

Federal Trade Commission

Report on Standalone Section 5 to Address High Pharmaceutical Drug and Biologic Prices

Congress directed the Federal Trade Commission (“FTC”) to report to the House and Senate Appropriations Committees (“Committees”) on the use of the FTC’s standalone authority under Section 5 of the Federal Trade Commission Act to address high pharmaceutical prices. Specifically, the Committees requested that the FTC, in consultation with the U.S. Food and Drug Administration (“FDA”), examine Congress’s intent regarding unfair methods of competition in 15 U.S.C. 45(n) and in the FTC’s standalone Section 5 authority with regard to unreasonable price increases, including those that occur over multiple years, on off-patent pharmaceutical drugs and biologics when there are no alternatives available to the consumer, and when price increases are unreasonable, unavoidable, and not due to increased manufacturing costs of the product.¹ The Committees requested that the Commission submit a report within 120 days of the bill’s enactment.

Section 5 gives the Commission authority to address both “unfair or deceptive acts or practices” (“UDAPs”) and “unfair methods of competition.” Although the directions for this report cite to the Commission’s authority over unfair methods of competition under § 45(n), we note that this subsection pertains to “unfair or deceptive acts or practices,” and not “unfair methods of competition” under 15 U.S.C. 45(a)(1). Consistent with the text of the bill, this report focuses on the FTC’s ability to use its antitrust authority over unfair methods of competition to address unreasonable drug price increases. Although the FTC has not ruled out the possibility that, in certain extreme circumstances, an excessive price increase on a pharmaceutical product could constitute a UDAP, to date, it has not challenged an adequately disclosed price increase.

Part I of this Report provides an overview of the scope of the FTC’s authority under Section 5(a) to address unfair methods of competition and the nexus to existing antitrust principles.² Part II explains how the Commission may combat high drug prices when a monopolist employs business practices that harm competition. For decades, the FTC has devoted substantial resources to anticompetitive practices in the pharmaceutical markets, which act to keep prices from being increased in violation of the law. However, the legal and economic analysis underlying the antitrust laws provides little basis for using standalone Section 5 to address high prices unaccompanied by exclusionary conduct, including high drug prices under the conditions of interest to the Committees. Part III briefly discusses other considerations that

¹ Joint Explanatory Statement published in the Congressional Record on Feb. 13, 2019 at H1831 <https://www.congress.gov/116/crec/2019/02/13/CREC-2019-02-13-pt2-PgH1589-2.pdf> that accompanied the Consolidated Appropriations Act, 2019, Pub. L. 116-6, incorporated by reference Senate Report 115-281 at 73 <https://www.congress.gov/115/crpt/srpt281/CRPT-115srpt281.pdf> that accompanied S. 3107, General Government and Financial Services Appropriations Bill, 2019.

² In a separate statement, Commissioners Chopra and Slaughter suggest that we should explore new ways of applying our standalone Section 5 authority to challenge “unreasonable” increases in drug prices for off-patent branded drugs. Their theories, however, neither define a clear legal standard under any aspect of Section 5, nor identify a case where a price increase alone would have violated their proposed application of Section 5. The theories would also require the FTC to decide acceptable pricing levels. Such a regime, which would involve barring excessive prices in the absence of anticompetitive conduct, would have the FTC act like a public utility commission, which sets rates, something for which we are ill equipped. This report outlines the contours of the FTC’s Section 5 authority, as defined by prior litigation and policy work, and we will continue to use the full extent of our authority to vigorously challenge anticompetitive conduct that results in higher drug prices.

may affect the FTC's use of its standalone Section 5 authority. Part IV examines how the FTC enforces the antitrust laws to combat anticompetitive conduct and preserve competition in pharmaceutical markets. Part V recounts our efforts to work with the FDA and other government agencies to promote competition and eliminate barriers to entry in pharmaceutical and emerging biologic markets.

I. Overview of the FTC's Section 5 Authority to Combat Unfair Methods of Competition

As described in Part IV, the Commission has an active program in place to investigate and challenge unfair methods of competition by pharmaceutical companies that harm competition and result in higher drug prices. The Commission's authority to address unfair methods of competition under Section 5 of the FTC Act covers conduct that violates the Sherman Act and the Clayton Act,³ and the vast majority of cases brought by the FTC alleging an unfair method of competition would also violate one of these two other U.S. antitrust laws.⁴ Section 5 legislative history and Supreme Court cases also confirm that Section 5 prohibits "not only practices that violate the Sherman Act and the other antitrust laws, but also practices that the Commission determines are against public policy for other reasons."⁵ Nevertheless, courts have been reluctant to expand the reach of Section 5 beyond the scope of the Sherman or Clayton Acts.

