did not involve the specific issues related to Respondents' practices involving insulin. See S. Pac. Commc'ns Co., 740 F.2d at 991 (stating that the standard is "whether the [adjudicator's] mind is 'irrevocably closed' on the issues as they arise in the context of the specific case"). His mere attendance does not show that his mind is irrevocably closed as to the merits of this case. See In re Aguinda, 241 F.3d 194, 204 (2d Cir. 2001) (stating that disqualification was not appropriate even if, among other factors, an event attended by a judge presumably favored one viewpoint); see also Bedoya Statement 3 (noting that Commissioner Bedoya has attended events and meetings with organizations representing a wide range of views, including the national association representing PBMs).

f. Respondents' Case Law is Distinguishable

Respondents rely on a line of cases involving allegedly disqualifying statements and actions of past Commission Chairman Paul Rand Dixon in an effort to show that Commissioner Bedoya should be disqualified here. However, Commissioner Bedoya's statements and conduct are demonstrably different in substance and context from the statements and conduct by Chairman Dixon in the *Texaco*, *Cinderella Career and Finishing Schools*, and *American Cyanamid* cases that Respondents cite.

In *Texaco*, while an enforcement matter was pending before the ALJ, Chairman Dixon gave a speech in which he identified by name several companies, including the respondent, as engaging in practices that "plague you [the audience]." 336 F.2d at 759. Chairman Dixon then listed the practices that were the subject of the enforcement proceeding before the ALJ and stated that the Commission would pursue more such cases to vindicate fair competition in the industry. *Id. Texaco* carries no weight because Respondents challenge no statement of Commissioner Bedoya's during the pendency of the proceeding. Beyond that, Commissioner Bedoya's statements never approach *Texaco's* fact pattern where an adjudicator identified specific parties that had engaged in unlawful conduct, describing the Commission's plans for future enforcement and thereby making manifest his predetermination that the respondent's conduct was illegal.

Cinderella II also is distinguishable. That case involved a speech by then-Chairman Dixon regarding a matter that at the time was pending, not before the ALJ, but before the Commission itself (including Dixon). 425 F.2d at 589–90. The court made clear that its concern was with Chairman Dixon's speaking on "a case awaiting his official action." *Id.* at 591. Moreover, Chairman Dixon's comments in *Cinderella II* betrayed a prejudgment that is absent here. ³² Thus, *Cinderella II* thus does not require recusal.

³² In *Cinderella II*, Chairman Dixon publicly importuned newspaper editors not to run ads for various types of patently fraudulent products, such as ads promising that one could "becom[e] an airline's hostess by attending a charm school." 425 F.2d at 589–90. Dixon made the comments while a case for false

In American Cyanamid, the Commission's underlying enforcement proceeding dealt with alleged misconduct including price fixing in the sale of tetracycline, an antibiotic. Am. Cyanamid Co. v. FTC, 363 F.2d 757, 761–62 (6th Cir. 1966). Before taking on the role of FTC Chairman, and while the Commission's complaint against the respondents was already pending, Dixon had served as Chief Counsel and Staff Director of the Senate Judiciary Committee's Subcommittee on Antitrust and Monopoly. Id. at 763, 765. In that role, he had played an active part in investigating the very same conduct by the very same parties that was the subject of the then-pending FTC proceeding. Id. at 765, 768. The court held that Chairman Dixon should have recused himself from the FTC proceeding. Id. at 768. The court reasoned that fundamental fairness requires that "one who participates in a case on behalf of any party... take no part in the decision of that case by any tribunal on which he may thereafter sit." Id. at 767 (emphasis added) (internal quotation omitted).

