PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Andrew Ferguson, Chair**
Melissa Holyoak
Mark Meador

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

RESPONDENTS' MOTION TO DISMISS PURSUANT TO RULE 3.22

Pursuant to Rule 3.22 of the Commission's Rules of Practice, 16 C.F.R. § 3.22, Respondents respectfully move for an order dismissing the complaint for the reasons stated in the attached memorandum.

Respondents are: OptumRx, Inc., OptumRx Holdings, LLC, and Emisar Pharma Services LLC ("OptumRx Respondents"); Express Scripts, Inc., Evernorth Health, Inc., Medco Health Services, Inc., and Ascent Health Services LLC ("ESI Respondents"); and Caremark Rx LLC, and Zinc Health Services, LLC ("Caremark and Zinc").

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INTRODUCTION

The complaint should be dismissed because it disregards established limits on the reach of Section 5 of the FTC Act. The Commission alleges that some patients are paying high out-of-pocket costs for insulin drugs, and seeks to hold Respondents, three of many pharmacy-benefit managers ("PBMs") and the group purchasing organizations ("GPOs") they utilize, liable for the purported injury to those patients. But in its rush to reach that result, the complaint blows by the statutory constraints that Congress imposed to prevent the agency from advancing limitless theories of "unfairness" on industry. The complaint claims that Respondents engaged in unfair methods of competition. But it does not even attempt to identify the relevant market or any harm to competition in any market where respondents compete. While the complaint says some patients paid higher prices for some insulins, it fails to connect any method of competition by Respondents to that alleged harm. It also fails to allege facts to support any claim that Respondents' conduct lessened competition in any market. The complaint also claims that Respondents committed unfair acts or practices. But its unfairness allegations do not satisfy the basic statutory requirements to state a claim: They are untethered to any established public policy, invert time-tested standards of causation, and make only conclusory claims that the costs of the supposedly unlawful conduct are not outweighed by the benefits.

Respondents are not the only actors in the U.S. pharmaceutical supply chain. Drug manufacturers—not PBMs—set the "list price" or sticker price for their drugs, as the complaint admits. PBMs work for plan-sponsor clients, which include employers, unions, and governments. Those plan sponsors decide how to balance issues of cost and coverage to design the most attractive plan offerings for their members—subject to various state and federal laws. For example, plan sponsors choose which formularies (*i.e.*, lists of drugs) to use for their plans, the design of any

plan benefits, and copayments charged to their members, including for insulin. PBMs push drug manufacturers to compete for plan sponsors' business by offering conditional discounts. In turn, PBMs pass those discounts—*i.e.*, rebates—back to their plan-sponsor clients pursuant to contracts with those clients, and plan sponsors can use the savings to drive down premiums, copayments, or other costs for members.

Then-Chair Khan and then-Commissioners Slaughter and Bedoya, however, voted out a complaint alleging that Respondents, without any agreements among themselves, violated the FTC Act by supposedly "systematically preferring" drugs with high list prices on some of the different formularies they provide as *options* to plan-sponsor clients. But the complaint defies Section 5's limits at every turn.

The first claim alleges Respondents' practices are "unfair methods of competition" ("UMC"). Under binding precedent, "standalone" UMC claims (*i.e.*, those claims brought without accompanying claims under the Sherman or Clayton Acts) can succeed only when liability is determined in a way that closely tracks traditional antitrust analysis under the Sherman or Clayton Acts. UMC claims must (1) identify the market where the method's deviser competes, and (2) identify unfair methods of competition—*i.e.*, conduct that "significantly lessen[s] competition" with anticompetitive effects in that market. *E.I. du Pont De Nemours & Co. v. FTC* ("*Ethyl*"), 729 F.2d 128, 141 (2d Cir. 1984). Were it otherwise, the Commission would have "too much power to substitute its own business judgment," and market participants would be subject to "uncertain guesswork rather than workable rules of law." *Off. Airline Guides, Inc. v. FTC*, 630 F.2d 920, 927 (2d Cir. 1980); *accord Ethyl*, 729 F.2d at 128, 140; *Boise Cascade Corp. v. FTC*, 637 F.2d 573, 579, 581 (9th Cir. 1980).

The complaint does not allege any relevant market or that Respondents' conduct has harmed competition between or among PBMs, or with other industry participants. To the extent it alleges any "harm," that harm is simply that some patients allegedly pay more for certain insulin drugs if a sponsor unilaterally designs its plans a certain way. But the complaint nowhere connects those supposedly high prices to any *competition-reducing* conduct undertaken by Respondents. Moreover, the complaint makes no allegations that Respondents—collectively or individually—had any intent to harm competition and it recognizes legitimate business reasons for the challenged conduct. Consistent with this lack of intent, the complaint confirms net prices of insulin products have fallen since 2012. Compl. ¶ 129.

The complaint's second and third claims allege "unfair acts or practices." Specifically, they assert that some manufacturers set high list prices for insulin drugs, some plan sponsors independently preferred those drugs, and some insulin patients were harmed because they independently enrolled in plans that tied out-of-pocket costs to list prices. But the complaint's theory requires ignoring three of Section 5's limits on unfair practices claims. First, the Commission must ground its allegations in notions of well-established public policies; the complaint points to none. Second, the FTC Act requires the Commission to allege causation, but it has not. Respondents did not plausibly cause the alleged harm, *i.e.*, the higher out-of-pocket costs (some) insulin patients allegedly paid. Instead, those costs were imposed by intervening actors, including drug manufacturers who set drug prices independent of Respondents, as the complaint concedes (as it must), and plan sponsors who set member copayment amounts. Third, the complaint fails to adequately allege facts to support its conclusory view that any injuries are not "outweighed by countervailing benefits" to the allegedly injured patients or to other patients or plans. In fact, Respondents prefer drugs with a lower net cost so they can *lower* the cost for

plans, who in turn can lower out-of-pocket costs, including premiums, for patients. Because the complaint fails to satisfy these statutory requirements, the unfair-acts claims fail as a matter of law.

The Commission should dismiss the complaint and confirm that it neither is a legislature nor has the power to ignore Section 5's important limitations on what it means for methods of competition or acts or practices to be "unfair."

BACKGROUND

I. The FTC Act Places Important Limits On The Commission's Section 5 Authority

This action arises from prior commissioners' attempt to rewrite Section 5. The Commission is "not a legislature" but "an administrative agency wielding only the power lawfully conferred on [it] by Congress." Dissenting Statement of Comm'r Andrew Ferguson, *In the Matter of Non-Compete Clause Rule* at 7, No. P201200 (June 28, 2024) ("Non-Compete Statement").[1] While the statute's reference to "unfair" methods of competition and acts or practices provides the Commission with some flexibility, the "Commission is hardly free to write its own law." *Am. Fin. Servs. Ass'n v. FTC*, 767 F.2d 957, 968 (D.C. Cir. 1985).

For decades, the Commission exercised its Section 5 authority within statutory limits. After courts in the 1980s rejected three Commission attempts to bring broad standalone UMC claims, the Commission virtually ceased litigating such claims. Even the Commission's bipartisan 2015 policy statement, which contemplated authority to bring *some* standalone UMC claims, reaffirmed that such claims must remain "aligned with the other antitrust laws." *Statement of Enforcement Principles*, 80 Fed. Reg. 57056, 57056 (Sept. 21, 2015).

Many of the limits on the Commission's Section 5 authority arose after the FTC "test[ed] the limits of" its authority over unfair acts or practices in the 1970s by asserting "broad, newly

[1] https://www.ftc.gov/system/files/ftc_gov/pdf/ferguson-noncompete-dissent.pdf.

found theories of unfairness" based on "personal values." J. Howard Beales, *The FTC's Use of Unfairness Authority*, FTC (May 30, 2003);[2] FTC Policy Statement on Unfairness (Dec. 17, 1980).[3] Congress responded by refusing to fund the agency, leading the FTC to adopt limitations on its authority. *Id.* Congress then codified those limitations, directing that a practice is "unfair" only if it is "likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition." 15 U.S.C. § 45(n).