In the 1970s, the Commission attempted to expand the use of its standalone Section 5 authority and suffered a string of federal court losses. In each of those cases, the Commission argued that it was only moderately expanding the reach of the agency's Section 5 authority beyond core antitrust prohibitions, but the courts nonetheless rejected those expansions. For example, courts expressed concerns that the FTC was substituting its own business judgment for that of the monopolist,⁶ was making decisions without showing collusion or anticompetitive effects,⁷ was prohibiting parallel conduct without a showing of collusive behavior,⁸ and might make enforcement decisions for social, political, or personal reasons.⁹

³ *FTC v. Actavis*, 570 U.S. 136, 145 (2013); *California Dental Ass'n v. FTC*, 526 U.S. 756, 762 & n.3 (1999); *FTC v. Motion Picture Adver. Serv. Co.*, 344 U.S. 392, 394-95 (1953), *Fashion Originators' Guild of Am., Inc. v. FTC*, 312 U.S. 457, 463-64 & n.4 (1941).

⁴ *See, e.g., In the Matter of Impax Labs., Inc.*, Dkt. 9373 at 15 (Mar. 29, 2019) (analysis of reverse payment patent settlement follows caselaw developed under Section 1 of the Sherman Act); *In the Matter of McWane, Inc.*, 2014 FTC LEXIS 28 *30 (F.T.C. 2014) (analysis of exclusive dealing relies on Sherman Act caselaw); *aff'd McWane, Inc. v. FTC*, 783 F.3d 814 (11th Cir. 2015). On review, appellate courts afford some deference to the FTC's judgment that the conduct under review constitutes an unfair method of competition.

⁵ *FTC v. Sperry Hutchinson Co.*, 405 U.S. 233, 244 (1972) (discussing Congressional intent behind the decision to ban "unfair methods of competition" rather than providing a more specific list of offenses); S. Rep. No. 597 63rd Cong. 2d Sess. 13 (1914).

⁶ *Official Airline Guides, Inc. v. FTC*, 630 F.2d 920, 926-27 (2d Cir. 1980).

⁷ *Boise Cascade Corp. v. FTC*, 637 F.2d 573, 578-80 (9th Cir. 1980) (holding pricing alone was insufficient to find a standalone Section 5 violation; instead the FTC must prove coordinated conduct or actual effect on competition)

⁸ *E.I. du Pont de Nemours & Co. v. FTC*, 729 F.2d 128, 135-142 (2d Cir. 1984) (declining to find unilateral parallel pricing decisions antitrust violations under a standalone Section 5 theory).

⁹ *Official Airline Guides, Inc.*, 630 F.2d at 926-27.

In August 2015, in response to concerns from Members of Congress and others that the FTC’s standalone Section 5 authority was too undefined, the FTC issued a written framework for the application of this authority to acts or practices that fall outside the scope of Sherman Act or Clayton Act violations. The statement affirmed that the Commission’s standalone Section 5 authority extends to unilateral conduct that violates the spirit of the antitrust laws and conduct that, if allowed to mature or complete, could violate the Sherman or Clayton Act.¹⁰ For instance, there is broad consensus that an invitation to collude, even if not accepted, violates Section 5.¹¹ In other instances where the Commission has invoked its standalone Section 5 authority, it has done so only after concluding that the conduct in question was likely to harm competition and consumers, and only after taking into account any efficiency justifications.¹²

According to the FTC’s statement, the Commission would adhere to three principles in deciding whether to challenge, as an unfair method of competition, an act or practice that does not otherwise violate another antitrust law:

1. the Commission will be guided by the public policy underlying the antitrust laws, namely, the promotion of consumer welfare;
2. the act or practice will be evaluated under a framework similar to the rule of reason; that is, an act or practice challenged by the Commission must cause, or be likely to cause, harm to competition or the competitive process, taking into account any associated cognizable efficiencies and business justifications; and
3. the Commission is less likely to challenge an act or practice as an unfair method of competition on a standalone basis if enforcement of the Sherman or Clayton Act is sufficient to address the competitive harm arising from the act or practice.¹³

II. Relying on Section 5 to Directly Combat High Drug Prices Alone Is Contrary to Existing Antitrust Jurisprudence

When relying on Section 5 on a standalone basis to address likely competitive harm that cannot be reached with other antitrust laws, judicial interpretations of the antitrust laws, especially the Sherman Act, will inform the Commission’s view of the appropriate goals and analysis under Section 5.

