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

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-

In August 2015, in response to concerns from Members of Congress and others that the FTC's standalone Section 5 authority was too

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 21 (e)-10 (em)-(

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.

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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 m reC88 (s), (t)-2 (o(,pt)-2 0e)4 (t)-2 (i)-2(r)-7 (ei)-2

A. Reverse Payment Patent Settlements

The FTC has challenged a number of pay-for-delay

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.

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 gr 2018,4gtu5.64 0 Tdx24mmc