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

STATEMENT OF COMMISSIONERS ROHIT CHOPRA AND REBECCA KELLY SLAUGHTER

Federal Trade Commission Report on the Use of Section 5 to Address Off-Patent Pharmaceutical Price Spikes

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Today, in response to a request from Congress, the Commission is issuing a report about its authority to address "unreasonable" price increases for off-patent pharmaceutical drugs and biologics and particularly those where consumers lack any therapeutic alternatives and where the price increases are "unreasonable, unavoidable, and not due to increased manufacturing costs of the product." The report does not fully outline the contours of Section 5 of the FTC Act as they relate to pricing practices under these specific circumstances,[1] so we write separately to provide our views.

Congress is rightly concerned about exorbitant price increases on off-patent drugs. So are we. For decades, the Commission has challenged a number of illegal anticompetitive practices in the pharmaceutical industry that result in high drug prices. The Commission should consider ways to build on this work by addressing emerging and evolving practices that harm consumers. While the problem of excessive drug prices for off-patent pharmaceuticals involves a complex set of issues, the stakes are too high to rely on the agency's standard approach. The Commission needs to consider the full breadth of its statutory authority under Section 5.

The Commission's report to Congress repeats an oft-stated perspective regarding the dangers of interfering with market pricing mechanisms. While this view is appropriate in many instances, the unique characteristics of the pharmaceutical market can make the application of typical market pricing mechanisms unreliable. Entry barriers and the existence of consumers who have nowhere to turn because their lives depend on a particular drug are just a few of the complexities that make this industry atypical.

The conventional wisdom is that America's high drug prices are necessary to fuel innovation and attract entry for life-saving therapies. This is highly questionable, particularly when it comes to high priced off-patent drugs that invite, but do not receive, competition from therapeutic alternatives. Even for new drugs, studies have shown that, since the mid-1990s, about 85 to 90

[1] We do not contend that Section 5 is a general price-setting statute. Instead, we confine our remarks regarding the scope of Section 5 to the circumstances outlined in the Committee's request.

percent of new drugs do not offer any meaningful clinical advantages for patients.[2] Market participants often devote significant energy and attention into activities that lead them to extend their patent exclusivity on existing therapies.

In many cases, massive price hikes are often employed by firms that do not meaningfully engage in research and development. For example, naloxone, an off-patent drug on the market since 1971 that can save the life of those suffering from an opioid overdose, has seen its price surge in the last few years.[3] While patients and taxpayers are bearing these costs, these price increases do not appear to be related to the recoupment of R&D or manufacturing costs.[4]

In some cases, the price increases are so sudden and significant that they appear to bear no reasonable relationship to any change in supply or demand conditions. For an economist, this leads to a transfer from consumer to supplier, a reduction in consumer welfare, and "deadweight loss." For American families, it can mean the difference between life and death. Congress requested an examination of its intent with respect to Section 5 of the FTC Act. Below we outline the legal authorities that Congress has entrusted to the Commission.

Enforcement:

Unfair Methods of Competition: Section 5 of the FTC Act prohibits unfair methods of competition in or affecting commerce. As articulated by then-Commissioner Jon Leibowitz, Congress intended Section 5 from its inception to reach conduct that violates the antitrust laws as well as conduct beyond the reach of the antitrust laws – for example, conduct that violates the policies that those laws were intended to promote.[5]

Some view this additional authority as limited to just a few specific exceptions to violations of the Sherman and Clayton Acts, but it is undisputed that Congress intended the FTC to have a broad mandate reaching beyond the traditional antitrust laws.[6] The Supreme Court has

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[2] *See* Donald W. Light and Joel R. Lexchin, *Pharmaceutical R&D: What do we get for all that money?*, 345 BMJ 22 – 28 (2012).

[3] *See* Matthew Rosenberg et al., *Trends and Economic Drivers for United States Naloxone Pricing, January 2006 to February 2017*, 86 Addictive Behav. 86 – 89 (2018) (finding that, although gradual price increases are attributable to increasing demand, sudden and sustained price increases across all naloxone products are significantly explained by the lack of competition).

[4] *See* Shefali Luthra, *Massive Price Hike for Lifesaving Opioid Overdose Antidote*, Kaiser Health News (Feb. 2, 2017), https://www.scientificamerican.com/article/massive-price-hike-for-lifesaving-opioid-overdose-antidote1/?redirect=1.