¹⁰ Fed. Trade Comm’n, Statement of Enforcement Principles Regard “Unfair Methods of Competition” Under Section 5 of the FTC Act (Aug. 13, 2015), https://www.ftc.gov/system/files/documents/public_statements/735201/150813section5enforcement.pdf.

¹¹ See, e.g., *In re U-Haul Int’l, Inc.*, 150 F.T.C. 1, 53 (2010); *In re Valassis Commc’ns, Inc.*, 141 F.T.C. 247 (2006); *In re Quality Trailer Prods.*, 115 F.T.C. 944 (1992); *In re AE Clevite*, 116 F.T.C. 389 (1993); *In re Precision Moulding*, 122 F.T.C. 104 (1996); *In re Stone Container*, 125 F.T.C. 853 (1998). This conclusion has been endorsed by leading antitrust scholars; see also P. Areeda & H. Hovenkamp, VI ANTITRUST LAW ¶ 1419 (2003).

¹² See Analysis to Aid Public Comment, *In the Matter of Bosley, Inc.*, Dkt. C-4404 (April 8, 2013) at 2 (“The Commission must weigh the potential for competitive harm from direct and repeated exchanges of competitively sensitive, nonpublic information against the prospect of legitimate efficiency benefits.”).

¹³ Fed. Trade Comm’n, Statement of Enforcement Principles Regard “Unfair Methods of Competition” Under Section 5 of the FTC Act (Aug. 13, 2015), https://www.ftc.gov/system/files/documents/public_statements/735201/150813section5enforcement.pdf.

The Sherman Act prohibits certain types of conduct that harm competition or the competitive process. Section 1 of the Sherman Act addresses the greatest risk of anticompetitive harm, which comes from collusive conduct among competitors to fix prices. Naked agreements to fix prices are routinely found to be *per se* illegal and may constitute criminal violations of Section 1 of the Sherman Act.¹⁴ The Supreme Court has imposed *per se* liability for price fixing agreements, in part to avoid judicial inquiry into what a reasonable price might be.¹⁵

We understand the Committees' main concern, for purposes of this required report, relates to unilateral (as opposed to concerted) price increases, which in some instances have been very sudden and extreme. Unilateral conduct is governed by Section 2 of the Sherman Act, which prohibits monopolization or attempts to monopolize. Generally, a violation of Section 2 has "two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident."¹⁶ As the courts have confirmed, it is not inherently unlawful to possess a monopoly; Section 2 law focuses on the means by which a monopolist attains or maintains monopoly power (often referred to as "exclusionary conduct"). Furthermore, courts have held that lawful monopolists may set their prices as high as they choose; again, the focus is on how monopoly power has been acquired or maintained, not on the price that the monopolist sets.¹⁷ In other words, even very high prices, standing alone, do not constitute unlawful exclusionary conduct under Section 2.

¹⁴ Based on public reports, forty-four states have charged 20 generic drug makers with violations of federal and state antitrust laws, including collusive price fixing. In addition, the Department of Justice has a pending criminal investigation involving generic drug price-fixing, which has resulted in felony charges against two executives. DOJ Press Release, Former Top Generic Pharmaceutical Executives Charged with Price-Fixing, Bid-Rigging and Customer Allocation Conspiracies (Dec. 14, 2016), <https://www.justice.gov/opa/pr/former-top-generic-pharmaceutical-executives-charged-price-fixing-bid-rigging-and-customer>.

¹⁵ *United States v. Trenton Potteries, Co.*, 273 U.S. 394, 397-98 (1926) ("The aim and result of every price-fixing agreement, if effective, is the elimination of one form of competition. The power to fix prices, whether reasonably exercised or not, involves power to control the market and to fix arbitrary and unreasonable prices. The reasonable price fixed today may through economic and business changes become the unreasonable price of tomorrow. Once established, it may be maintained unchanged because of the absence of competition secured by the agreement for a price reasonable when fixed. Agreements which create such potential power may well be held to be in themselves unreasonable or unlawful restraints, without the necessity of minute inquiry whether a particular price is reasonable or unreasonable as fixed and without placing on the government in enforcing the Sherman Law the burden of ascertaining from day to day whether it has become unreasonable through the mere variation of economic conditions. Moreover, in the absence of express legislation requiring it, we should hesitate to adopt a construction making the difference between legal and illegal conduct in the field of business relations depend upon so uncertain a test as whether prices are reasonable—a determination which can be satisfactorily made only after a complete survey of our economic organization and a choice between rival philosophies.").