Courts rigorously enforce these restraints, dismissing FTC complaints that target conduct without satisfying Section 5(n)'s unfairness criteria, such as conduct that does not *directly* cause consumer injury. *E.g.*, *FTC v. Kochava Inc.*, 671 F. Supp. 3d 1161, 1171 (D. Idaho 2023). They also require the FTC to "find the standards of unfairness it enforces in 'clear and well-established' policies that are expressed in the Constitution, statutes, or the common law." *LabMD, Inc. v. FTC*, 894 F.3d 1221, 1231 (11th Cir. 2018). Courts thus ensure that the Commission is not "allowed to intervene at will whenever it believes the market is not producing the 'best deal' for consumers." *Am. Fin.*, 767 F.2d at 982.

Under then-Chair Khan, however, the Commission ignored these statutory constraints. In 2022, the FTC adopted a novel view of the Commission's authority to enforce its standalone UMC claims. Policy Statement Regarding the Scope of Unfair Methods of Competition (Nov. 10, 2022) ("2022 UMC Statement").[4] The 2022 UMC Statement purports to state "general principles" for determining whether business practices violate the UMC provision. *Id.* at 2. The statement asserts

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[2] https://www.ftc.gov/news-events/news/speeches/ftcs-use-unfairness-authority-its-rise-fall-resurrection.

[3] https://www.ftc.gov/legal-library/browse/ftc-policy-statement-unfairness.

[4] https://www.ftc.gov/system/files/ftc_gov/pdf/P221202Section5PolicyStatement.pdf.

that, contrary to binding judicial precedent, a method of competition is unfair if it meets only "two key criteria." *Id.* at 9. "First, the conduct may be coercive, exploitative, collusive, abusive, deceptive, predatory, or involve the use of economic power of a similar nature." *Id.* And "[s]econd, the conduct must tend to negatively affect competitive conditions." *Id*.

As Chairman Ferguson later explained, the 2022 UMC Statement defies established law, is of "incredible breadth," and "purport[s] to declare *ipse dixit* the elements of an unfair-method-of-competition claim." *In the matter of Grubhub, Inc.*, No. 2023157 (Dec. 17, 2024) ("Grubhub Statement") at 3-4.[5] Instead of "providing meaningful guidance to business," the 2022 UMC Statement purported to give the Commission "authority summarily to condemn essentially any business conduct it finds distasteful." Dissenting Statement of Comm'r Christine S. Wilson Regarding 2022 Policy Statement, No. P221202 (Nov. 10, 2022).[6]

II. Congress And Agencies Have Acknowledged And Often Protected Longstanding Rebate And Formulary Practices

Congress gave agencies other than the FTC primary responsibility to oversee certain rebate and formulary practices. For instance, the Departments of Health and Human Services ("HHS"), Labor ("DOL"), and Treasury oversee or administer Medicare, Medicaid, Affordable Care Act, and ERISA plans, 42 U.S.C. §§ 1395b-2-10, 1395kk, 1396(b)(14), 1396c, 18031(c); 29 U.S.C. §§ 1302-05.

Further, Congress has recognized that rebates negotiated by PBMs benefit those federal programs and competition generally. For example, in the Medicare Part D context, Congress explicitly contemplates the use of "rebates" and "discounts" from manufacturers to reduce the net

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[5] https://www.ftc.gov/system/files/ftc_gov/pdf/ferguson-grubhub-statement.pdf.

[6] https://www.ftc.gov/system/files/ftc_gov/pdf/P221202Section5PolicyWilsonDissentStmt.pdf.

cost of prescription drugs. 42 U.S.C. § 1395w-102(d)(1)(B). Congress also mandated that HHS "may not interfere with the negotiations between drug manufacturers and pharmacies and [Part D] sponsors," including the rebates that flow from those negotiations, in "order to promote competition." *Id.* § 1395w-111(i)(1). Consistent with that mandate, HHS "may not require a particular formulary" when it reviews proposed health plans. 42 C.F.R. § 1395w-111(i)(2).

Similarly, the Office of Personnel Management expects its Federal Employee Health Benefit plans to contract with PBMs to negotiate rebates and "[p]ass-through transparent pricing … based on the PBM's costs in which the Carrier receives the value of the PBM's negotiated discounts, rebates, or other credits."[7]

In the ERISA context, too, Congress left the design and implementation of employer-sponsored plan structures exclusively to plan sponsors by preempting state laws that relate to employee benefit plans. 29 U.S.C. § 1144(a); *see Lockheed Corp. v. Spink*, 517 U.S. 882, 887 (1996). Plan sponsors may hire PBMs to help administer their plans. *PCMA v. Mulready*, 78 F.4th 1183, 1196-97 (10th Cir. 2023) ("regulating PBMs function[s] as a regulation of an ERISA plan itself"). But Congress intended that plan sponsors—not the FTC, PBMs, or anyone else—have control over selecting formulary products, using rebates to lower plan costs, and setting member copayments.

Indeed, Congress has even acted to preserve the existing rebate system, enacting legislation requiring drug manufacturers to pay rebates to Medicare if the manufacturers increase list prices faster than the rate of inflation. Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 11301 (2022). And when HHS, DOL, and Treasury promulgated a "Rebate Rule" to eliminate certain

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[7] https://www.ftc.gov/system/files/ftc_gov/pdf/P221202Section5PolicyWilsonDissentStmt.pdf.

safe harbors for rebates negotiated by PBMs, 85 Fed. Reg. 76666 (Nov. 30, 2020), Congress prohibited HHS from implementing or enforcing the rule before January 2032, Pub. L. No. 117-169, § 11301. The Congressional Budget Office projected a "significant" cost increase in federal spending of "about $177 billion over the 2020-2029 period" if the Rebate Rule took effect. CBO, *Incorporating the Effects of the Proposed Rebate Rule* 1 (May 2019).[8]

III. The Commission Voted Out A Complaint Alleging That Rebating And Formulary Exclusions Violate The FTC Act, While Acknowledging Competition Among PBMs

In September 2024, then-Chair Khan and then-Commissioners Slaughter and Bedoya—with Commissioner Ferguson and Commissioner Holyoak recused—voted to issue the complaint in this case against Respondents. They decided to bring this complaint and its untested theories in an in-house administrative proceeding rather than in federal court.

Respondents include three of many competing PBMs and the GPOs they utilize. Compl. ¶¶ 15-27. PBM clients include health-plan sponsors, which, as described above, have control over designing formularies and their benefit plans. *Id.* ¶ 4. In response to demand from some health-plan sponsors for PBMs to design formulary options that reduce costs for their plan members, PBMs offer a menu of formulary designs that plan sponsors can choose to adopt as their own or customize. *Id.* ¶¶ 28, 32-38, 50.

As the complaint repeatedly admits, Respondents do not set the prices of prescription drugs. Instead, each drug manufacturer sets the list price—in the complaint's terms, the wholesale acquisition cost ("WAC")—for its own prescription drugs. Compl. ¶¶ 2, 6, 40, 78, 119-23, 134-35, 139-43, 236-41. List prices—like a car's sticker price—do not reflect discounts. *Id.* Some

[8] https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf.

manufacturers choose to offer the same drug at "high WAC" and "low WAC" list price points. *Id.* ¶ 139.

PBM Respondents "[n]egotiate with pharmaceutical manufacturers for rebates" off manufacturers' list prices to satisfy their clients' demand for lower net costs. Compl. ¶ 28; *see also id.* ¶¶ 31, 40. The complaint admits Respondents' services are a "game changer" for plan sponsors because their services provide "significant leverage to extract price concessions from drug manufacturers." *Id.* ¶¶ 5, 38. Respondents negotiate price concessions from drug manufacturers in part by offering formulary options that prefer the manufacturer's drug, which can boost a given drug's sales. *Id.* ¶¶ 38-39, 43-44. Drug manufacturers thus compete against other manufacturers by offering deeper discounts to PBM clients, and plan sponsors can use formulary positioning (like exclusions) to bring that competition to bear. *Id.* ¶¶ 43-44. This results in lower net costs. *Id.* ¶ 129 (charting Humalog price history).

