Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products

American families and businesses should never pay higher prices for medicine due to unlawful business practices. For this reason, challenging healthcare industry conduct that may raise prices and stifle innovation is a top priority for the Federal Trade Commission ("FTC" or "Commission"), and the Commission will use its full authority under the FTC Act to do so. The FTC has long pursued a comprehensive agenda to address unlawful conduct in the healthcare and pharmaceutical industries.[1]

For many years, the Commission has received complaints about rebates and fees paid by drug manufacturers to pharmacy benefit managers (PBMs) and other intermediaries to favor high-cost drugs that generate large rebates and fees that are not always shared with patients.[2] These rebates and fees may shift costs and misalign incentives in a way that ultimately increases patients' costs and stifles competition from lower-cost drugs, especially when generics and biosimilars are excluded or disfavored on formularies.

[1] For an overview of FTC healthcare actions generally, *see* MARKUS H. MEIER ET AL., OVERVIEW OF FTC ACTIONS, FED. TRADE COMM'N (Apr. 2022).

[2] *See* H. Rep. 16-456, 116th Cong., (2021), www.congress.gov/116/crpt, (that accompanied H.R. 7668, Fin. Serv's and General Gov't Appropriations Bill, (2021)). The Report states: "The Committee urges the FTC to prioritize investigations into manufacturers that erect rebate walls to block competition from new branded therapies, biosimilars, generics, and other innovative products." *Id* at 67; *see also* FED. TRADE COMM'N, REP. ON REBATE WALLS, at 1 n. 3. Previous discussions of the potential for pharmaceutical rebate agreements to foreclose competition were discussed at an FDA/FTC Workshop on a Competitive Marketplace for Biosimilars and an FTC workshop on prescription drug markets. *See Public Workshop: FDA/FTC Workshop on a Competitive Marketplace for Biosimilars*, U.S. FOOD AND DRUG ADMIN. (Mar. 9, 2020), https://www.fda.gov/drugs/news-events-human-drugs/public-workshop-fdaftc-workshop-competitive-marketplace-biosimilars-03092020-03092020#event-materials; *Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics*, FED. TRADE COMM'N (Nov. 8, 2017), https://www.ftc.gov/news-events/events/2017/11/understanding-competition-prescription-drug-markets-entry-supply-chain-dynamics. The FTC has been aware of the issues surrounding drug rebate practices since at least 1999. *See* ROY LEVY, THE PHARMACEUTICAL INDUSTRY: A DISCUSSION OF COMPETITIVE AND ANTITRUST ISSUES IN AN ENVIRONMENT OF CHANGE, BUREAU OF ECON. STAFF REP., FED. TRADE COMM'N (Mar. 1999).

The Commission is issuing this Policy Statement to explain its enforcement policy with respect to these practices.[3] We do so by highlighting insulin, which many have cited as one prominent example of a prescription drug impacted by high rebates and fees to PBMs and other intermediaries.[4] Insulin is a life-sustaining treatment for roughly 8 million Americans who rely on it to control diabetes.[5] Research indicates that the wholesale price of insulin nearly tripled between 2009 and 2017,[6] increasing out-of-pocket costs for both insured[7] and uninsured patients.[8] The list price for a year's supply of insulin has risen to nearly $6,000, with out-of-pocket costs for insulin alone averaging $1,288 for uninsured patients and $613 for insured patients as of 2017.[9]

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[3] This Policy Statement does not confer any rights on any person and does not operate to bind the FTC or the public. In any enforcement action, the Commission must prove the challenged act or practice violates one or more existing statutory or regulatory requirements. In addition, this Policy Statement does not preempt federal, state, or local laws. Compliance with those laws, however, will not necessarily preclude Commission law enforcement action under the FTC Act or other statutes. Pursuant to the Congressional Review Act (5 U.S.C. § 801 *et seq*.), the Office of Information and Regulatory Affairs designated this Policy Statement as not a "major rule," as defined by 5 U.S.C. § 804(2).