¹⁶ *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966).

¹⁷ *Verizon Comm'ns v. Trinko*, 540 U.S. 398, 407 (2004) ("[T]he mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system."); *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 297 (2d Cir. 1979) ("[a] pristine monopolist . . . may charge as high a rate as the market will bear"); *Blue Cross and Blue Shield United of Wisconsin v. Marshfield Clinic*, 65 F.3d 1406, 1413 (7th Cir. 1995) ("[a] natural monopolist that acquired and maintained its monopoly without excluding competitors by improper means is not guilty of 'monopolizing' in violation of the Sherman Act . . . and can therefore charge any price that it wants . . . for the antitrust laws are not a price-control statute or a public utility or common-carrier rate-regulation statute") (citing *National Reporting Co. v. Alderson Reporting Co.*, 763 F.2d 1020, 1023-24 (8th Cir. 1985)); *U.S. v. Aluminum Co. of America*, 148 F.2d 416, 430 (2d Cir. 1945); *Ball Memorial Hosp., Inc. v. Mutual Hosp. Ins., Inc.*, 784 F.2d at 1325, 1339 (7th Cir. 1986); *Berkey Photo*, 603 F.2d at 296-98.

Nevertheless, when the Commission has found high prices accompanied by conduct that can be characterized as monopolizing, it has challenged the conduct under Section 5. For instance, in the *Lundbeck* case described in Part IV.C., the Commission challenged the acquisition under Section 5 of the FTC Act and Section 7 of the Clayton Act and would investigate similar fact patterns today. In fact, the Commission is actively investigating companies for conduct that has resulted in high drug prices.

III. Other Considerations, Including Those Emphasized by Courts, May Limit the Application of Section 5 to Combat Excessive Prices Increases

Courts have consistently narrowed the scope of legal and economic justifications to use the antitrust laws to address unilateral pricing decisions. Were the Commission to invoke its standalone Section 5 authority to challenge high drug prices, and were the Commission to pursue theories not tied to harm from collusive or exclusionary conduct recognized under Section 1 or Section 2 of the Sherman Act, courts likely would be hostile to the attempted expansion of liability.

The issue of excessive drug pricing, and drug price increases specifically, has prompted an interest in various policy interventions, including antitrust enforcement, to ensure consumer access to vital medications and to promote innovation and investment. But, given concerns about institutional competence and administrability, among other considerations, courts have limited the use of antitrust to combat excessive drug prices unmoored from conduct that harms the competitive process.

A. Limiting the Unilateral Freedom to Set Prices Diminishes Incentives to Compete and Innovate

Courts typically decline to impose antitrust liability for unilateral pricing decisions, in large part, because pricing plays such an important role in driving competition: where a firm has attained a monopoly position through legitimate means, denying that firm the fruits of its monopoly can diminish its incentives to compete in the first place.¹⁸ “The mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system. The opportunity to charge monopoly prices—at least for a short period—is what attracts ‘business acumen’ in the first place; it induces risk taking that produces innovation and economic growth.”¹⁹ Therefore, limiting the freedom to set prices may well conflict with the underlying premise of antitrust policy, *i.e.* promoting a robust competitive process that produces high-quality, innovative goods at low prices.

¹⁸ *Aluminum Co. of America*, 148 F.2d at 430 (“A single producer may be the survivor out of a group of active competitors, merely by virtue of his superior skill, foresight and industry. In such cases a strong argument can be made that, although the result may expose the public to the evils of monopoly, the [Sherman] Act does not mean to condemn the resultant of those very forces which it is its prime object to foster: *finis opus coronat*. The successful competitor, having been urged to compete, must not be turned upon when he wins.”).

¹⁹ *Trinko*, 540 U.S. at 407 (2004).