The complaint concedes both that plan sponsors benefit from these multiple layers of competition—among manufacturers and among PBMs—and that plan sponsors, not Respondents, determine which formularies to use within this competitive landscape. Some plan sponsors prefer formularies that prioritize lowest net costs, while other plan sponsors prefer formularies that prioritize expanded choices of drugs. Compl. ¶ 34; *see also id.* ¶¶ 35-37, 174. Respondents compete with each other to offer plan sponsors menus of formulary options to address all these diverse preferences, and Respondents also work with plan sponsors to implement customized formularies or those developed by third parties. *Id.* ¶ 50. Plan sponsors use competition among PBMs to help decide what type of formulary best serves their members. *Id.*

Despite joining three Respondent groups in a single action, the complaint also makes clear Respondents act independently and compete with one another to provide the greatest savings to

plan sponsors through different "rebate payments" as Respondents "pursue clients." Compl. ¶ 106. The complaint makes no allegation that Respondents have taken any action collectively or individually to reduce this competition between PBMs, and indeed the complaint highlights that PBM-to-PBM competition is robust. For example, each Respondent allegedly introduced different "exclusive" formularies several years apart, *id.* ¶¶ 103-05, negotiated different rebate rates with the insulin manufacturers, *id.* ¶ 44, developed formulary options that prefer different drugs with different manufacturers, *id.* ¶ 111, and independently negotiated different fees with drug manufacturers, *id.* ¶¶ 46, 48-49.

Respondents pass the majority of rebates through to their plan-sponsor clients, Compl. ¶ 52, and plan sponsors decide how rebates are used. For example, plan sponsors may share rebates with their members at the point of sale, which can reduce out-of-pocket costs for members who buy rebated drugs. *Id.* ¶¶ 55, 66, 184, 196-97. Plan sponsors can also use rebates to reduce plan premiums, lower certain other members' out-of-pocket costs, or otherwise improve plan benefit offerings through richer offerings and greater coverage. *Id.* Again, plan sponsors, not Respondents, have control over these decisions.

By giving manufacturers an incentive to compete for formulary placement and by negotiating substantial rebates off the list price of drugs, PBMs compete to lower the net cost of drugs for their plan-sponsor clients. Compl. ¶ 129 (charting Humalog price history). What's more, the complaint reflects stale concerns that have not kept up with this dynamic, competitive marketplace. The complaint challenges formularies that do not cover both low-WAC and high-WAC versions of the same drug, despite recognizing that at least some Respondents' current formularies cover both. *Id.* ¶ 247. And the complaint admits that "some insulin products" have experienced "recent list price decreases." *Id.* ¶ 234.

The complaint pleads three claims, each under Section 5 of the FTC Act. The first is an "unfair method of competition" claim. Compl. ¶ 261. The complaint alleges that Respondents engage in "coercive, exploitative, and restrictive" conduct by "systematically" favoring high-WAC insulin products with high rebates over low-WAC insulin products with low rebates. *Id.* ¶¶ 256, 258. This conduct allegedly affects competitive conditions because manufacturers purportedly inflate list prices to counteract the discounts they provide in the form of rebates, plan sponsors choose formularies with large rebates, and consumers are prescribed and purchase high-WAC products. *Id.* ¶ 259.

The second and third claims allege unfair acts or practices. Similar to the first claim, the complaint alleges that Respondents exclude low-WAC insulin products from certain standard formulary options in favor of high-WAC insulin products and "shif[t] the cost" of insulin prices onto "certain insulin patients." Compl. ¶¶ 263, 269. These acts or practices, the complaint alleges, injure "certain patients" whose "out-of-pocket costs are based on list prices." *Id.* ¶¶ 264, 271.

Based on these alleged practices with respect to insulin, the complaint seeks three broad forms of injunctive relief that would: (1) force PBMs to include low-WAC versions of drugs when a formulary covers the high-WAC version of the same drug (regardless of whether a low-WAC drug has a higher net cost or would drive up other costs); (2) prohibit PBMs from negotiating for rebates by accepting compensation based on a drug's list price, which would limit plan sponsors' and PBMs' flexibility to negotiate payment structures that incentivize PBMs to obtain greater discounts off list prices; and (3) prohibit PBMs from assisting plan sponsors that choose to design "a benefit plan that bases patients' deductibles or coinsurance" on the list price. Compl. Notice of Contemplated Relief ¶¶ 1-3. This relief would expressly limit PBMs' ability to generate competition between drug manufacturers, which would necessarily raise costs for plan sponsors

and increase premiums for many members. This relief would also eliminate the freedom of plan sponsors to design plan benefits, instead having the Commission dictate plan designs.

IV. After The Complaint Was Filed, The Commission's Composition Changed And This Case Was Stayed

The Commission's composition has changed since the complaint issued. Former Chair Khan resigned in January 2025, and the President removed Commissioners Slaughter and Bedoya in March 2025.[9] Because there were no sitting Commissioners participating in the matter at that time, the General Counsel granted a joint motion to stay the proceeding "for a minimum of 105 days"—until July 15, 2025, at the earliest. Order Granting Stay at 2 (Apr. 1, 2025).

On August 27, the Commission lifted the stay. The parties were notified on August 28.

LEGAL STANDARD

In evaluating motions to dismiss, the FTC applies "the standards a reviewing court would apply" under Federal Rule of Civil Procedure 12(b)(6). *In re LabMD, Inc.*, 2014 FTC LEXIS 2, *5. Thus, the Commission "inquires whether the complaint's allegations, if proved, are sufficient to make out a violation of Section 5." *Union Oil*, 138 F.T.C. 1, 16 (2004). The "complaint must plead actual facts sufficient to allege that [each] defendant committed 'each element' of the claim." Grubhub Statement at 4. Where an "obvious alternative explanation" for the challenged conduct appears from the facts alleged, unlawful conduct is "not a plausible conclusion." *Ashcroft v. Iqbal*, 556 U.S. 662, 682 (2009).

[9] Respondents sued in federal court, alleging Article II, Article III, and due process violations. That suit is pending. *Express Scripts, Inc. v. FTC*, No. 25-1383 (8th Cir.).

ARGUMENT

I. Count I Must Be Dismissed Because The Complaint Fails To Allege An Unfair Method Of Competition

The complaint's UMC claim (Count I) reflects a disregard of the limits on Section 5. The complaint alleges that Respondents' "systematic preferencing of products with a high rebate and fee value ... constitutes an unfair method of competition in violation of Section 5(a) of the FTC Act." Compl. ¶¶ 256, 261. Using undefined buzzwords from the 2022 UMC Statement, the complaint alleges that these practices are "coercive, exploitative, and restrictive" and "negatively affect competitive conditions." *Id.* ¶¶ 257-59; *compare* 2022 UMC Statement at 9.

But stating a UMC claim under Section 5 requires more than reciting buzzwords from a partisan policy statement. The Commission must plausibly allege that two "distinct elements" are met. GrubHub Statement at 3. First, it must identify "the market where the method's devisor competes." *Id.* at 4 n.40. Second, it must identify unfair "methods"—not results—of competition in that market. 15 U.S.C. § 45(a)(1). To be "unfair," those methods must "significantly lessen[] competition" in the relevant market. *Ethyl*, 729 F.2d at 141. The "central question" in "distinguishing between competition on the merits and unfair methods of competition" is whether the conduct is "in the form of collusion or exclusion." Statement of Comm'r Mark Meador, *Antitrust Myth Busting* at 3 (May 5, 2025).[10] This parallels the showings that the Commission must make to prevail under traditional antitrust statutes.