[4] U.S. SEN. FINANCE COMM., STAFF REP., INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG, at 71 (Jan. 2021) ("certain contracting and business practices may create incentives for PBMs to favor drugs with high rebates and, in turn, discourage manufacturers from competing to lower WAC prices."). *See also* Karen Von Nuys et al., *Estimation of the Share of Net Expenditures on Insulin Captured by US Manufacturers, Wholesalers, PBMs, Pharmacies, and Health Plans from 2014 to 2018*, 2 J. AM. MED. ASSOC. H. FORUM 1, 3 (2021) (suggesting business practices of intermediaries may influence rising list prices for insulin).

[5] *See* CARDINAL H., 2022 BIOSIMILARS REPORT: THE U.S. JOURNEY AND PATH AHEAD, at 18 ("over eight million people use insulin daily to effectively manage their diabetes"); William T. Cefalu et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, 41 DIABETES CARE 1299 (2018).

[6] *See* Brian Sable-Smith, *How Much Difference Will Eli Lilly's Half Price Insulin Make*, KAISER FAMILY FOUNDATION (Mar. 12, 2019), https://khn.org/news/how-much-difference-will-eli-lillys-half-price-insulin-make/ ("Between 2009 and 2017 the wholesale price of a single vial of Humalog . . . nearly tripled — rising from $92.70 to $274.70.").

[7] Cefalu et al., *supra* note 5, at 1302; Samantha Willner et al., "*Life or death": Experiences of insulin insecurity among adults with type 1 diabetes in the United States,* 11 SSM POPULATION H. 1, 3 (2020).

[8] *See* Cefalu et al., *supra* note 5, at 1308 (explaining uninsured patients pay the full list price without financial assistance).

[9] *See* Sherry Glied & Benjamin Zhu, *Not so sweet: Insulin Affordability over Time*, THE COMMONWEALTH FUND (Sept. 25, 2020), https://www.commonwealthfund.org/publications/issue-briefs/2020/sep/not-so-sweet-insulin-affordability-over-time; Chien-Wen Tseng et al, *Impact of Higher Insulin Prices on Out-of-Pocket Costs in Medicare Part D,* 43 J. DIABETES CARE 50 (2020) ("From 2014 to 2019, the average annual insulin price rose 55% from $3,819 to $5,917… the projected yearly out-of-pocket cost for insulin increased 11% from $1,199 to $1,329."). These studies note significant heterogeneity in patient out-of-pocket costs depending on several factors including which insulin product(s) is used, the amount of insulin needed, and whether the patient has commercial insurance, Medicare, Medicaid or is uninsured.

Patients with diabetes have described how rising insulin costs have rendered this essential product unaffordable and harmed them in different ways.[10] The increased cost of insulin has caused many patients to ration it,[11] causing suffering, severe illness, and death.[12] During the Commission's Open Meeting in October 2021, one commenter discussed the death of her son who was forced to ration insulin due to high costs.[13] Others have described how insulin costs and the fear of losing health insurance have dissuaded them from leaving their current jobs and limited their ability to pursue other opportunities[14] For example, one small business owner expressed the fear of expanding his business because of insulin costs.[15] High insulin costs also have an outsized impact on those least able to absorb or avoid these additional costs, including patients from historically underserved communities.[16]

In addition to other factors, some have suggested that high rebates and fees to PBMs and other intermediaries may incentivize higher list prices for insulin and discourage coverage of the

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[10] Willner et al., *supra*, note 7; Fed. Trade Comm'n, Tr. of Open Comm'n Meeting, at 14-15, 19-20 (Oct. 21, 2021), www.ftc.gov/openmeetingtranscript.pdf.

[11] *See* Darby Herkert et al., *Cost-Related lnsulin Underuse Among Patients With Diabetes*, 179 J. AM. MED. ASSOC. INTERN MED. 112-114 (2019) (finding one of every four patients rations insulin due to cost within one sample); INSULIN SENATE REP., *supra* note 4, at 14.

[12] *See* FTC Open Meeting Tr., *supra* note 10, at 14 -15, 18-19 (public commenters Matthew Dinger, Anna Squires, and Nicole Smith Holt); *see also* S. Vincent Rajkumar, *The High Cost of Insulin in the U.S.: An Urgent Call to Action,* 95 MAYO CLINIC PROC. 22 (Jan. 2020) ("Alec Smith was 23 when he was diagnosed with type 1 diabetes.… At age 26, he could no longer stay on his mother's health care insurance plan and needed to find his own coverage. …The insurance available to him came with a $7600 deductible and a monthly premium of approximately $440. Because he could not afford this, Alec decided to temporarily forego insurance coverage and purchase insulin with cash. Unfortunately for him, the cash price of insulin was far beyond his means. He decided to try and ration the amount of insulin he took till he had enough savings to purchase insurance. Sadly, on June 27, 2017, he was found dead in his apartment of diabetic ketoacidosis.").