Unlike in *American Cyanamid*, Commissioner Bedoya did not "participate[] in [the] case" now before the Commission. *Id.* As the court explained, the Congressional "hearings were concerned specifically, among other things, with issues which were decided against petitioners by the Commission in the instant case." *Id.* at 765. The court emphasized that the Commission is a fact-finding body and that, as Chairman, Dixon sat as a trier of many of the same facts that he himself had developed as Chief Counsel. *Id.* at 767. Respondents do not allege that Commissioner Bedoya had any role in developing the facts of this proceeding in a legislative capacity or otherwise. ³³ Thus, *American Cyanamid* is inapposite.

g. The Federal Ethics Regulations and Judicial Code Do Not Provide a Basis to Disqualify

The ESI Respondents claim in their Motion that government ethics regulations and/or the code of judicial conduct require Commissioner Bedoya to recuse himself from this proceeding.³⁴ However, neither of those sources of authority changes our view that Commissioner Bedoya may properly participate in the adjudication here. The government ethics regulation at 5 C.F.R.

advertising against respondent's career college and finishing school was pending before him. *Id.* at 589. The court found the connection between the pending case and the comments to be sufficiently close that the speech gave the appearance that "the ultimate determination of the merits [would] move in predestined grooves." *Id.* at 590; *see also id.* at 591 (noting that Dixon showed poor judgment in "directing his shafts and squibs at a case awaiting his official action"). Here, Commissioner Bedoya made no comments during a pending adjudication indicating that he had made a decision that the PBMs' conduct was unlawful. *Cinderella II* thus has no application.

³³ The court explained the limitation of its holding, stating that "[o]ur decision on this issue goes no further than to hold that disqualification is required when, as in the present case, the legislative committee investigation involved the same facts and issues concerning the same parties named as respondents before the administrative agency" *Am. Cyanamid*, 363 F.2d at 768.

³⁴ ESI Motion 7–8 (citing, *inter alia*, 5 C.F.R. § 2635.501(a); Code of Conduct for U.S. Judges, https://www.uscourts.gov/sites/default/files/code_of_conduct_for_united_states_judges_effective_march_12_2019.pdf).

§ 2635.501(a) is intended to ensure that an employee takes appropriate steps to avoid participating in particular matters involving specific parties that may cause a reasonable person with knowledge of the relevant facts to question their impartiality. Section § 2635.502(a) of the government ethics regulations addresses (1) financial interests of members of the employee's household, and (2) matters involving persons with whom the employee is in a covered relationship, such as persons with whom the employee seeks a business or financial relationship. No one alleges any financial interest of any member of Commissioner Bedova's household in this proceeding, nor any covered relationship with any party involved in the matter, so these parts of the rule are not pertinent. To the extent Respondents raise an issue under a final, catchall clause, which covers other circumstances that raise questions regarding impartiality, 5 C.F.R. §§ 2635.501(a), 2635.502(a)(3), Commissioner Bedoya concluded that none of his prior statements creates the appearance that he lacks impartiality in this matter, see Attachment A, and we find no basis for his disqualification. As we have explained above, a reasonable person would not question Commissioner Bedoya's ability to judge this proceeding impartially based merely on his attendance at certain meetings, his factual statements about the Commission's activities, and his statements about the PBM industry that do not judge particular claims or parties, including statements only relaying the concerns that other stakeholders have raised with the Commission. Supra at Sections VI.a-e. Respondents have failed to demonstrate that Commissioner Bedoya's mind is closed or that a reasonable person would perceive it to be. See Facebook, Inc., 581 F. Supp. 3d at 65.³⁵

Further, the ESI Respondents' citation to the code of conduct applicable to federal judges is inapposite. First, the judicial disqualification case on which the ESI Respondents rely, *School Asbestos Litigation*, is readily distinguishable. ESI Motion 7. As discussed above in Section VI.e, in that case a federal judge attended a putative scientific conference at which the speakers were expert witnesses whom the plaintiffs proposed to call at trial. 977 F.2d at 779–80. The conference was organized by plaintiffs' counsel using settlement fund monies that had been approved by the judge without defendants' knowledge. *Id.* at 779. No facts alleged here even approach those presented in *School Asbestos. Cf. United States v. Sampson*, 148 F. Supp. 3d 75, 80, 82 (D. Mass. 2015) (a reasonable person could not question a judge's impartiality in a death penalty case where the judge moderated a panel discussion and one panelist later submitted an affidavit before him).

