



Office of the Chair

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

**Remarks of Chair Lina M. Khan Regarding
Policy Statement on Rebates and Fees in Exchange
for Excluding Lower-Cost Drug Products
Commission File No. P221201**

June 16, 2022

Today the Federal Trade Commission is voting on a policy statement that lays out concerns about certain business practices that may be resulting in Americans having to pay higher prices for essential medicines.

For patients in America, the cost of medicines over the last decade has soared, and studies suggest that prescription drug prices are now more than 2.5 times higher in the United States than in other countries.¹ Prices have even soared for medicines developed decades ago, including many of the top-selling insulins. The wholesale price of insulin nearly tripled between 2009 and 2017, increasing out-of-pocket costs for insured and uninsured patients alike.² An uninsured patient or those on high deductible insurance plans might pay more than \$500 per month for insulin.³

These rising prices have led over 10% of Americans to routinely forego or ration medicines, with close to 20% of those from lower-income households reporting that they or a family member had skipped prescription drugs to save money.⁴ In the context of insulin, the Commission has heard directly at our open meetings about the deadly effects of these soaring prices. Last October, for example, Nicole Smith Holt shared how her 26-year-old son Alec tried

¹ Benjamin N. Rome et al., *Trends in Prescription Drug Launch Prices, 2008-2021*, 327 J. AM. MED. ASSOC. 2145 (2022); Press Release, RAND Corp., Prescription Drug Prices in the United States Are 2.56 Times Those in Other Countries (Jan. 28, 2021), <https://www.rand.org/news/press/2021/01/28.html>.

² 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.”).

³ Sherry A. 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>.

⁴ Dan Witters, *In U.S., an Estimated 18 Million Can't Pay for Needed Drugs*, GALLUP (Sept. 21, 2021), <https://news.gallup.com/poll/354833/estimated-million-pay-needed-drugs.aspx>.

to ration insulin after being unable to afford a monthly dose, which ended up proving fatal.⁵ Countless other commentators have shared similarly harrowing tales.

The FTC has long focused on stopping unlawful business practices that lead to higher drug prices, and the FTC teams who have led this work deserve enormous credit. It is vital that we continue building on this critical work, including in the context of insulin and other life-saving drugs. I am committed to ensuring that we are scrutinizing all business practices across the pharmaceutical supply chain that may be contributing to this urgent problem.

The policy statement we are voting on today notes the many complaints we have received about the rebates and fees that drug manufacturers pay pharmacy benefit managers. Drug manufacturers pay these fees in exchange for having their drugs included on key PBM formularies that determine which drugs are covered by patients' insurance.

Some have suggested that these rebates and fees, in turn, encourage drug manufacturers to further increase their pre-rebate list prices in a cycle of ever-increasing list prices and ever-increasing middlemen rebates. Others have noted that PBMs and other middlemen may exclude the lowest-cost generic and biosimilar drugs from patients' formularies entirely to maximize rebates and fees. Such practices violate the fundamental bargain at the center of the American prescription drug system, which is that brand drugs are given a period of patent exclusivity that is then followed by free and fair competition from generic or biosimilar alternatives at dramatically lower prices.⁶

The policy statement notes that the FTC has a variety of statutory authorities that it can apply to assess whether these rebates and fees may in some instances be illegal.

For example, Section 3 of the Clayton Act specially addresses anticompetitive "rebates" and makes it illegal to condition rebates on not dealing with competitors when doing so may "substantially lessen competition or tend to create a monopoly."⁷ The FTC has also determined that commercial bribery practices, commonly referred to as "kickbacks," constitute an unfair method of competition under Section 5 of the FTC Act.⁸ Similarly, Section 2(c) of the Robinson-

⁵ Fed. Trade Comm'n, Tr. of Open Comm'n Meeting, at 18 (Oct. 21, 2021), https://www.ftc.gov/system/files/documents/public_events/1597522/20211021opencommissionmeetingtranscript.pdf.

⁶ See *Generic Competition and Drug Prices, New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*, U.S. FOOD AND DRUG ADMIN (content current as of Dec. 13, 2019), <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices> (showing that generic drug prices measured as AMP or invoice price are 95% lower than brand drug prices without generic competition).

⁷ 15 U.S.C. § 14. See also, *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 35 (1961) (recognizing "substantial foreclosure" to trigger liability under Clayton Act, § 3).

⁸ 15 U.S.C. § 45; See Hon. Garland S. Ferguson, Jr., Chairman, Fed. Trade Comm'n, Address at the Conference on Commercial Bribery to the Commercial Standards Council and the Better Business Bureau of New York City, at 3 (Oct. 17, 1930), www.ftc.gov/systemstatementsferguson_commercial_bribery ("From the time of its creation the Federal Trade Commission has recognized commercial bribery as an unfair method of competition. One of the first cases in which the Commission ordered a respondent to cease and desist from an unfair method of competition was

Patman Act, which courts have interpreted as prohibiting commercial bribery,⁹ makes it illegal to compensate anyone who owes a duty to another party in connection with the purchase or sale of goods, except as payment for legitimate services.¹⁰

Today's enforcement policy statement should put prescription drug manufacturers and pharmacy benefit managers on notice that these longstanding FTC statutory authorities may prohibit certain drug rebate practices, especially to the extent that fees are paid to foreclose competition from more affordable generic and biosimilar alternatives. I am committed to ensuring that the FTC is bringing all our tools to bear on unlawful business practices that may be resulting in Americans paying higher prices for medicines.

one involving commercial bribery. Up to the present time the Commission has issued orders in one hundred and eighty-eight (188) such cases.”). The FTC has recognized that certain payments to intermediaries and commercial bribery practices can constitute unfair methods of competition because such payments can promote competition over who can pay the largest bribe rather than competition over who can deliver the highest quality or lowest price. *See id.* at 3 (“In addition to the immorality of the practice because of fraud and betrayal of trust, commercial bribery is unfair to competitors and against the interest of the consumer. It eliminates competition based on quality and service, and provides only competition for the good will of the agent or employee who is bribed. This leads inevitably to increase in price or deterioration in quality or both. For this the consumer must suffer. When bribery attracts trade by the fraud it perpetrates, the trade is diverted from honest and upright competitors. In order to meet this unlawful competition the honest merchant must suffer loss in price, reduce the quality of his goods, or himself become dishonest.”).

⁹ *See F.T.C. v. Henry Broch & Co.*, 363 U.S. 166, 169 n. 6 (1960) (“[A]lthough not mentioned in the Committee Reports, the debates on the bill show clearly that § 2(c) was intended to proscribe other practices such as the “bribing” of a seller's broker by the buyer.”).

¹⁰ 15 U.S.C. § 13(c).