[5] *See* Concurring Opinion of Commissioner Jon Leibowitz, *In the Matter of Rambus, Inc.*, Docket No. 9302, and cites therein, https://www.ftc.gov/sites/default/files/documents/cases/2006/08/060802rambusconcurringopinionofcommissionerleibowitz.pdf.

[6] While it is correct that FTC cases cited in the Commission's Report to Congress such as *Official Airline Guides, Inc. v. FTC*, 630 F.2d 920 (2d Cir. 1980); *Boise Cascade Corp. v. Fed. Trade Comm'n*, 637 F.2d 573 (9th Cir. 1980), and *E.I. Du Pont de Nemours & Co. v. FTC*, 729 F.2d 128 (2d Cir. 1984) found that Section 5 did not apply to the practice at issue, each decision turned primarily on an evidentiary failure by the FTC to demonstrate that the challenged conduct constituted an effort to acquire market power, tacitly collude, or manipulate price for anticompetitive purposes. Importantly, the courts nonetheless recognized that Section 5 allows the FTC to challenge behavior beyond the reach of the antitrust laws.

repeatedly and consistently affirmed the breadth of Section 5 authority in terms that both subsume and go beyond the prohibitions of the Sherman Act.[7]

As the Supreme Court noted in *Federal Trade Commission v. Cement Institute*, the purpose of Congress in enacting Section 5 was to vest the Commission with "powers to hit at every trade practice, then existing or thereafter contrived, which restrained competition or might lead to such restraint if not stopped in its incipient stages."[8] More recently, in *Federal Trade Commission v. Indiana Federation of Dentists*, the Court confirmed that the unfair methods of competition language in Section 5 extends beyond the traditional antitrust laws.

As a practical matter, the Commission can bring, and has brought, enforcement actions when excessive drug price increases are accompanied by exclusionary conduct or the result of a merger. For example, the FTC can consider whether an acquisition facilitates the exercise of monopoly power or represents an attempt to monopolize. But when the price of vital and sometimes life-saving medication with no therapeutic alternatives suddenly increases, there may be other bases upon which the Commission could challenge an excessive price increase that the Commission could further explore.[9] While excessive pricing enforcement efforts may face significant challenges, such challenges alone should not deter exploration of all powers provided under Section 5.

Unfair or Deceptive Acts or Practices (UDAP): Section 5 also includes a broad prohibition on unfair or deceptive acts or practices. In a situation where the maker of an off-patent drug dramatically raises prices, the facts and circumstances might meet the criteria Congress enumerated for an unfair practice: (1) substantial consumer injury, (2) without offsetting benefits, and (3) one that consumers cannot reasonably avoid.[10]

To date, the Commission has not used this unfairness authority to challenge excessive, unjustified drug price increases.[11] However, in situations where (1) a price increase involves off-patent drugs that lack therapeutic alternatives, and where research, production, and regulatory barriers would prevent near-term entry, (2) the price increase bears no reasonable relationship to manufacturing or production cost increases or changes in supply and demand conditions, and (3) the harm to patients is not outweighed by other benefits, the conduct might meet the definition of an unfair practice. In these situations, firm tactics force consumers to pay exorbitant prices or

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[7] *See, e.g., Fed. Trade Comm'n v. Indiana Fed. of Dentists*, 476 U.S. 447, 454 (1986); *Fed. Trade Comm'n v. Brown Shoe. Co.*, 384 U.S. 316, 322 (1966); *Fed. Trade Comm'n v. Cement Inst.*, 333 U.S. 683, 693 (1948); *Fed. Trade Comm'n v. Beech-Nut Packing Co*., 257 U.S. 441, 453 (1922).

[8] 333 U.S. 683, 693 (1948).

[9] *See, e.g.*, Concurring Statement of Commissioner J. Thomas Rosch, *Federal Trade Commission v. Ovation Pharmaceuticals, Inc.*, Civil No. 08-6379 (U.S. D. Minn.) (Dec. 16, 2008), https://www.ftc.gov/system/files/documents/public_statements/418091/081216ovationroschstmt.pdf; Thomas B. Leary, *Antitrust Scrutiny of a Pure Conglomerate Merger: The Ovation Case* 23 Antitrust 74 – 79 (2009).

[10] FTC Amendments of 1994, 15 U.S.C. § 45(n).