Moreover, the statutory standards that govern disqualification of federal judges are not designed to, and do not, mirror the due process standard that applies to administrative adjudicators. The latter standard is more flexible, such that a comment that would not disqualify a federal judge would necessarily also not disqualify an administrative adjudicator. See S. Pac. Commc'ns, 740 F.2d at 990 n.9 (explaining that, because the statutory requirements for disqualification of federal judges establish a broader basis for disqualification than applies in ensuring the right to a fair trial guaranteed by the due process clause, a determination that a judge is not disqualified for bias "necessarily includes a determination that the right to a fair trial is not violated by the judge's presiding over the case"); see also N.Y. State Inspection, Sec. & L. Enf't Emps., Dist. Council 82 v. N.Y. State Pub. Emp. Rels. Bd., 629 F. Supp. 33, 48 (N.D.N.Y. 1984)

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³⁵ As we noted in *Meta Platforms, Inc.*, the district court in *Facebook* found the analysis under the ethics regulation to be subsumed in, and disposed of by, the due process analysis that it had conducted. Order Den. Pet. for Recusal, *In re Meta Platforms, Inc.*, No. 9411, 2023 WL 1861224 (F.T.C. Feb. 1, 2023).

("Instead of transplanting standards from the judicial to the administrative context, the court finds that it must evaluate the procedures allegedly employed by the defendants against a more flexible touchstone derived from *Withrow* and its progeny"); Order Den. Mot. to Disqualify, *In re Intuit Inc.*, No. 9408, 2023 WL 7104051, at *2 n.3 (F.T.C. Oct. 19, 2023); Order Den. Pet. for Recusal, *In re Meta Platforms, Inc.*, No. 9411, 2023 WL 1861224, at *4 (F.T.C. Feb. 1, 2023).

VII. Conclusion

For the foregoing reasons, we find no basis to disqualify Commissioner Bedoya from participating in this proceeding.

IT IS HEREBY ORDERED THAT the Respondents' Motions to disqualify Commissioner Bedoya are **DENIED**.

By the Commission, Commissioners Ferguson and Holyoak recused, Commissioner Bedoya not participating.

April J. Tabor Secretary

SEAL: ISSUED: January 14, 2025

Attachment A



UNITED STATES OF AMERICA Federal Trade Commission

WASHINGTON, D.C. 20580

Statement of Commissioner Alvaro M. Bedoya Regarding Petitions for Recusal from Involvement in the Matter of Insulin Commission File No. D09437

January 10, 2025

On October 8, 2024, Caremark, LLC and Zinc Health Services, LLC ("Caremark"); Express Scripts, Inc., Evernorth Health, Inc., Medco Health Services, Inc., and Ascent Health Services LLC ("ESI"); and Optum Rx, Inc., Optum Rx Holdings LLC, and Emisar Pharma Services LLC ("Optum Rx") (collectively, "Respondents") filed petitions seeking my recusal from *In the Matter of Insulin: Caremark Rx et al.*

Respondents assert that my participation as an adjudicator in this matter would violate both due process and my obligations under the federal ethics rules. In support of their respective motions, Respondents cite to several pieces of evidence: (1) a Statement regarding 6(b) Orders to Study Contracting Practices of Pharmacy Benefit Managers issued on June 7, 2022; (2) a Statement regarding the Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products issued on June 16, 2022; (3) Prepared Remarks entitled "Return to Fairness" delivered on September 22, 2022; (4) a June 7, 2023 interview with *The Capitol Forum*; (5) an October 26, 2023 Fireside Chat at *The Capitol Forum* 's Healthcare Competition Conference; and (6) my attendance at two events where I spoke with community pharmacists. In addition, Optum Rx cites to the Commission's decisions to issue staff's interim PBM 6(b) report in July 2024 and withdraw prior guidance relating PBMs in July 2023. After careful examination of my prior statements and actions, for the reasons discussed below, I decline to recuse myself from this matter.

Recusal of an administrative adjudicator is required only in instances where a "disinterested observer may conclude that [the adjudicator] has in some measure adjudged the facts as well as the law of a particular case in advance of hearing it." None of the statements nor actions cited by Respondents demonstrate that I have prejudged "the facts as well as the law" of this matter. Respondents seek to create the appearance of prejudgment by cherry-picking partial quotes and, in some instances, misrepresenting my prior statements. When reviewed in their entirety, in context, it is clear that none of my prior statements or actions satisfy the test for disqualification.