B. Interfering with Market Pricing Mechanisms Typically Distorts Supply and Demand and May Lead to Reduced Supply Rather than Lower Pricing

A second rationale for not intervening in a firm's unilateral pricing relates to the crucial role prices ordinarily play in determining the allocation of scarce resources among competing uses. In a market-based economy, prices determine these allocations by signaling where more resources are required. For example, although prescription drug markets are typically characterized by substantial barriers to entry, high prices (relative to costs) can often attract new market entry by producers lured by potentially lucrative profits, thus increasing output. Placing artificial limits on prices may reduce supply by reducing or removing the incentive for new companies to enter or for existing competitors to expand.

C. Difficulty Determining an Excessive Price Increase Standard and Crafting Remedies

U.S. courts have consistently found that determining the "reasonableness" of prices charged by lawful monopolists goes beyond their competence. This notion goes back to early U.S. antitrust jurisprudence.²⁰ Courts have deemed themselves not sufficiently equipped to determine what constitutes a "fair" or "excessive" price.²¹ Indeed, the Supreme Court stated:

[H]ow is a judge or jury to determine a 'fair price?' Is it the price charged by other suppliers of the primary product? None exist. Is it the price that competition 'would have set' were the primary level not monopolized? How can the court determine this price without examining costs and demands, indeed without acting like a rate-setting regulatory agency, the rate-setting proceedings of which often last for several years? Further, how is the court to decide the proper size of the price 'gap?' Must it be large enough for all independent competing firms to make a 'living profit,' no matter how inefficient they may be? . . . And how should the court respond when costs or demands change over time, as they inevitably will?²²

For these reasons, absent detailed statutory guidance, both courts and the FTC would find it extremely difficult to set up and enforce an accurate and meaningful standard for excessive price increases that would adequately account for the various considerations at issue, including (1) the threshold of an offending change in price, (2) the extent of harm to consumer drug affordability and access, (3) the reward to prior investments and innovation by the drug company, (4) the incentive for new investments, expanded output, and innovation by the drug company and any potential entrants, (5) the feedback effects on initial drug prices, and (6) the certainty and predictability concerns for companies subject to any ruling. Courts have declined to do so under Section 2 of the Sherman Act. There is little reason to think the FTC, applying similar legal and economic principles, would fare any better under Section 5 of the FTC Act.

²⁰ *United States v. Addyston Pipe & Steel Co.*, 85 F. 271, 283-284 (6th Cir. 1898) ("It is true that there are some cases in which the courts, mistaking . . . the proper limits of the relaxation of the rules for determining the unreasonableness of restraints of trade, have set sail on a sea of doubt . . .").

²¹ *Pacific Bell Tel. Co. v. linkLine Comm'ns, Inc.*, 555 U.S. 438 (2009) (holding that even in cases where telephone companies must provide interconnect services to its rivals, a firm is not required to price those services in a manner that preserves its rivals' profit margins).

²² *Id.* at 454 (quoting *Town of Concord v. Boston Edison Co.*, 915 F.2d 17, 25 (1st Cir. 1990)).

Even if the FTC were to take on this task, in addition to developing a viable enforcement standard, the FTC also would need a standard for crafting an appropriate remedy. Unfortunately, the FTC is not well-equipped to determine “reasonable” pricing levels and enforce compliance with a pricing mechanism divorced from market-based competition. For example, the theoretical “best” price for society in a market with competing firms balances the considerations outlined above, including the consumer benefits of lower prices against the need to provide firms with incentives to invest and enter the market. These pricing decisions generally depend on cost and demand factors that the FTC cannot observe. As discussed above, any FTC remedial action to dictate prices could easily reduce supply at established prices (possibly leading to shortages), discourage entry and investment, and ultimately harm consumers.

D. Market Conditions or Government-Granted Barriers to Entry May Contribute to the Ability to Raise Prices and Thereby Inhibit Antitrust Enforcement Over Excessive Price Increases

Patents and similar government-granted exclusivities may provide a pharmaceutical firm with significant pricing power, but we understand that the Committees are primarily concerned with price increases for products that are no longer subject to these protections.

Even setting those reasons aside, our economy is shaped by numerous supply and demand forces, such as input price increases, supply disruptions, demand spikes, or other public policies (e.g., FDA approval for other drugs). As with other goods and services, pharmaceutical prices may reflect these forces. Other factors particularly impact drug markets and stifle entry by additional firms, even in markets with high-priced products. For instance, the U.S. Government Accountability Office (“GAO”) found that inadequate access to active pharmaceutical ingredients, decreased volume of drug production, and lack of incentive to enter a market serving a small population all contribute to price increases.²³ In addition, the time and expense of developing a new drug and obtaining FDA approval can delay entry for years, allowing existing suppliers to keep prices high in the meantime.