[13] FTC Open Meeting Tr., *supra* note 10, at 18-19 (public commenter Nicole Smith Holt describes the death of her son, Alec Smith, and others from rationing insulin).

[14] *See* Willner et al., *supra* note 7, at 6 ("the only reason that I'm working my job currently … is because I'm afraid to get off of it because there goes my insurance, there goes my method to get any kind of insulin or supplies for anything); *see also* FTC Open Meeting Tr*., supra* note 10, at 14-15; *see also* COLORADO ATT'Y GEN., PRESCRIPTION INSULIN DRUG PRICING REP., at 53 (2020) ("Many survey respondents reported they feel hostage to jobs they would like to leave but need to keep for the insurance because they could not afford insulin and supplies without it.").

[15] *See, e.g.,* COLORADO ATT'Y GEN. INSULIN REP., *supra*, note 14, at 53 ("One survey respondent expressed the fear of expanding his small business because of high insulin costs and overall expensive insurance costs.").

[16] *See* Herkert, et al., *supra* note 11 ("Patients with lower incomes were more likely to report cost-related underuse…").

lowest-cost insulin products.[17] As the Commission's previous Report on Rebate Walls explained, most consumers have insurance that covers a portion of their prescription costs.[18] Health plans, usually through PBMs, use formularies to define which drugs are covered. Drug manufacturers commonly pay PBMs and other intermediaries rebates and fees to have their drugs included on formularies or placed on preferred formulary tiers.[19] Some rebates and fees are conditioned on the sales volume of specific drugs or the exclusion of competing drug products from the same formulary tier.[20]

These rebate and fee agreements may incentivize PBMs and other intermediaries to steer patients to higher-cost drugs over less expensive alternatives.[21] This practice could lead to increased costs for both patients and payers, including increased out-of-pocket costs at the point of sale. It may also insulate more expensive drugs from competing with less expensive alternatives. Nothing prevents drug manufacturers, PBMs, and health plans from negotiating good-faith rebates and fees for legitimate services that increase value to payers and patients. However, when dominant drug manufacturers or intermediaries stifle or foreclose competition from significantly less expensive generic and biosimilar alternatives, the Commission has the

[17] Cefalu et al., *supra* note 5, at 1309 ("The current pricing and rebate system encourages high list prices. . . PBMs negotiate rebates from manufacturers using formulary placement as leverage. PBMs often exclude from formularies the insulins made by the manufacturer who offers the lowest rebate. . . People with diabetes are financially harmed by high list price and high out of pocket costs."); INSULIN SENATE REP., *supra* note 4, at 71 ("Information collected for this investigation suggests that certain contracting and business practices may create incentives for PBMs to favor drugs with high rebates and, in turn, discourage manufacturers from competing to lower WAC prices.").
[18] *See* FTC REBATE WALL REP., *supra* note 2, at 2.
[19] *Id.* at 2; INSULIN SENATE REP., *supra* note 4, at 67 ("manufacturers offer substantial rebates to PBMs and their clients for the purposes of securing preferred formulary placement for their products").
[20] *See id*., at 68 ("Manufacturers have increased their rebates in order to win preferred formulary placement and block competitors.").
[21] *See e.g*., Stacie Dusetzina et al., *Patient and Payer Incentives to Use Patented Brand-Name Drugs vs Authorized Generic Drugs in Medicare Part D*, 181 J. AM. MED. ASSOC. INTERN. MED. 1605, 1611 (2021) (describing Part D plans' use of high-list price brand insulins, including insulin lispro (Humalog), and insulin as part (Novolog) over 50% lower-list price authorized generic versions).

legal authority to investigate these practices and take enforcement action against unlawful conduct.[22]

The Commission has several legal authorities that may apply to these practices, including Section 5 of the FTC Act, Section 3 of the Clayton Act, Section 2 of the Robinson-Patman Act, and the Sherman Act.[23]

Exclusionary rebates that foreclose competition from less expensive alternatives may constitute unreasonable agreements in restraint of trade under Section 1 of the Sherman Act; unlawful monopolization under Section 2 of the Sherman Act; or exclusive dealing under Section 3 of the Clayton Act.[24] Moreover, inducing PBMs or other intermediaries to place higher-cost drugs on formularies instead of less expensive alternatives in a manner that shifts costs to payers and patients may violate the prohibition against unfair methods of competition or unfair acts or practices under Section 5 of the FTC Act.