And for good reason. If standalone authority under Section 5 were untethered from the antitrust statutes, nearly any "Section 5 theory … no matter how controversial or convoluted" could be used to impose liability. Dissenting Statement of Comm'r Ohlhausen, 2015 Policy

[10] https://www.ftc.gov/system/files/ftc_gov/pdf/meador-antitrust-myth-busting-remarks-5.5.25.pdf.

Statement, 80 Fed. Reg. at 57058. Such unbridled discretion to prohibit whatever conduct a majority of the Commission dislikes at a particular moment in the name of combatting "unfairness," regardless of whether the conduct limits competition or is responsive to plan sponsor demand, would implicate the "obvious" "nondelegation problem with Section 5," Non-Compete Statement at 24, and give the Commission unchecked power to pick winners and losers throughout "a significant portion of the American economy" without clear statutory authorization, *West Virginia v. EPA*, 597 U.S. 697, 721 (2022). These same concerns were raised on the only other two occasions the Commission invoked the 2022 UMC Statement and also apply to the Commission here. Grubhub Statement at 6 & n.48.

The UMC claim here is far outside the bounds federal courts have set on the FTC Act and thus fails to allege the necessary elements. First, the complaint does not define any relevant market. Second, the complaint does not allege any market in which Respondents compete or any market in which competition is restricted. Third, the complaint does not allege any practice that constitutes "unfair methods of competition": The complaint makes no allegation that Respondents have colluded with each other or excluded rivals. Fourth, Respondents' conduct constitutes legitimate business practices.

A. The Complaint Fails To Identify Any Relevant Market

Pleading a standalone UMC claim requires identifying a market in which the challenged method is employed: To "be unfair, a method of competition must affect competition in the market where the method's devisor competes." Grubhub Statement at 4 (citing *FTC v. Raladam*, 283 U.S. 643, 649 (1931)). After all, "[w]ithout a definition of the market, there is no way to measure the defendant's ability to lessen or destroy competition." *Ohio v. Am. Express*, 585 U.S. 529, 543 (2018) (Sherman Act).

Here, nothing in the complaint purports to define *any* market, much less the one in which Respondents compete. That failure is unsurprising because the 2022 UMC Statement says, with no legal support, that "Section 5 does not require a separate showing of market power or market definition." 2022 UMC Statement at 10. This assertion directly contravenes prevailing legal precedent that requires an allegation of a relevant market in a standalone Section 5 claim, as Chairman Ferguson's *Grubhub* statement explains. Count I must be dismissed for this reason alone.

B. The Complaint Fails to Allege Harm In Any Market In Which Respondents Plausibly Compete

The supposed "harm" alleged in the complaint also does not occur in any market in which Respondents plausibly compete. *Off. Airline Guides*, 630 F.2d at 927-28 (rejecting standalone UMC claim because effect occurred in a market in which Respondent did not compete).

As relevant here, a properly defined market consists of "reasonabl[y] interchangeabl[e]" products and services. *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962). While the complaint in this case fails to identify any plausible relevant market, the FTC and the Department of Justice ("DOJ") have elsewhere alleged that PBMs "compete" in markets related to "PBM services," FTC, Statement Concerning Proposed Acquisition of Medco Health Sols. by Express Scripts at 9 (Apr. 2, 2012),[11] by offering different "price and non-price dimensions" to *plan sponsors*, FTC & DOJ, *Improving Health Care: A Dose of Competition* at 290 (July 2004) ("FTC 2004 Report").[12] Recent mergers, DOJ concluded, have been "unlikely to lessen competition" in

[11] https://www.ftc.gov/sites/default/files/documents/public_statements/statement-commission-concerning-proposed-acquisition-medco-health-solutions-express-scripts-inc./120402expressmedcostatement.pdf.

[12] https://www.ftc.gov/sites/default/files/documents/reports/improving-health-care-dose-competition-report-federal-trade-commission-and-department-justice/040723healthcarerpt.pdf.

the market for the "sale of PBM services." DOJ Statement on Cigna-Express Scripts Merger (Sept. 17, 2016).[13] Notably, the FTC and DOJ did not claim that PBMs compete to set patients' out-of-pocket costs, nor could they. As the FTC has previously recognized, PBMs compete for *plan sponsors*, not patients served by those sponsors.

In those conceivable markets, the complaint contains no allegations of reduced competition, whether caused by an unfair method of competition or not. Aside from a passing reference to "increasing[] concentrat[ion]" in the PBM industry "[o]ver the last 20 years," Compl. ¶ 29, which is not alleged to have anything to do with rebates or formulary designs, there are no claims that Respondents "exclude[d] competitors" from any conceivable PBM-services markets by "'impair[ing] the opportunities of rivals,'" *Retractable Techs. v. Becton Dickinson*, 842 F.3d 883, 891 (5th Cir. 2016), or are "predator[s]" who have "drive[n] rivals from the market," *Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1433 (9th Cir. 1995). The most the complaint says is that Respondents allegedly "shaped competition for providing PBM services" and "incentivize[d] a mode of competition that is detrimental for patients." Compl. ¶¶ 173, 193. But neither shaping competition nor "incentivizing" it is the same thing as lessening it. Without any allegations "about the number and behavior of [Respondents'] competitors" that show "the effects of [any Respondent's] practices on its own or its competitors' relative positions" in a relevant market, GrubHub Statement at 5, the UMC claim must be dismissed.

To the extent the complaint gestures toward any competitive harms, it does so in an entirely different, ill-defined marketplace: one where plan sponsors compete for members by designing health plans. Compl. ¶¶ 259, 56-73, 92-98. But the asserted harm is higher out-of-pocket costs for some insulin patients with certain plan designs, *e.g.*, *id.* ¶ 259, which is not a harm to

[13] https://www.justice.gov/atr/closing-statement.

competition itself. Further, the plan sponsors (not Respondents) compete in that marketplace by setting the parameters of their plan designs, including member copayments, and choosing formularies to offer to their members. *Id.* ¶¶ 50, 60, 66, 67, 71. The complaint does not allege that PBMs control those decisions, nor does it allege that those decisions by plan sponsors flow from a loss of competition. The complaint acknowledges clients "generally avoid formulary options that provide fewer rebates." *Id.* ¶ 174. Similarly, to the extent the complaint alleges harm in a space where patients buy drugs without the involvement of a PBM or plan sponsor, there is no allegation that PBMs control those decisions either.

Plan sponsors sell health plans to patients who want to buy benefit coverage, and PBMs sell services to plan sponsors who want to buy assistance administering their prescription drug benefit plans. Health plans and PBM services thus are not "roughly equivalent to another," *Chapman v. N.Y. Div. for Youth*, 546 F.3d 230, 238 (2d Cir. 2008), or "readily substitutable for one another," and the complaint does not allege otherwise, *Mylan Pharms. v. Warner Chilcott Pub.*, 838 F.3d 421, 435 (3d Cir. 2016). Courts have also recognized the common-sense distinction that an alleged harm to insulin purchasers is not a harm to competition in any market for PBM services. For example, in *Hawai'i v. CaremarkPCS Health*, 2024 WL 4625719 (D. Haw. Oct. 30, 2024), Hawaii brought a state-law unfair-methods-of-competition claim, alleging that PBMs used "rebates and fees to manipulate the price of prescription drugs" and "exclude[d] one or more drugs used to treat the same condition from [their] formular[ies]," resulting in high insulin prices. *Id.* at *1-2. The court dismissed that claim because the "relevant market[]" was "other PBMs that compete with Defendants and/or manufacturers that utilize and compete for Defendants' PBM services," and because Hawaii failed to adequately allege the nature of the anticompetitive effect within the market. *Id.* at *11.