[11] The Commission has applied unfairness to other new problems in the market as they arise, including data security, cramming, and in-app purchases.

forego potentially life-saving drugs; while applying our unfair practice authority to these fact patterns would be novel, it may well be warranted.[12]

If the Commission determined that the pricing practice was unlawful, it could bring an enforcement action to seek redress to patients, disgorgement of ill-gotten gains, and other relief. The FTC Act generally does not provide for civil penalties on the first offense using these procedures.

However, first-time offenses involving an opioid treatment drug may violate the SUPPORT for Patients and Communities Act ("SUPPORT Act"), which was signed into law late last year.[13] The Act makes any unfair or deceptive acts regarding substance use disorder treatment services or products subject to civil penalties on the first offense.

Rulemaking:

Unfair Methods of Competition: The Commission also has authority to define unfair methods of competition through participatory rulemaking under the Administrative Procedure Act.[14] The Commission could theoretically use this authority to develop a factual record that provides the basis for a rule defining the circumstances when an excessive price increase on an off-patent drug constitutes an unfair method of competition. While a rule would help to provide clear notice to the marketplace and to courts, violations of a rule under this section do not lead to civil penalties, though the Commission could seek redress for patients and disgorgement of ill-gotten gains from a federal court.

Unfair or Deceptive Acts or Practices: The Commission has authority to define, by rule, conduct that is an unfair or deceptive act or practice. The process for promulgating a rule under this authority is more cumbersome and potentially time-consuming compared to rules defining unfair methods of competition.[15] However, violations of the rule would be subject to substantial civil penalties, in addition to other relief granted by a court, which may advance the goal of general deterrence.

Defining an excessive price increase by rule under either of these authorities would not be without challenges. It is worth noting that Congress has routinely enacted legislation that defines certain proscribed conduct as a violation of a Commission rule. While the FTC could pursue a

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[12] *See generally* Fed. Trade Comm'n Policy Statement on Unfairness (appended to *Int'l Harvester Co.*, 104 F.T.C. 949, 1070 (1984)). The Policy Statement on Unfairness emphasizes that most of the Commission's unfairness matters have been brought where tactics interfere with consumer choice or unreasonably creates or takes advantage of an obstacle to consumers' ability to exercise consumer choice.

[13] SUPPORT for Patients and Communities Act, H.R. 6 -- 115th Congress (2017-2018).

[14] *See* Comment of Fed. Trade Commn'r Rohit Chopra, Hearing #1 on Competition and Consumer Protection in the 21st Century, Docket ID No. FTC-2018-0074, at 4 (Sept. 6, 2018) (the Case for Rulemaking Under "Unfair Methods of Competition"), https://www.ftc.gov/system/files/documents/public_statements/1408196/chopra_-_comment_to_hearing_1_9-6-18.pdf/.

[15] The Magnuson-Moss Warranty – Federal Trade Commission Improvement Act, Pub. L. No. 93-637, 88 Stat. 2183 (1975) (codified at 15 U.S.C. §§ 2301-2312 (2012)), introduced heightened procedural requirements for rulemaking defining an unfair or deceptive act or practice.

rulemaking on its own, Congress could itself define an excessive price increase in this marketplace or require the FTC to promulgate a rulemaking meeting certain specifications, thereby subjecting violators to penalties. Given the significant concerns in this marketplace, we urge Congress to carefully consider this approach.[16]

Conclusion

It was no accident that, over one hundred years ago, Congress granted the FTC broad authority under Section 5 of the FTC Act. Congress specifically foresaw the changing nature of business practices, and Congress wanted an expert administrative agency with broad and flexible authority to "hit at every trade practice, then existing or thereafter contrived, which restrained competition or might lead to such restraint if not stopped in its incipient stages."[17]

We should carefully examine and aggressively employ new ways to utilize our enforcement tools that restore competition and eliminate unfair or deceptive acts or practices in the pharmaceutical industry. Given the market failures in this industry, it will be critical for Congress and the FTC to work together to combat the harm that can make the difference between life and death.

[16] If Congress chooses to authorize the Commission to promulgate a rule by statute, Congress should be aware that the Commission sometimes declines to do so. For example, in 1994, Congress authorized the Commission to promulgate a rule regarding Made in USA claims. In 2010, Congress gave the Commission authority to promulgate a rule in the auto sales, financing, and leasing. In both instances, the Commission did not act. As a result, the agency cannot seek civil penalties on the first offense for violators. If Congress seeks to assist patients in a more expedited manner, it should ensure that it develops legislation that removes the negative effects that might stem from Commission inaction.

[17] *Cement Inst.*, 333 U.S. at 693, supra note 7.