Finally, paying or accepting rebates or fees in exchange for excluding lower-cost drugs may violate Section 2(c) of the Robinson-Patman Act, which prohibits payments to agents, representatives, and intermediaries who represent another party's interests in connection with the purchase or sale of goods.[25] At least one court has held that this provision may reach rebates paid

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[22] At the request of Congress, the FTC has previously investigated certain PBM business practices. *See* FED. TRADE COMM'N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES (Aug. 2005).

[23] The Commission's authority to address unfair methods of competition under Section 5 of the FTC Act include, but are not limited to, conduct that would violate the Sherman Act. *See, e.g.*, *Oregon Lithoprint, Inc*., Analysis to Aid Public Comment, 83 Fed. Reg. 11529, 11531 (Mar. 15, 2018) ("The Commission has long held that an invitation to collude violates Section 5 of the FTC Act even where there is no proof that the competitor accepted the invitation.").

[24] *See* Fed. Trade Comm'n Act, 15 U.S.C. § 45; Sherman Act §§ 1 and 2; Clayton Act, 15 U.S.C. § 14.

[25] 15 U.S.C. § 13(c) ("It shall be unlawful for any person engaged in commerce, in the course of such commerce, to pay or grant, or to receive or accept, anything of value as a commission, brokerage, or other compensation, or any allowance or discount in lieu thereof, except for services rendered in connection with the sale or purchase of goods, wares, or merchandise, either to the other party to such transaction or to an agent, representative, or other intermediary therein where such intermediary is acting in fact for or in behalf, or is subject to the direct or indirect control, of any party to such transaction other than the person by whom such compensation is so granted or paid.").

by drug manufacturers to PBMs.[26] The Commission has a long history of addressing commercial bribery and will continue to do so.[27]

The FTC intends to closely scrutinize the impact of rebates and fees on patients and payers to determine whether any of these provisions have been violated. In addition, the Commission will monitor private litigation and file amicus briefs where it can aid courts in analyzing unlawful conduct that may raise drug prices. The Commission will also continue to study this issue to understand the full range of practices and implications.

The Commission recognizes the life-and-death stakes of this work and is committed to acting expeditiously. As it has done throughout its history, the FTC will bring an interdisciplinary approach, using resources and expertise from throughout the agency to combat unlawful practices in the prescription drug industry.

See also PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 2362i (4th & 5th ed. 2015-2021) (collecting and discussing cases involving commercial bribery under Section 2(c)); JOSEPH BAUER ET AL., KINTNER'S FEDERAL ANTITRUST LAW § 26.12 (2021).

[26] *In re Warfarin Sodium Antitrust Litig.,* Civ. No. 97-659 (D. Del.)1998 WL 883469, at *16 (D. Del. Dec. 7, 1998), *rev'd on other grounds,* 214 F.3d 395 (3d Cir. 2000).

[27] *See* Hon. Garland S. Ferguson, Jr., Chairman of FTC, Commercial Bribery: An Address to the Conf. on Com. Bribery to the Comm. Standards Council and the Better Bus. Bureau of N.Y .City (Oct. 17, 1930), www.ftc.gov/systemstatementsferguson_commercial_bribery (explaining the Commission's focus on commercial bribery as an unfair method of competition even before it gained authority under the Robinson-Patman Act); *see also* Donald S. Clark, Sec'y of FTC, Remarks Regarding The Robinson-Patman Act: Annual Update, Before the Robinson Patman Act Comm., Section of Antitrust Law, 46th Annual Spring Meeting (Apr. 2, 1998), www.ftc.gov/public-statements/1998/04/robinson-patman-act-annual-update (recognizing the Robinson-Patman's prohibition on commercial bribery).