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¹ Cinderella Career & Finishing Schs., Inc. v. FTC, 425 F.2d 583, 591 (D.C. Cir 1970) (quoting Gilligan, Will & Co. v. SEC, 267 F.2d 461, 469 (2d Cir. 1959)); Texaco Inc. v. FTC, 336 F.2d 754 (D.C. Cir. 1964), vacated on other grounds, 381 U.S. 739 (1965).

Respondents argue that various statements contained in my June 7, 2022 statement regarding 6(b) Orders to Study Contracting Practices of Pharmacy Benefit Managers² ("June 7 statement") are evidence that I have prejudged this matter. Read in its entirety, it is readily apparent the June 7 statement provides no support for Respondents' motions. Indeed, my June 7 statement never mentions rebates—*not once*. Nor does it make any reference to insulin or the legality of "PBM business practices." In my statement, I make the observation that PBMs "control" to some degree patients' access to medication. However, I did not at any time assert that any PBM has violated the law.

Respondents also take issue with the statement I issued on June 16, 2022, alongside the issuance of the Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products ("June 16 statement"). Respondents selectively quote portions of the June 16 statement, without providing relevant context, creating a misimpression of bias and prejudgment. However, a full reading of my June 16 statement makes clear to any "disinterested observer" that I retained a "completely open mind to decide the facts and apply the applicable law to the facts" in this matter. Indeed, my June 16 statement explicitly acknowledges that we as a Commission had work to do to understand the facts, declaring that "we have to investigate what's going on with drug manufacturers, pharmacy middlemen, and insulin prices." That being said, I will address the specific statements highlighted by Respondents in their motions.

All three Respondents cite to portions of the second sentence of my June 16 statement which, in its entirety, reads: "The companies, who make insulin, and the middlemen who control our access to insulin, make billions off of it." Respondents, in their briefing, insert their own language or language from other parts of the statement in an effort to change the meaning of my words. However, on its face, it is clear this sentence is merely an observation that stakeholders in the pharmaceutical supply chain, including PBMs and manufacturers, earn substantial revenue from sales of insulin. Respondents do not contend that this is a fact in dispute, nor do they identify anywhere in the statement where I draw conclusions about the legality of *any* PBM practice, much less PBM rebating practices, in connection with insulin.

Caremark went a step further in its misrepresentation of my June 16 statement, asserting that I had "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." This quoted language is demonstrably incomplete: Caremark selectively removed key language that made clear I was summarizing the conclusions of a multi-year bipartisan Senate report on the issue of insulin prices and not drawing the conclusion myself.

² Alvaro Bedoya, Commissioner, Fed. Trade Comm'n, Statement Regarding 6(b) Orders to Study Contracting Practices of Pharmacy Benefit Managers (June 7, 2022),

 $https://www.ftc.gov/system/files/ftc_gov/pdf/Bedoya_Statement_re_PBM_Study_\%28FINAL\%29_6-7-2022.pdf.$

³ See S. Pac. Commc'ns Co. v. Am. Tel. & Tel. Co., 740 F.2d 980, 991 (D.C. Cir. 1984).

⁴ Alvaro Bedoya, Commissioner, Fed. Trade Comm'n, *Statement Regarding Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Product* (June 16, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/P214501BedoyaStatementRebatePolicy.pdf ⁵ *Id.* at 1.

Caremark also takes issue with the portion of the June 16 statement where I state: "If buyers (say, an insurer and their insured customers) use an agent (say, a PBM) to negotiate on their behalf, and that agent takes payment from the seller (say, a drug manufacturer), this may create a conflict of interest. It may also be commercial bribery violating Robinson-Patman." This statement provides no support for Caremark's allegations. To the contrary, it clearly demonstrates that my mind remained very much open on both law and facts. First, my statement makes clear that in my view payments to a PBM by a drug manufacturer *may* create a conflict of interest not that it *would* create a conflict. Second, I suggested that such payments *may* be a violation of the Robinson-Patman Act, yet the complaint in this matter does not allege such a violation. Moreover, the quoted language does not state that any particular PBM has violated the law. Rather, it identifies tools available to the Commission in the event a law violation is uncovered.

