

**DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE**

Excessive Pricing in Pharmaceutical Markets - Note by the United States

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More documents related to this discussion can be found at

www.oecd.org/daf/competition/excessive-pricing-in-pharmaceuticals.htm

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1. Introduction

1. This paper responds to the Chairman’s letter of July 18, 2018 inviting submissions for the Competition Committee’s upcoming roundtable on Excessive Pricing in Pharmaceuticals. The U.S. Federal Trade Commission (Commission or FTC) and Antitrust Division of the U.S. Department of Justice (DOJ) (collectively, the Agencies) are pleased to provide our perspective on this issue and explain why excessive pricing in pharmaceuticals by itself is not an antitrust violation under U.S. antitrust law,¹ although high prices may be indicative of anticompetitive conduct.

2. U.S. Antitrust Law does not Prevent Firms with Legally Acquired Market Power from Charging Profit Maximizing Prices

2. U.S. antitrust law distinguishes between monopolies attained or maintained through improper means from monopolies attained or maintained through lawful, procompetitive means. U.S. antitrust law allows lawful monopolists, and *a fortiori* other market participants, to set their prices as high as they choose. This central tenet of U.S. antitrust law is well supported by court decisions that have held, for example, that “[a] pristine monopolist...may charge as high a rate as the market will bear”² and that “[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.”³ Rather than focusing

¹ Excessive pricing, without more, does not violate federal antitrust laws. Several U.S. states, however, have enacted legislation prohibiting “price gouging” and imposing financial penalties on drug manufacturers that significantly increase their prices over specified time periods. See <https://nashp.org/state-legislative-action-on-pharmaceutical-prices/>. The pharmaceutical industry has challenged these state statutes as unconstitutional. See, e.g., *Association for Accessible Medicines v. Frosh*, 1:17-cv-1860. In April 2018, the U.S. Court of Appeals for the Fourth Circuit ruled Maryland’s statute unconstitutional <http://www.ca4.uscourts.gov/opinions/172166.P.pdf> and the State of Maryland has petitioned the U.S. Supreme Court for certiorari.

² *Berkey Photo, Inc. v Eastman Kodak Co.*, 603 F.2d 263, 297 (2d Cir. 1979).

³ *Blue Cross and Blue Shield United of Wisconsin v. Marshfield Clinic*, 65 F.3d 1406, 1413 (7th Cir. 1995),

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 Hospital, Inc. v. Mutual Hospital Ins., Inc.*, 784 F.2d at 1325, 1339 (7th Cir. 1986); *Berkey Photo*, 603 F.2d at 296-98.

on whether a particular price is excessive, U.S. law focuses on the means by which a monopolist attains or maintains monopoly power.⁴

3. The reasons that U.S. law does not deem excessive pricing in and of itself to be an antitrust violation are examined below.

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

4. Denying a lawful monopolist the fruits of its monopoly can diminish its incentive to compete in the first place. As Judge Learned Hand aptly put, “[t]he successful competitor, having been urged to compete, must not be turned upon when he wins.”⁵ The Supreme Court further elaborated on this notion in its 2004 *Trinko* decision, noting that “[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. 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.”⁶ In the pharmaceutical industry, a patent holder’s ability to exclude other sellers of its product during the patent term can motivate additional research and development, often leading to new treatments. Periods of marketing exclusivity may spur innovation, which can ultimately increase competition. 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.

2.2. Interfering with Market Pricing Mechanisms Typically Distorts Supply and Demand and Impedes Efficient Allocation of Resources

5. A second rationale for not intervening in firms’ pricing relates to the crucial role prices ordinarily play in determining the allocation of scarce resources among competing uses. One common definition of economics is “the study of how societies use scarce resources to produce valuable commodities and distribute them among different people.”⁷ In a free market economy in most industries, prices determine these allocations in two ways. First, they serve a signaling function, demonstrating where more resources would be productive and where they are not. For example, rising consumer demand typically

⁴ Note that the FTC maintains a comprehensive merger review program to identify and prevent pharmaceutical mergers that may reduce competition and lead to higher prices for specific pharmaceutical products. See Overview of FTC Actions in Pharmaceutical Products and Distribution (August 2018), which summarizes FTC enforcement, including merger actions, in the pharmaceutical industry. https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_pharma_august_2018.pdf

⁵ *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.”).

⁶ *Verizon Comm’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004).

⁷ Paul A. Samuelson and William D. Nordhaus, *Microeconomics* 3 (McGraw-Hill, 14th Ed. 1992).

raises prices, thus signaling to suppliers to expand their production (output) to meet the growing demand. High prices may also attract new market entry, thus promoting output. Conversely, lower demand typically results in falling prices, signaling suppliers to reduce production or allocate resources to other uses. In other words, prices allow consumers to express their preferences, thus sending important information to producers about the changing nature of their needs and wants. Second, prices balance market supply and demand in a way that efficiently allocates scarce resources. For example, if demand exceeded supply in a market, the price would rise until only the consumers that value the product the most would purchase the product. Thus, the market price is a mechanism for efficiently allocating scarce resources and balancing market demand and supply.