The Second Circuit's decision in *Official Airline Guides* confirms the importance of adhering to the requirement that harm to competition must be alleged in a market in which the respondent competes. There, a monopolist publisher of flight schedules declined to list certain airlines' flights, which the FTC argued put certain airlines at a "competitive disadvantage." 630 F.2d at 925. The Second Circuit rejected the FTC's standalone UMC claim against the publisher because the publisher was "engaged in a different line of commerce from that of the air carriers" that were alleged to be put at a competitive disadvantage. *Id.* at 926. Because the publisher did not seek to "gain an improper advantage or destroy threatened competition" in a market "in which it … operates," there was no Section 5 violation. *Id.*

The same type of market mismatch applies here. Like the publisher in *Official Airline Guides*, Respondents here are not alleged to have harmed competition within any market in which they are alleged to compete. The Commission's UMC authority is not broad enough to enable the FTC "to substitute its own business judgment for that of the [Respondents] in any decision that arguably affects competition in *another* industry." *Official Airline Guides*, 630 F.2d at 927 (emphasis added). A contrary conclusion would "give the FTC too much power" to regulate economy wide. *Id.* Accordingly, dismissal of Count I is also required for this reason.

C. The Complaint Fails To Allege Facts Connecting The Alleged Harm Of Higher Insulin Costs For Some Patients To Any Alleged Unfair Methods

The complaint also fails to allege any harm that results from unfair conduct or a reduction in competition.

The only three precedential judicial decisions on unfair methods of competition from the last 45 years make clear that Section 5 at most prohibits only a narrow category of "standalone" anticompetitive conduct. To state a standalone UMC claim, a complaint must plausibly allege practices that "significantly lessened competition," such as "collusive, coercive, predatory, or

exclusionary conduct." *Ethyl*, 729 F.2d at 140-42. As explained more recently, one must "distinguish[] between competition on the merits and unfair methods of competition—whether in the form of collusion or exclusion." Meador Remarks, *Antitrust Myth Busting* at 3. Without these limits, regulated parties would be victim to "uncertain guesswork rather than workable rules of law." *Ethyl*, 729 F.2d at 139.

Enforcing these statutory limits, the Second Circuit in *Official Airlines Guides* rejected the FTC's claim where the defendant, the monopolist publisher of airline flight schedules, "ha[d] no purpose to restrain competition or to enhance or expand [its] monopoly, and d[id] not act coercively." 630 F.2d at 927. The same year, the Ninth Circuit held that absent a basis for the "traditional ingredients of Sherman Act conspiracy," the fact that businesses were merely engaged in "parallel action" did not "establish a section 5 violation." *Boise Cascade Corp. v. FTC*, 637 F.2d 573, 576-77 (9th Cir. 1980). Finally, the Second Circuit held that manufacturers who independently adopted most-favored-nation clauses did not violate Section 5 because they "acted independently and unilaterally," not "by agreement or collusively," and because they "adopted [their] practices for legitimate business reasons." *Ethyl*, 729 F.2d at 139.

The complaint, if accepted, would eviscerate these decades-old limits. The FTC Act's plain text prohibits unfair "methods" of competition. 15 U.S.C. § 45(a)(1). The complaint challenges only one alleged method: "Respondents systematically prefer high list price insulin products, with high rebates and fees, over similar low list price products, with low rebates and fees, on formularies." Compl. ¶ 256; *see also id.* ¶¶ 50, 60, 66, 71, 191, 258 (challenging formulary options). Although the complaint alleges that Respondents' practices are unfair methods of competition because they "negatively affect competitive conditions" and are "coercive, exploitative, and restrictive," *id.* ¶¶ 257-59, the complaint fails to allege the critical elements of

"collusion or exclusion," Meador Remarks, *Antitrust Myth Busting* at 3, and its allegation of "coercion" bears no resemblance to how courts have defined that term. The complaint thus improperly challenges conduct that, on its face, does not reduce competition and is lawful under "well forged" antitrust precedent. *Boise*, 637 F.2d at 582; *cf. A Conversation with FTC Commissioner Andrew Ferguson*, Mercatus Center (June 13, 2024) (explaining that standalone UMC claims will be subject to "a more searching inquiry" when they are not "very closely tied to the sort of conduct" that traditional antitrust laws prohibit).[14]

To start, because "[a]ntitrust enforcement should protect the conditions that allow innovation to thrive," Meador Remarks, *Antitrust Myth Busting* at 3, there is nothing unlawful about "shap[ing] competition" or "incentiviz[ing] a mode of competition" to focus primarily on rebates or selective contracting. Compl. ¶¶ 173, 193. When a company shapes competition via the "mere introduction" of a product or "[p]roduct improvement," that "does not violate" traditional antitrust laws. *Berkey Photo v. Eastman Kodak*, 603 F.2d 263, 286 (2d Cir. 1979) (product creation); *Allied Orthopedic Appliances v. Tyco Health Care Grp.,* 592 F.3d 991, 998 (9th Cir. 2010) (product improvement). The former FTC Commissioners might not have agreed with the introduction or improvement of certain formulary designs options, Compl. ¶¶ 104, 191, but if "products gain acceptance in [a] market," it is "of no importance that a judge or jury may later regard them as inferior, so long as that success was not based on any form of coercion" that reduces competition. *Berkey*, 603 F.2d at 287. Respondents win plan sponsor customers because they offer products that are responsive to what plan sponsors want, and there is no allegation that Respondents are preventing others from offering products either directly or by forcing consumers

[14] https://www.mercatus.org/economic-insights/event-videos/conversation-ftc-commissioner-andrew-ferguson-hosted-alden-abbott.

(here, plan sponsors) to purchase their products and eliminating opportunities for rivals. The FTC has no authority to take issue with a product design deemed "superior" by consumers (*i.e.*, plan sponsors) free to choose among multiple providers simply because the FTC does not like the choices plan sponsors have made. *Id.*

More specific to the practices alleged in the complaint, no allegations show that Respondents' rebating and formulary practices have "significantly lessened competition" through "collusive, coercive, predatory, or exclusionary conduct." *Ethyl*, 729 F.2d at 141. Collusion refers to competitors reaching an "agreement," while exclusion refers to conduct beyond competition on the merits that "exclude[s] competing product lines" from the market. *Id.* at 137 & n.7. The complaint does not allege collusive or exclusionary methods of competition, and it does not mention predation at all. Rather, the complaint alleges that Respondents introduced formularies that vary widely at different times, Compl. ¶¶ 103-05, 114, and negotiated different rebates with different insulin manufacturers, *id.* ¶ 44. The complaint also confirms insulin costs declined in parallel with these new formulary options. *Id.* ¶ 129.

While the complaint simply asserts that Respondents' conduct is "coercive," Compl. ¶ 258, there are no facts alleged to support that legal conclusion. And the threadbare statement that follows bears no relationship to the way courts have used the term "coercion." The complaint alleges that Respondents "induce[]" manufacturers to compete for formulary placement through rebates. *Id*. But competition is not coercive (and is not anticompetitive). Rather, "coercion" exists only when parties with "market power" force consumers to make a purchase in a way that harms competition by impairing rivals. *Ethyl*, 729 F.2d at n. 7 (citing cases). There are no allegations that any Respondent has market power, nor that any Respondent forced any of its consumers to

purchase anything. Moreover, there is no allegation that any supposed "coercion" of insulin manufacturers harmed competition.