Respondents also cite to remarks that I delivered on September 22, 2022 as evidence of my alleged bias. All three Respondents specifically focus on the closing line of the speech where I declare: "We all know that that is not what fair markets look like." Respondents' contention that this statement relates in any way to PBM rebating practices is again false. The speech makes no mention of rebates or insulin.

Respondents also argue that statements I made during a June 7, 2023 interview and an October 26, 2023 Fireside Chat with *The Capitol Forum* warrant my disqualification. Notably, the only reference to insulin during the entirety of either the interview or fireside chat was a description of anecdotes regarding patients' inability to fill their insulin prescriptions following a natural disaster. I did discuss the general topic of rebates during both the June 7 Fireside Chat and the October 26 Interview. However, a full reading of both the interview and fireside chat clearly shows that my mind remained open and the facts and the law at issue in this matter had not been adjudged. I specifically acknowledged that "I can see a world where rebates are good. And so I don't think the rebates as a whole are a bad idea" and that we needed to "kick the tires" on allegations around rebating practices.

Respondents claim that my attendance at events hosted by the National Community Pharmacists Association (NCPA) is evidence that I am biased and lack impartiality. However, they do not point to any statements at any of these events demonstrating this purported bias. As a Commissioner, I have attended events and hosted meetings with many different organizations with wide ranging views. In my capacity as FTC Commissioner, I specifically and without prompting requested and hosted a meeting with the Pharmaceutical Care Management Association (PCMA), which is the national association representing PBMs, to understand the perspective of its members. Respondents' claims that my participation in events with NCPA somehow evince bias lack merit.

⁶ *Id*. at 2.

⁷ Alvaro Bedoya, Commissioner, Fed. Trade Comm'n, Remarks on "Returning to Fairness" to the Midwest Forum on Fair Markets (Sept. 22, 2023),

 $https://www.ftc.gov/system/files/ftc_gov/pdf/returning_to_fairness_prepared_remarks_commissioner_alvaro_bedoy\ a.pdf.$

OptumRx asserts that the release of an interim staff report on PBMs in July 2024 is evidence of prejudgment. The interim staff report stems from the Commission's ongoing 6(b) study of PBMs and their impact on the access to and affordability of prescription medications. As Commissioner Ferguson noted in his concurring statement, the interim staff report "is not a statement or report of the Commission. It is instead the staff's report to the Commission about how it understands our complex healthcare markets..." Section 6 of the FTC Act provides the Commission with a powerful investigative tool allowing it to conduct wide-ranging studies that do not have a specific law enforcement purpose. Section 6(f) authorizes the Commission to "make public from time to time" portions of the information that it obtains, where disclosure would serve the public interest. 15 U.S.C. Sec. 46(f). The Commission exercised that congressionally mandated authority when it authorized the release of staff's interim report.

OptumRx also cites the Commission's withdrawal of prior PBM-related advocacy statements and reports as evidence of impermissible bias. The Commission's statement announcing the withdrawal cautioned the public against relying on eleven prior FTC statements and reports on the PBM industry "published or issued between 2004 and 2014." The statement noted that there have been substantial changes to the industry over the last 20 years and as a result the Commission was no longer confident that the Commission's prior conclusions about the PBM industry remained valid. The Commission did not, however, draw any legal conclusions, nor did it suggest that any PBM had violated the law. Rather, it specifically acknowledged the need to continue studying the industry so that the Commission could determine which of the agency's prior conclusions remain valid.