6. The efficient allocation of resources based on market prices is the bedrock of antitrust policy and enforcement in the U.S., as well as other OECD member jurisdictions. “There is general consensus that the basic objective of competition policy is to protect competition as the most appropriate means of ensuring the efficient allocation of resources—and thus efficient market outcomes—in free market economies.”⁸ In the U.S., the concern is that proscribing excessive pricing may interfere with markets’ price-setting mechanism and with the important signaling and resource allocation functions it carries out.

7. Of course, pharmaceutical markets do not operate in a vacuum and must be understood within the context of the regulated nature of the pharmaceutical industry. Pharmaceutical markets have high barriers to entry such as the time and expense of FDA approval, patents and other market exclusivities, and limited therapeutic substitutes. Moreover, drug markets are unique in that the ultimate consumer has little influence over what products to purchase. Physicians, health plans, federal and state governments, pharmaceutical benefit managers (PBMs), group purchasing organizations (GPOs), hospitals, wholesalers, distributors, and pharmacies all play roles in making purchasing decisions for drug products in the U.S. and the laws of supply and demand are less impacted by changes in price.

2.3. Institutional Difficulty Determining What Constitutes An Excessive Price

8. An equally important reason for not condemning excessive pricing, as such, is institutional. U.S. courts and antitrust agencies have found that determining the reasonableness of prices charged by a lawful monopolist goes beyond their competence. This notion goes back to early U.S. antitrust jurisprudence, when then Court of Appeals Judge William Taft suggested that basing antitrust decisions on the reasonableness of the prices charged by an alleged monopolist or cartel would be to “set sail on a sea of doubt.”⁹ A more recent rejection of the proposition that courts construing competition laws are not sufficiently equipped to determine what constitutes a “fair” or “excessive” price, can be found in the Supreme Court’s 2009 decision in *Pacific Bell Telephone Co. dba AT&T v.*

⁸ See Organization for Economic Co-operation and Development, COMPETITION POLICY AND EFFICIENCY CLAIMS IN HORIZONTAL AGREEMENTS, OECD/GD (96) 65, Paris (1996), available at <http://www.oecd.org/dataoecd/1/4/2379526.pdf>.

⁹ *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....”).

*linkLine Communications, Inc.*¹⁰ In that case, which involved what is called a “price-cost squeeze” or “margin squeeze,” the plaintiffs offered high-speed DSL Internet service. The U.S. Federal Communications Commission’s regulations required AT&T to provide interconnection service to competing DSL providers, such as linkLine. Plaintiffs alleged that AT&T squeezed their profit margins by charging a high wholesale price for DSL transport and a low retail price for DSL service.

9. Earlier trial court decisions suggested that a vertically integrated monopolist, such as AT&T, should be required to leave a “fair” or “adequate” margin between the wholesale price and the retail price, and that failure to do so could be viewed as illegal exclusionary conduct.¹¹ Dismissing the price squeeze claims, the U.S. Supreme Court, quoting an earlier opinion by Justice Breyer, asked rhetorically:

*“[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?”*¹²

10. The Court instead ruled that liability for such conduct is based on the liability standard for predatory pricing.

11. Antitrust agency officials have similarly expressed skepticism as to their agencies’ ability to determine which prices constitute excessive prices. For example, former FTC General Counsel, William Blumenthal, has noted that:

*“[I]n cautioning against even limited intervention by competition agencies against high prices, I am focusing...principally on considerations of institutional design.... Simply put, we need to question whether competition agencies have the competence to engage in classical price-and-profits public-utility-style regulation.”*¹³

12. The challenge in determining what price constitutes an excessive price means that it is inherently difficult to set up an accurate excessive pricing antitrust enforcement standard that will guide agencies both as to when to intervene and, if intervening, how to devise a remedy to ensure that price.

¹⁰ *Pacific Bell Telephone Co. v. linkLine Communications, Inc.*, 555 U.S. 438 (2009).

¹¹ *Pacific Bell*, 129 S. Ct. at 1121, (citing *Town of Concord v. Boston Edison Co.*, 915 F.2d 17, 23-25 (1st Cir. 1990)); *United States v. Aluminum Co. of America*, 148 F.2d at 437-438.

¹² *Pacific Bell* 129 S. Ct. at 1121, quoting *Town of Concord v. Boston Edison Co.*, 915 F.2d at 25.