IV. Antitrust Enforcement Supports Lower Drug Costs By Prohibiting Conduct that Unlawfully Restrains Competition or Excludes Generic Competition

Although the antitrust laws may not be an effective tool for directly attacking high drug prices resulting from broader market forces, the FTC has aggressively challenged anticompetitive conduct that results in high drug prices. The Commission maintains a robust program to identify and stop anticompetitive mergers and conduct in critical health care markets.²⁴ Whenever high prices stem from conduct that violates the antitrust laws, the remedy prescribed to correct the underlying antitrust violation may also lower prices.

²³ U.S. Gov’t Accountability Office, GAO-16-706, 23-24, *Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases* (Aug. 2016), <https://www.gao.gov/assets/680/679022.pdf>.

²⁴ See Fed. Trade Comm’n, *Overview of FTC Actions in Pharmaceutical Products and Distribution* (Aug. 2018), https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_pharma_august_2018.pdf.

A. Reverse Payment Patent Settlements

The FTC has challenged a number of pay-for-delay or “reverse payment” agreements in which the branded drug firm pays its potential generic competitor to abandon a patent challenge and refrain from entering the market with a lower cost, generic product. In 2013, the FTC obtained a landmark ruling in *FTC v. Actavis* when the Supreme Court held that reverse payment patent settlements are subject to antitrust scrutiny.²⁵ Branded manufacturers have used such agreements to buy more protection from competition than their patent rights provide, at the expense of competition and consumers.²⁶ The core concern with these agreements is that they will allow the branded manufacturer to “prevent the risk of competition” by sharing its monopoly profits, which are preserved by the agreement, with the prospective generic entrant.²⁷ Earlier this year, the Commission unanimously held that Impax Laboratories violated the antitrust laws by entering into such a reverse-payment agreement with Endo Pharmaceutical to block consumers’ access to a lower-cost generic version of Endo’s branded oxymorphone ER—an extended-release pain reliever.²⁸ The Commission’s Final Order bars Impax from entering into any type of reverse payment that defers or restricts generic entry or into any agreement with another oxymorphone ER manufacturer that prevents or restricts competition between oxymorphone ER products.²⁹

FTC staff recently released its FY 2016 annual report of agreements filed under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”).³⁰ According to staff’s report, the third since the Supreme Court’s decision in *FTC v. Actavis*, although the total number of final Hatch-Waxman patent settlements entered by pharmaceutical companies increased dramatically in FY 2016, agreements using reverse payments that are most likely to be anticompetitive continue to decline. Indeed, reverse-payment agreements using side deals and no-authorized generic commitments have declined to their lowest level in 15 years. The Commission will continue to closely scrutinize MMA filings, including agreements related to biologic products, and to pursue vigorous antitrust enforcement to put an end to anticompetitive patent settlement agreements that forestall entry and keep prices high.

B. Abuse of Government Processes

The FTC also has challenged unilateral conduct by branded manufacturers for illegally maintaining a monopoly position. For example, the FTC charged several major pharmaceutical

²⁵ *FTC v. Actavis, Inc.*, 570 U.S. 136, 160 (2013). The Supreme Court remanded the case back to the district court for further proceedings, and in February 2019, the last defendant settled with the FTC in February 2019. See FTC Press Release, *FTC Enters Global Settlement to Resolve Reverse-Payment Charges against Teva* (Feb. 19, 2019), <https://www.ftc.gov/news-events/press-releases/2019/02/ftc-enters-global-settlement-resolve-reverse-payment-charges>.

²⁶ *Actavis*, 570 U.S. at 148. (“There is reason for concern that settlements taking this form tend to have significant adverse effects on competition.”).

²⁷ *Id.* at 157-8.

²⁸ Commission Op., *In the Matter of Impax Labs., Inc.*, Dkt. 9373 at 3-4 (Mar. 29, 2019).

²⁹ Final Order, *In the Matter of Impax Labs., Inc.*, Dkt. 9373 at 34 (Mar. 28, 2019).