The complaint's remaining allegations stray from the agency's statutory mandate to regulate "methods" of competition, 15 U.S.C. § 45(a)(1), seeking to mandate a preferred outcome of *fair* competition. The complaint alleges that because of Respondents' rebate and formulary methods, manufacturers "inflat[e] list prices" and insulin patients "pay higher out-of-pocket costs." Compl. ¶ 259. But Respondents don't set list prices. And in any event the alleged price-setting cannot be collusive, exclusionary, or even "predatory" conduct, *Ethyl*, 729 F.2d at 137, because it is not alleged to be competition-reducing, *see supra*, at 15-18. As the Commission has recognized, claims premised on "high prices unaccompanied by exclusionary conduct" are "unlikely to find success in the courts." FTC, *Report on Standalone Section 5 to Address High Pharmaceutical Drug and Biologic Prices* at 1, 11 (June 24, 2019).[15]

The Commission's standalone claim is thus the kind of claim challenging "normally acceptable business behavior," untethered to "an antitrust violation" that courts repeatedly rejected so as not "to permit arbitrary or undue government interference with the reasonable freedom of action that has marked our country's competitive system." *Ethyl*, 729 F.2d at 137-38. To bring a Section 5 claim here "would be to blur the distinction between guilty and innocent commercial behavior." *Boise*, 637 F.2d at 582. Where, as here, there's "no fraud," "no monopolization," and "no collusion" in the market, the Commission should (and under the case law must) "stay out of the way." CNBC, *FTC Chair Andrew Ferguson Speaks With CNBC* (Mar. 13, 2025).[16]

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[15] https://www.ftc.gov/system/files/documents/reports/ftc-report-standalone-section-5-address-high-pharmaceutical-drug-biologic-prices/p180101_drug_prices_appropriations_report_6-27-19.pdf.

[16] https://www.cnbc.com/2025/03/13/cnbc-exclusive-transcript-ftc-chair-andrew-ferguson-speaks-with-cnbcs-squawk-box-today.html.

D. Respondents' Practices Serve Independent Business Reasons And Embody Merit-Based Competition, Not Anticompetitive Intent

Far from being collusive or exclusionary, Respondents have "an independent business reason" for the challenged business practices, which further refutes any allegation of unfairness. *Ethyl*, 729 F.2d at 139-40.

Although the complaint alleges that "[t]here is no valid or cognizable justification for" Respondents' practices, Compl. ¶ 260, the Commission is "not bound to accept" this "legal conclusion … as true." *Iqbal*, 556 U.S. at 678. To the contrary, federal courts have previously recognized that PBM rebate agreements are "a normal competitive tool … to stimulate price competition." *In re EpiPen Litig.*, 44 F.4th 959, 989 (10th Cir. 2022). So, too, are formularies that exclude some drugs. Indeed, since the early 2000s, when the FTC studied PBMs and recognized that exclusionary formularies confer benefits, *e.g.*, 2005 FTC PBM Report at 11, 54, the FTC has endorsed selective contracting as a *pro*competitive way to reduce healthcare costs via "competition on the merits," where "payors leverag[e] drugs off one another to secure lower prices." Dkt. 106 at 6, *FTC v. Amgen Inc.*, No. 1:23-cv-03053 (N.D. Ill. Jul. 14, 2023). Likewise, the FTC has recognized the importance of selective contracting to lower healthcare costs. *E.g.*, Compl. ¶¶ 60-61, *FTC v. U.S. Anesthesia Partners*, No. 4:23-CV-03560-KH (S.D. Tex. Sept. 21, 2023) ("In exchange for being included in an insurer's network, providers typically agree to give a discount off the total amount they charge."); FTC Staff Letter to CMS at 1 (Mar. 7, 2024) (selective contracting "has long been seen as an important tool to enhance competition and lower costs in markets for health care goods and services. Both economic principles and empirical evidence

support that view.").[17] The complaint offers no basis to treat selective contracting here as a *sui generis* unfair method of competition. Nor could it—selective contracting with drug manufacturers does not exclude any rival PBMs from any market.

In addition, the complaint acknowledges that Respondents' conduct is beneficial for some patients, *e.g.*, Compl. ¶ 235, which echoes the FTC's previous determinations. "Most empirical evidence suggests that PBMs have lowered costs for health plan sponsors." FTC 2004 Report at 278. Before Chair Khan's tenure, the FTC similarly found that "[r]ebates can lead to lower health care costs," so efforts to "limit a PBM's ability to effect certain drug substitutions" because of its formulary design are "likely to increase the cost of pharmaceuticals" and "health insurance premiums." FTC Staff Letter to Richard L. Brown, Senator, North Dakota Senate at 5-7 (Mar. 8, 2005).[18] It likewise has determined that "competition between pharmaceutical companies for preferred placement on [formularies] can lead to lower drug prices." FTC Staff Letter to Cal. Assembly Member Greg Aghazarian at 6 (Sept. 7, 2004).[19]

Finally, the complaint does not plausibly allege "anticompetitive intent." *Ethyl*, 729 F.3d at 139. Anticompetitive intent includes the monopolistic "intent to control prices or exclude competition in the relevant market," *Dreamstime.com v. Google LLC*, 54 F.4th 1130, 1138 (9th Cir. 2022), such as a "deliberate plan to prevent [rivals] from reaching any critical market mass,"

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17 https://www.ftc.gov/system/files/documents/advocacy_documents/federal-trade-commission-staff-comment-centers-medicare-medicaid-services-regarding-proposed-rule/140310cmscomment.pdf.

18 https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-richard-l.brown-concerning-north-dakota-h.b.1332-regulate-contractual-relationship-between-pharmacy-benefit-managers-and-covered-entities/050311northdakotacomnts.pdf.

19 https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-comment-hon.greg-aghazarian-concerning-ca.b.1960-requiring-pharmacy-benefit-managers-make-disclosures-purchasers-and-prospective-purchasers/v040027.pdf.

McWane, Inc. v. FTC, 783 F.3d 814, 840 (8th Cir. 2014) (cleaned up). Although the complaint alleges that Respondents' conduct has harmed certain patients indirectly by resulting in higher out-of-pocket drug costs under certain plan sponsors' decisions, *e.g.*, Compl. ¶¶ 6-11, 56-98, 182-201, there are no allegations that any Respondent intended to harm competition among PBMs or foreclose the opportunities of rival PBMs.

Respondents provide plan-sponsor clients with a menu of options that serve each client's objectives—by, for example, offering lower-cost health plan options for their employees and their beneficiaries. Or, when a plan sponsor feels that a PBM's menu of options does not resolve these tradeoffs, they are free to customize their own formulary or switch to a rival PBM. This does not evince anticompetitive intent to throttle rival PBMs or to suppress competition in the market. It evinces the exact opposite: competition on the merits to attract and retain plan-sponsor clients. In short, the Commission that voted out the complaint may not have liked where market demand has led; but the FTC does not get to displace the market's judgment with its own preferences.

Under a proper understanding of the FTC Act, therefore, Count I fails.

II. Counts II And III Must Be Dismissed Because The Complaint Fails To Allege An Unfair Or Deceptive Act Or Practice

The complaint likewise reflects an improperly expansive view of the Commission's authority to regulate unfair acts or practices. Its concept of unfairness is not informed by "'clear and well-established' policies that are expressed in the Constitution, statutes, or the common law"—an important statutory limitation that ensures the Commission does not regulate based on amorphous views of good and bad practices. *LabMD*, 894 F.3d at 1231 (quoting FTC Policy Statement on Unfairness). It also brushes past the statutory requirements that an act or practice cannot be unfair unless it "causes or is likely to cause substantial injury to consumers," and is "not outweighed by countervailing benefits to consumers." 15 U.S.C. § 45(n).

The complaint alleges two unfair acts or practices: (1) "systematic exclusion of low WAC insulin products" from certain formularies "in favor of identical high WAC insulin products" (Count II); and (2) supposed "cost-shifting of the high insulin list prices of drugs onto certain patients" (Count III). Compl. ¶¶ 263, 274. Even setting aside the factual defects in these allegations, these claims are premised on legal theories that, if adopted, would read Section 5(n)'s express limitations out of the statute entirely. Put simply, the complaint claims Respondents are liable because some insulin patients allegedly paid higher out-of-pocket costs, even though other actors (manufacturers and plan sponsors) independently made drug-price and plan-design choices, and even though other patients benefitted from lower premiums because of their plan's formulary design. Compl. ¶¶ 184, 226. The Commission should reject those theories and dismiss these claims.

A. The Complaint Does Not Allege that Respondents' Practices Violate Established Public Policy

The unfair-acts-or-practices claims first fail because they are untethered from "'clear and well-established' policies" that could support a finding of unfairness. *LabMD*, 894 F.3d at 1231. The complaint fails to allege any well-established legal policy applicable to the challenged conduct, much less allege facts establishing that Respondents violated such a policy.