Due process requires the recusal of an administrative adjudicator only where "a disinterested observer may conclude that [the adjudicator] has in some measure adjudged the facts as well as the law of a particular case in advance of hearing it." To disqualify an agency adjudicator based on a public statement there must be a showing that the adjudicator "is not capable of judging a particular controversy fairly on the basis of its own circumstances." Merely expressing public views on legal or policy issues that may be implicated in the current proceedings does not require disqualification. Indeed, "[i]t is well established that the mere fact that [an adjudicator] holds views on law or policy relevant to the decision of a case does not disqualify him from hearing the case." Nor is disqualification required when an adjudicator has expressed those views. In each new case the [adjudicator] confronts a new factual context, new evidence, and new efforts at persuasion." As long as the adjudicator is capable of refining his views and "maintaining a completely open mind to decide the facts and apply the applicable

⁸ *Cinderella Career & Finishing Schs.*, 425 F.2d at 591 (quoting *Gilligan, Will & Co. v. SEC*, 267 F.2d 461, 469 (2d Cir. 1959)); *Texaco*, 336 F.2d at .

⁹ Hortonville Joint Sch. Dist. No. 1 v. Hortonville Educ. Ass'n, 426 U.S. 482, 493 (1976).

¹⁰ S. Pac. Commc'ns, 740 F.2d at 990; see also Phillip v. ANR Freight Sys., Inc., 945 F.2d 1054, 1056 (8th Cir. 1991) ("[R]ecusal is not required where the [adjudicator] has definite views as to the law of a particular case.") (quotation omitted).

¹¹ Cement Inst., 333 U.S. at 702-03; Ass'n of Nat'l Advertisers, Inc. v. FTC, 627 F.2d 1151, 1171 n.51 (D.C. Cir. 1979) (adjudicators "are free to decide cases involving policy questions on which they previously have expressed a view").

¹² S. Pac. Commc'ns, 740 F.2d at 991.

law to the facts, personal views on law and policy do not disqualify him from hearing the case."13

Courts have repeatedly resisted calls to order recusal based on general statements of law or policy. The Supreme Court in *FTC v. Cement Institute* addressed such a situation. There, the Commission had published reports condemning the industry-wide use of a basing point pricing system before it brought an administrative enforcement action against various companies for using this pricing system. ¹⁴ The Court rejected the argument that the Commission's reports and commissioners' congressional testimony that stated that the pricing system at issue was equivalent to price fixing in violation of antitrust laws was evidence of prejudgment in the price fixing case against the respondent. The Court ultimately held that, notwithstanding the prior reports and testimony, the FTC could still fairly adjudicate the case. ¹⁵

None of the statements or actions Respondents cite show that I have prejudged the "facts as well as the law" in the present case. Most of the cited statements were unrelated to insulin or rebating practices. However, in the few instances where I did discuss rebates, insulin, or both, I expressly acknowledged the need to investigate or "kick the tires" on various allegations. While I may have expressed general views of law and/or policy as it relates to insulin or rebating practices, none of my statements or actions satisfy the bar that must be met to require my disqualification. Respondents have simply failed to establish that any of my prior statements or actions give even the appearance that I have prejudged the facts at issue in this case or that I am incapable of deciding this case fairly based on the evidence presented.

In support of their respective petitions, Respondents cite three cases involving the disqualification of FTC Chairman Paul Rand Dixon. All three cases are factually distinct and easily distinguishable from the present matter.

In American Cyanamid Co. v. FTC, the court found that Chairman Dixon should have recused himself based on his prior involvement in a congressional investigation of the drug industry, including the sale by petitioners of the same drug at issue in the FTC's case. ¹⁶ The court pointed to the "depth of the investigation and the questions and comments by Mr. Dixon as counsel, as shown by the record in this case," as basis for requiring recusal. ¹⁷ The congressional investigation was "concerned specifically, among other things, with issues which were decided against petitioners by the Commission in the instant case and which are involved on the present petitions to review." The court found that during his congressional investigation work, the Chairman had "formed the opinion that [the drug's] prices were artificially high and collusive"—which were conclusions as to facts at issue in the case. ¹⁹

¹³ *Id*.

¹⁴ Cement Inst., 333 U.S. at 701. The Court also noted that the Commission's prior investigation of an industry cannot immunize practices investigated from any cease and desist order by the Commission, because that would frustrate the purpose of the FTC Act. *Id.* at 701-02.

¹⁵ *Id.* at 701.

¹⁶ 363 F.2d 757 (6th Cir. 1966).