³⁰ Section 1112 of Subtitle B (“Federal Trade Commission Review”) of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires that brand drug manufacturers and generic drug applicants file certain agreements with the FTC and the Antitrust Division within 10 business days of execution of the agreement. This requirement has been in place since January 7, 2004.

companies with illegally blocking consumers' access to lower-cost versions of the blockbuster drug AndroGel both by filing baseless patent infringement lawsuits against potential generic competitors and by alleging that AbbVie entered into an anticompetitive settlement agreement with Teva to further delay competition.³¹ In May 2015, the district court dismissed claims that the patent settlement agreement with Teva was an anticompetitive reverse payment. However, the case went forward on the other claims, and in June 2018, the court held that the defendants illegally and willfully maintained their monopoly power by filing sham litigation, which delayed the entry of generic competition to the detriment of consumers. The court awarded equitable monetary relief to the FTC in the amount of \$448 million and also awarded \$46 million in prejudgment interest.³² The FTC's appeal on the district court's dismissal of the reverse payment settlement and the court's remedy in this case is pending before the Third Circuit.

In another type of abuse of government process, in some instances, branded manufacturers may have restricted access to drug samples that generic manufacturers require to conduct the necessary testing for FDA approval. In particular, generic manufacturers require brand drug samples to conduct bioequivalence testing needed to demonstrate that the generic drug is therapeutically equivalent to the brand drug. However, brand manufacturers may implement FDA-mandated risk management programs known as Risk Evaluation and Mitigation Strategies ("REMS") to limit access to these drugs. In some cases, these REMS programs are designed to ensure drugs are distributed safely to patients. In other cases, however, brand manufacturers may abuse REMS programs to eliminate competition from generic drugs, which very likely will preserve high prices. When Congress authorized the FDA to require REMS programs, it stated that REMS programs were not intended to block or delay approval of generic drug products. As discussed in Part V below, the FTC has filed amicus briefs in private litigation focused on these issues.³³

C. Merger Enforcement to Preserve Competition In Pharmaceutical Markets

Increased market concentration following a merger or acquisition may change the incentives of market participants in ways that reduce competition and drive up the price of drugs. The FTC has challenged pharmaceutical acquisitions that preceded a sudden and significant price increase. For instance, in the *Lundbeck* case, the FTC sued Ovation Pharmaceuticals for purchasing the rights to a drug that was newly approved to treat a condition that one of Ovation's own drugs already treated and for dramatically raising the price on the newly acquired drug.³⁴ The FTC challenged this acquisition under the FTC Act and Clayton Act. Although the court ruled against the FTC in that case, the Commission would not hesitate to investigate other

³¹ *FTC v. AbbVie Inc., et al.*, Case No. 2:14-cv-051510-HB, FTC File No. 121-0028 (complaint filed seeking a permanent injunction and other equitable relief on September 8, 2014) <https://www.ftc.gov/enforcement/cases-proceedings/121-0028/abbvie-inc-et-al>.

³² *FTC v. AbbVie Inc.*, 329 F. Supp. 3d 98, 146 (E.D. Pa. 2018).

³³ *Mylan Pharmaceuticals v. Celgene Corp.*, Case No. 2:14-CV-2094-ES-MAH (D. N.J. June 17, 2014), https://www.ftc.gov/system/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.v.celgene-corporation/140617celgeneamicusbrief.pdf. The Commission vote approving filing of the brief was 4-1. *Actelion Pharmaceuticals Ltd. v. Apotex Inc.*, Case No. 1:12-cv-05743-NLH-AMD (D. N.J. March 11, 2013) https://www.ftc.gov/sites/default/files/documents/amicus_briefs/actelion-pharmaceuticals-ltd.et-al.v.apotex-inc./130311actelionamicusbrief.pdf. The Commission vote approving filing of the brief was 4-0.

³⁴ *FTC v. Lundbeck, Inc.*, 2010 WL 3810015 (D. Minn. Aug. 31, 2010), *aff'd*, 650 F.3d 1236 (8th Cir. 2011).

instances where a pharmaceutical company acquired a drug and engaged in efforts to maintain its monopoly by acquiring real or nascent competitors or by engaging in other activities to entrench its existing monopoly position.³⁵

Over the last few years, the FTC has challenged a number of mergers and acquisitions involving pharmaceuticals that had the potential to diminish competition and increase drug prices.³⁶ The final orders in most of these cases required the parties to divest or transfer assets related to the lost competition in order to keep the markets competitive. The FTC has also obtained equitable monetary relief and required licensing remedies to correct an acquisition that allowed a drug company to maintain artificially high prices.³⁷