"[I]n measuring a practice against" the standard of unfairness, the FTC has flexibility—but it must "consider[] public values" rather than the value judgments of the Commissioners. *FTC v. Sperry & Hutchinson Co.*, 405 U.S. 233, 244 (1972). This limitation ensures that the Commission is not "allowed to intervene at will whenever it believes the market is not producing the 'best deal' for consumers." *Am. Fin.*, 767 F.2d at 982. Thus, the FTC must allege that the challenged act "meets the consumer-injury factors listed [in 15 U.S.C. § 45(n)] *and* is grounded in well-established legal policy." *LabMD*, 894 F.3d at 1231 (emphasis added); *accord FTC v. Ind. Fed'n*

of Dentists, 476 U.S. 447, 454 (1986) (Section 5's "standard of 'unfairness'" demands a showing that the targeted conduct is "against public policy" by reference to a "particular legal rationale.").

Absent this public-policy grounding, the FTC's enforcement discretion would present serious constitutional and statutory concerns that the Commission ought to avoid. Unfettered discretion to judge unfairness based on the individual views of current (or former) Commissioners, rather than established public policy, would risk (1) violating the non-delegation doctrine; (2) imposing liability without giving parties fair notice about what standards govern their conduct; and (3) giving the FTC significant power over American businesses without a clear statutory mandate. The Commission should "hesitate to impute to Congress ... a purpose to give [the FTC] unbridled discretion" in judging unfairness "for any substantive reason [the Commissioners] may choose," given the "important constitutional questions" such delegation would raise. *Kent v. Dulles*, 357 U.S. 116, 128, 130 (1958).

Here, the complaint reflects the belief of former Commissioners that "the market is not producing the 'best deal' for consumers," *Am. Fin.*, 767 F.2d at 982, without a basis in "'clear and well-established' policies ... expressed in the Constitution, statutes, or the common law" to condemn Respondents' conduct, *LabMD*, 894 F.3d at 1231. To the extent the complaint challenges high list prices that result in high out-of-pocket costs under certain plan designs established by plan sponsors, that does not state a plausible claim because "allegations of high pricing, by themselves, do not constitute unfair or deceptive trade practices." *Leslie v. Quest Diagnostics*, 2018 WL 1535235, at *4 (D.N.J. Mar. 29, 2018) (collecting cases interpreting state-law analogues to Section 5). The complaint does not identify any "well-established legal policy" that prohibits PBMs from working with plan sponsors, some of which choose to trade high out-of-pocket expenses for lower premiums and vice versa.

To the extent the complaint challenges PBM formulary and rebate practices, it simply labels those practices unfair as if *ipse dixit* alone could make it so. But again, the complaint fails to even cite any well-established legal policy, let alone allege facts that plausibly suggest Respondents violated such a policy. *E.g.*, Compl. ¶¶ 12, 214, 221, 223. As courts have explained, PBMs' "rebate and formulary-placement strategies" that allegedly "inflate the WAC price for prescription drugs" do "not rise to the level of the type of conduct" that has supported "unfair acts" claims. *Hawai'i*, 2024 WL 4625719, at *9. To the contrary, rebate agreements are "a normal competitive tool ... to stimulate price competition." *EpiPen*, 44 F.4th at 989.

Far from showing that public policy condemns rebating that lowers the net cost of insulin for plan sponsors, federal statutes and regulations recognize, approve, and even require it. *Supra*, at 6-8. For example, HHS "may not interfere with the negotiations between drug manufacturers and pharmacies and [Part D] sponsors," including the rebates that flow from those negotiations. 42 U.S.C. § 1395w-111(i)(1). HHS also "may not require a particular formulary" when it reviews proposed health plans every year. 42 C.F.R. § 1395w-111(i)(2). And Congress imposed a 10-year prohibition on HHS implementing or enforcing a rule that would have eliminated certain safe harbors for PBM rebates. Pub. L. No. 117-169, § 11301 (Aug. 16, 2022); *see* 85 Fed. Reg. 76666 (Nov. 30, 2020). It would be incongruous for the Commission to deem unlawful the types of rebates and selective contracting Congress and other agencies have endorsed as beneficial for federal programs. It would also appoint the Commission to act as ERISA plan administrator—a task Congress assigned to plan sponsors.

B. The Complaint Fails to Plausibly Allege Respondents' Practices Cause The Alleged Injury

The complaint concludes that Respondents' practices "cause[] or [are] likely to cause substantial injury to consumers." 15 U.S.C. § 45(n). But the complaint fails to allege facts to

support that legal conclusion. Instead, its theory rests on an unsupported and expansive view of what qualifies as "cause." The principal alleged injury is that "some patients pay more for insulin." Compl. ¶¶ 264, 271. The complaint points to other injuries—"decreased adherence and adverse health outcomes"—only as indirect consequences of the supposed "[h]igher prices" of insulin. *Id.* But the complaint severs causation by conceding that independent actors—drug manufacturers and plan sponsors, not PBMs—set list prices, select formularies, and set member copayments.

To satisfy their pleading obligation as to causation, the FTC must at least allege facts that plausibly suggest Respondents engaged in conduct that "raise[s] a significant risk of concrete harm." *Am. Fin.*, 767 F.2d at 972. Where "third parties must take additional steps" to bring about the feared injury, causation is lacking. *FTC v. Kochava*, 671 F. Supp. 3d 1161, 1172 (D. Idaho 2023); *accord Guy v. Convergent Outsourcing*, 2023 WL 4637318, at *4 (W.D. Wash. July 20, 2023) ("Plaintiffs have failed to show how Section 5 of the FTC Act is intended to protect Plaintiffs from [an injury] caused by a third party."). That rule is consistent with longstanding legal concepts of causation. *E.g.*, Restatement (Second) of Torts § 440 ("A superseding cause relieves the actor from liability"). It also makes sense. If the FTC could punish a company for any act that harms consumers only if *other* intervening parties also make *other* independent decisions, the Commission could regulate all commercial conduct, no matter how tenuous the connection between the defendant's conduct and the alleged injury. That would render Section 5's plain text superfluous.

Here, the complaint claims there is harm to patients "whose out-of-pocket costs are based on artificially inflated list price[s]." Compl. ¶ 222; *see id.* ¶¶ 10, 57, 68, 95, 193. But as the complaint concedes, "PBMs ... do not contract directly with patients." *Id.* ¶ 223; *accord Rutledge v. PCMA*, 592 U.S. 80, 83-84 (2020) (PBMs "serve as intermediaries between prescription-drug

plans and the pharmacies that [patients] use"). And the complaint admits that the alleged injury is caused not by Respondents but by three types of independent third parties over which Respondents have no control: drug manufacturers, plan sponsors, and patients themselves. Compl. ¶¶ 2, 6, 55-57, 60, 62, 64, 66-67, 133, 135, 139, 143, 202, 204.

To start, the complaint itself describes that manufacturers are solely responsible for setting the list price of drugs. Manufacturers, not Respondents, allegedly "increased the list price" for insulin drugs, Compl. ¶¶ 120-23, "considered reducing the list prices of *their* current insulin products" but declined to do so, *id.* ¶ 134 (emphasis added), and chose whether to offer high-WAC and low-WAC drugs at "roughly 'net price parity,'" *id.* ¶ 143.

Plan sponsors, for their part, are solely responsible for the benefit plan options offered to their members, including what insulin patients pay. "How much an insured patient pays for a prescription is determined by the drug benefit in the patient's health plan." Compl. ¶ 60. Respondents make standard formulary options available to plan sponsors, but plan sponsors decide whether to "adopt" those formularies, whether to customize or create their own, or otherwise. *Id.* ¶ 50. And it is health plan sponsors who are solely responsible for designing health plan benefits, including whether to "apply[] drug rebates" at the point of sale. *Id.* ¶ 66; *see also id.* ¶ 67 (similar).