¹⁷ *Id.* at 768.

¹⁸ *Id.* at 767.

¹⁹ *Id*.

The facts in *American Cyanamid* are distinguishable from the present case. Unlike Chairman Dixon, all of my statements and actions cited by Respondents in support of their motions were made or taken while serving in my current role as Commissioner; I have made no prior, separate, investigation into the allegations of any "depth" whatsoever. Additionally, unlike the statements at issue in *American Cyanamid*, none of my statements reached conclusions about whether PBM practices with respect to insulin or rebates were unlawful.

In *Cinderella*, the court held that statements made during a speech given by Chairman Dixon while an administrative appeal was pending before him warranted disqualification. The case before the Commission alleged that Cinderella had made false, deceptive, and misleading statements in its advertising. While the appeal was pending before the Commission, Chairman Dixon gave a speech on the topic of deceptive advertising and offered conduct that Cinderella had engaged in as an example of deceptive conduct. fIn the court's view, although Chairman Dixon did not name Cinderella in his speech, one could infer that his statement was related to the case pending before him. The court found the temporal proximity of the speech combined with the specific reference to the very conduct in which Cinderella had allegedly engaged allowed "the reasonable inference" that the remarks were related to the pending case. ²⁰

Finally, in *Texaco v. FTC*, the court determined that Chairman Dixon's participation in the adjudicatory proceeding violated due process based on a speech he gave while the matter was before the administrative law judge. In his speech, Chairman Dixon specifically identified respondents by name as engaging in practices that he believed violated the FTC Act. Explaining its decision, the court stated "[Chairman Dixon's] Denver speech, made before the matter was submitted to the Commission but while it was before the examiner, plainly reveals that he had already concluded that Texaco and Goodrich were violating the Act, and that he would protect the petroleum retailers from such abuses."²¹

Respondents attempt to draw parallels between the facts in *Cinderella* and *Texaco* with those in the present case. However, their reliance on *Cinderella* and *Texaco* is misplaced. Unlike Chairman Dixon, all of my prior statements challenged by Respondents were made well before the current case entered administrative adjudication. Additionally, unlike Chairman Dixon's statements, none of my prior statements mention any of the Respondents by name or describe facts with such specificity that their identity could be inferred. They also demonstrate my open mind with respect to the ultimate legality of any of the conduct in question.

Lastly, I reject Respondents argument that, even if I am not disqualified on due process grounds, federal ethics rules require my disqualification or recusal in this matter. I take seriously and have carefully reviewed, in consultation with the FTC's designated agency ethics official, my obligations under federal ethics rules. Federal ethics rules direct federal employees not to participate in matters that are "likely to have a direct and predictable effect on the financial interest of a member of the employee's household" or when "the employee has a covered

²⁰ Cinderella, 425 F.2d at 590, n. 10.

²¹ Texaco, 363 F.2d at 760.

relationship" with "a party to a particular matter" or a person who "represents a party to a particular matter." 5 C.F.R. § 2635.502.

The federal ethics rules also contain a catch-all provision, which directs federal employees to consider whether the facts are "likely to raise a question in the mind of a reasonable person about an employee's impartiality." 5 C.F.R. § 2635.502(a)(3). Although this provision appears in the context of a rule about financial conflicts and is most appropriately interpreted as applying to financial relationships that are not captured by other parts of the rule, some have argued that it applies to any situation that may "raise a question in the mind of a reasonable person about an employee's impartiality." Assuming for the sake of argument that this interpretation is correct, examination of the present facts reveals that federal ethics rules do not indicate that my recusal is warranted here.

First, I do not, and no one has alleged, that I have a "covered relationship" with a party or party representative in this proceeding. Further, this proceeding does not, and no one has alleged that it would, affect the financial interests of any member of my household. Finally, to the extent the catch-all provision is interpreted to capture situations outside the scope of possible financial conflicts, none of my prior statements create the appearance that I lack impartiality in this matter. Rather, I have expressed general concerns about the pharmaceutical supply chain industry and the impact on patients.

For all these reasons, I decline to recuse myself from this matter.