V. Working with Pharmaceutical Industry Regulators to Promote Competition and Lower Drug Prices

Productive working relationships with industry regulators, such as the U.S. Department of Health and Human Services (“HHS”) and the FDA, are increasingly important as the FTC and its sister antitrust agency, the Antitrust Division of the Department of Justice, strive for improved access to affordable drugs. As the Commission has noted elsewhere and above, there are significant barriers to entry in pharmaceutical markets. The Commission is committed to working with the FDA and other stakeholders including Congress, to reduce or eliminate barriers to new drug development in hopes of increasing competition, especially in markets with few suppliers. Working together, U.S. health care regulators and antitrust enforcers are formulating policy and implementing strategies to increase competition, promote innovation, and lower drug costs.

A. U.S. Department of Health and Human Services Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

In May 2018, President Donald Trump and HHS Secretary Alex Azar released the American Patients First blueprint, a comprehensive plan to bring down prescription drug prices and out-of-pocket costs.³⁸ The four strategies contemplated in the blueprint are increased competition, better negotiation, incentives for lower list prices, and reducing out-of-pocket costs. The FTC filed public comments regarding HHS’ efforts to increase competition and end the gaming of regulatory processes that may keep drug prices artificially high, such as combatting abuse of REMS and spurring biologic competition.³⁹

³⁵ See *FTC v. Mallinckrodt ARD, Inc.*, No. 1:17-CV-00120-EGS (D.D.C. Jan. 30, 2017).

³⁶ Fed. Trade Comm’n, Overview of FTC Actions in Pharmaceutical Products and Distribution (Aug. 2018), https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_pharma_august_2018.pdf. Note, in one case, the shareholders did not approve the transaction and the parties did not consummate the merger.

³⁷ See *FTC v. Mallinckrodt ARD, Inc.*, No. 1:17-CV-00120-EGS (D.D.C. Jan. 30, 2017).

³⁸ Dep’t of Health & Human Serv., American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (May 2018), <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf>.

³⁹ Fed. Trade Comm’n, Statement of the Federal Trade Commission to the Department of Health and Human Services Regarding the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (July 16, 2018), <https://www.ftc.gov/policy/advocacy/advocacy-filings/2018/07/statement-federal-trade-commission-department-health-human>.

B. U.S. Food and Drug Administration Drug Competition Action Plan

Also in May 2018, the FDA announced its Drug Competition Action Plan, designed to remove barriers to generic drug development and strengthen competition that results in greater access and lower drug costs for patients.⁴⁰ In June 2018, the FDA announced important steps toward increasing competition in the market for prescription drugs, publishing off-patent branded drugs without generic counterparts, and implementing a policy to expedite the agency’s review of generic drug applications.⁴¹ The FTC and the FDA are working together to improve access to affordable drugs, including finding ways to keep drug companies from gaming the regulatory system to deter generic and biosimilar competition. In his July 18, 2018 remarks, “Dynamic Regulation: Key to Maintaining Balance Between Biosimilars Innovation and Competition,” former FDA Commissioner Scott Gottlieb discussed the importance of FDA and FTC working together to promote competition in pharmaceutical markets, especially given the growing critical role that biologic medicines play in the treatment of many serious diseases, such as cancer and autoimmune disorders.⁴²

VI. Conclusion

Affordable drugs are critical for consumers. The FTC has vigorously enforced federal antitrust laws where pharmaceutical companies have violated those laws in ways that harm competition and consumers. However, courts have confirmed that the unilateral exercise of lawfully acquired market power does not violate the antitrust laws. Therefore, the attempted use of standalone Section 5 to address high prices, untethered from accepted theories of antitrust liability under the Sherman Act, is unlikely to find success in the courts.

⁴⁰ U.S. Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D., on the Trump Administration’s plan to lower drug prices (May 11, 2018), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm607495.htm>.

⁴¹ U.S. Food & Drug Admin. Press Release, FDA Tackles Drug Competition to Improve Patient Access (June 27, 2017), <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm564725.htm>.

⁴² Scott Gottlieb, M.D., Comm’r, Food & Drug Admin., Dynamic Regulation: Key to Maintaining Balance Between Biosimilars Innovation and Competition (July 18, 2018), <https://www.fda.gov/NewsEvents/Speeches/ucm613452.htm>.