Finally, the complaint obliquely acknowledges that patients decide in which plan option to enroll themselves, with one option potentially including high-deductible and high-out-of-pocket-cost options. Compl. ¶ 64. The complaint does not allege that any patient is forced to choose one plan option over another, much less forced by Respondents. Nor could it, because insulin patients "have options when choosing an insurance plan" and can "elect trade-offs such as selecting a higher premium plan for lower deductible or a plan with co-payment obligations rather than coinsurance obligations." *In re Insulin Pricing Litig.*, 2024 WL 416500, at *46 (D.N.J. Feb. 5,

2024). And to the extent uninsured patients face higher prices for insulin products, that result is the direct consequence of manufacturers' choices in setting list prices. The complaint fails to explain how these patients can be injured when it acknowledges that low-WAC versions of insulin drugs are available to them. The causal link between the prices these patients pay and Respondents' practices is simply too attenuated for liability under Section 5.

Accordingly, the complaint's alleged injury—certain insulin patients paying high out-of-pocket costs tied to list prices—rests on allegations that drugs have high list prices (which manufacturers control), that plan sponsors choose formularies with high-WAC drugs (which sponsors control), that plan sponsors offer and patients enroll in plans with out-of-pocket costs based on list prices (which plan sponsors and their members control), and that the subgroup of patients that allegedly pays high amounts for insulin products chooses not to mitigate those costs (which those patients control). Respondents cannot inflict the alleged harm without numerous independent "third parties tak[ing] additional steps," repeatedly breaking the causal chain. *Kochava*, 671 F. Supp. 3d at 1172.

The complaint attempts to link the separate acts of these independent actors by asserting that Respondents' conduct "incentivize[s] insulin manufacturers to raise list prices," Compl. ¶¶ 216, 231, 254, and "incentivize[s]" plan sponsors to design plans "where patients' contributions are based on ... inflated list prices," *id.* ¶¶ 191, 221. The notion that "encourag[ing]" third-party behavior equates to *causing* the injuries inflicted by that third-party behavior has been rejected by courts. *Simon v. E. Ky. Welfare Rts.*, 426 U.S. 26, 42-44 (1976); *accord Marceau v. Int'l Bhd. of Elec. Workers*, 618 F. Supp. 2d 1127, 1167 (D. Ariz. 2009) ("[T]he causal chain is simply too attenuated" to show that "discounts and incentives" caused alleged injuries.); *Wright v. R.K.O. Radio Pictures*, 55 F. Supp. 639, 641 (D. Mass. 1944) ("Although the defendant may have

indirectly encouraged the sale of the book it was not a proximate cause of a sale."). The Commission should reject the complaint's attempt to import this vast theory of causation into Section 5.

C. The Complaint Fails To Plausibly Allege That The Purported Injury Outweighs Countervailing Benefits

Finally, the complaint fails to plausibly allege that any injuries caused by the challenged conduct are not "outweighed by countervailing benefits" to those patients or to other patients. 15 U.S.C. § 45(n). Recognizing that "[m]ost business practices entail a mixture of economic and other costs and benefits for purchasers," the FTC "will not find that a practice unfairly injures consumers unless it is injurious in its net effects." FTC Policy Statement on Unfairness, *supra*. The complaint fails to allege facts supporting "the cost-benefit analysis required by" Section 5 or plausibly show that the costs outweigh the benefits. *FTC v. Wyndham Worldwide*, 799 F.3d 236, 256 (3d Cir. 2015).

The complaint does not even meaningfully allege the costs of the purported practices. References to unidentified and unquantified "list-price-sensitive patients" are ubiquitous, Compl. ¶¶ 185, 224, 230, 243, 254, but the complaint includes no allegations measuring the supposed harm faced by this alleged subgroup to facilitate comparison with any benefits. The best it offers are vague allegations that "some" or "many" patients may pay some undefined "high" amount for insulin out of pocket. *Id.* ¶¶ 6, 156, 264.

At the same time, the complaint does not plead facts that plausibly establish the alleged costs outweigh the countervailing benefits. The complaint begrudgingly admits one obvious benefit from Respondents' rebates: they "lower premiums *across patients* in a health plan." Compl. ¶ 226 (emphasis added); *see also id.* ¶ 184 (rebates allow sponsors to lower costs that "may in turn partially reduce ... premiums."). But the complaint then contradicts itself by asserting that

rebates "may have little impact on the patient's premium." *Id.* ¶ 197. And its only statement purporting to weigh those costs is conclusory: The complaint baldly asserts that higher out-of-pocket costs for an unspecified percentage of insulin patients "are significantly more harmful than the possibility of slightly lower premiums," *id.* ¶ 226, but never explains why or provides any basis to evaluate the plausibility of this conclusory statement.

That "naked assertion[] devoid of further factual enhancement" does not suffice. *Iqbal*, 556 U.S. at 678 (cleaned up). The complaint must allege sufficient "factual content" to push the claim "across the line from conceivable to plausible." *Id.* at 683. But without any facts alleged about how many patients pay more out-of-pocket costs for insulin, how much more they pay, how many patients benefit from reduced premiums, how much money patients save on those premiums, the impact of hitting deductibles or out-of-pocket maximums through costs unrelated to insulin, the availability of low-WAC products outside of plan benefits, and the impact of insulin affordability programs, it "is impossible to assess whether" the alleged harms plausibly outweigh the admitted benefits. Grubhub Statement at 5 (faulting majority for issuing complaint alleging unfair competition because it did not allege specific facts "about the nature or volume of business" at issue). Otherwise, the Commission would be free in any case to simply declare, based on its own "broad, unfocused, policy-based" views, that the challenged conduct is more bad than good. Beales, *The FTC's Use of Unfairness Authority*, *supra*.

The complaint's failure to balance benefits and harms is even more glaring because the rest of the complaint acknowledges that Respondents' practices give them the ability to "extract price concessions" from manufacturers that can lower net costs for plan sponsors, enabling plan sponsors to reduce premiums—and offer products that help patients pay less out of pocket. Compl. ¶¶ 38, 55, 129-31, 186, 247. Further, the Commission itself has previously stated that "contracts

with [PBMs] may reduce payers' costs and enable payers to lower the price of health insurance and reduce patients' out-of-pocket medical care expenditures." Compl. ¶¶ 7-8, *FTC v. Cooperativa de Farmacias Puertorriquenas*; *see also supra*, at 10-11 (detailing the benefits of Respondents' practices). The complaint fails to balance any of these benefits against the harms it alleges.

* * *

The former Commissioners voted out a complaint that disregards the express limits in the FTC Act and hearkens back to a bygone era in which the FTC acted as though there were no limits on its Section 5 authority. *LabMD,* 894 F.3d at 1228 & n.21; *see supra*, at 5. To avoid backsliding into the ignominious tradition of the FTC "gallivanting across the land searching for monsters to destroy," Mercatus Center, *Conversation with Commissioner Ferguson*, *supra*, and to avoid the "important constitutional questions" that the FTC's "unbridled discretion" would raise, *Kent*, 357 U.S. at 128, 130, the Commission should dismiss Counts II and III.

CONCLUSION

The Commission should dismiss the complaint.

Dated: August 29, 2025

Respectfully submitted,

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PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Andrew Ferguson, Chair**
Melissa Holyoak
Mark Meador

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**

[PROPOSED] ORDER

This matter comes before the Commission on Respondents' Motion to Dismiss Pursuant to Rule 3.22. Having considered this motion, IT IS HEREBY ORDERED that the Motion is GRANTED and the complaint is DISMISSED.

By the Commission.

ORDERED:

April Tabor
Secretary

Date: _____

PUBLIC

CERTIFICATE OF SERVICE

I hereby certify that on August 29, 2025 I filed the foregoing document electronically using the FTC's E-Filing system, which will send notification of filing to:

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I further certify that on August 29, 2025, I caused the foregoing document to be e-served to:

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