¹³ William Blumenthal, FTC General Counsel, DISCUSSANT COMMENTS ON EXPLOITATIVE ABUSES UNDER ARTICLE 82 EC, Remarks before the European University Institute Twelfth Annual Competition Law and Policy Workshop: “A Reformed Approach to Article 82 EC” (June 9, 2007), available at <http://www.ftc.gov/speeches/blumenthal/070731florence.pdf>.

2.4. Difficulty Crafting an Antitrust Remedy for Excessive Pricing

13. If excessive pricing were an antitrust violation, the Agencies would need not only a procedure for determining what constitutes an excessive price to formulate an accurate enforcement standard – a similar procedure would also be necessary for crafting an appropriate remedy. The Agencies are ill-equipped to enforce compliance with a pricing mechanism over time divorced from free market competition. For example, the theoretical “best” price for society in a market with competing firms balances the consumer benefits of lower prices against the need to provide firms with incentives to invest and enter the market. These prices generally depend on cost and demand factors that are difficult to gauge. Absent evidence of harm to the competitive process, one cannot be certain that the prices that arise from the competitive process would exceed the theoretical “best” prices. Therefore, actions that antitrust enforcers might take to cap prices may discourage entry and investment and ultimately harm consumers.

3. Drug Price Spikes May be Indicative of Market Disruptions Other Than Antitrust Violations

14. The Agencies’ experience in analyzing competition in pharmaceutical markets shows that market factors other than anticompetitive conduct may explain why drug prices rise in some markets. A few such factors are discussed below.

3.1. Drug Shortages

15. Drug shortages, whether caused by manufacturing problems, supply disruptions, spikes in demand, or suspended production, frequently lead to price increases.¹⁴ According to the FDA:

a major reason for these shortages has been quality/manufacturing issues. However there have been other reasons such as production delays at the manufacturer and delays companies have experienced receiving raw materials and components from suppliers. Discontinuations are another factor contributing to shortages. FDA can't require a firm to keep making a drug it wants to discontinue. Sometimes these older drugs are discontinued by companies in favor of newer,

¹⁴ When drug shortages occur, drug prices typically increase. In early 2012, the FTC’s Office of Policy Planning and Bureau of Competition staff reviewed FTC merger investigations since 2000 and identified three mergers that involved drugs on the FDA’s shortage list. In all three matters, the FTC maintained competition for the drugs by requiring divestiture to another pharmaceutical company. In the Wyeth/Baxter merger, the drug propofol, used to relax patients before and during general anesthesia for surgery, was divested as a part of a consent order on December 20, 2002. When Teva acquired Ivax, the drug leuprolide injection, a man-made hormone used to treat various conditions, including anemia, cancer, and pain, was divested as a part of a consent order on January 23, 2006. And in the merger of Hospira and Mayne, the drug nalbuphine, a treatment for severe pain, was divested as a part of a consent order on January 18, 2007. Since the 2012 review, additional merger investigations have maintained competition for additional drugs on the FDA’s shortage list. In the Watson/Actavis merger, generic Adderall XR, a treatment for attention deficit hyperactivity disorder, was divested as part of a consent order on December 14, 2012. And in the Mylan/Agila merger, four drugs were divested as part of a consent order on October 3, 2013.

more profitable drugs. With fewer firms making older sterile injectable drugs, there are a limited number of production lines that can make these drugs. The raw material suppliers the firms use are also limited in the amount they can make due to capacity issues at their facilities. This small number of manufacturers and limited production capacity for older sterile injectables, combined with the long lead times and complexity of the manufacturing process for injectable drugs, results in these drugs being vulnerable to shortage. When one company has a problem or discontinues, it is difficult for the remaining firms to increase production quickly and a shortage occurs.¹⁵

3.2. Regulatory Factors

16. Quality control issues and safety-related recalls may also lead to drug price hikes. The time and money required by the FDA approval process, as well as FDA regulatory changes that can require facilities to shut down for some time, all may contribute to increasing a drug's price. Finally, exercise of previously unexploited but legitimate sources of market power such as patents or FDA-granted exclusivities may drive up drug prices.

3.3. Unilateral Conduct Other Than Antitrust Violation

17. Price spikes may also occur when a market participant engages in conduct that disrupts drug markets, but does not rise to the level of an antitrust violation. Examples of unilateral conduct resulting in market disruptions, but not necessarily creating anticompetitive concerns, include accidental misclassification of a drug, such as labeling a generic drug a brand, resulting in overcharge. Another example is non-collusive parallel conduct that lessens competition, such as a situation where separate manufacturers of a drug independently decide to increase prices or decrease production.

4. Antitrust Enforcement Supports Lower Drug Costs By Prohibiting Conduct that Unlawfully Restrains Competition

18. Prices lawfully set by market participants, no matter how high, generally do not raise antitrust concerns among U.S. enforcers. However, high prices may be a result of conduct that violates the antitrust laws. In such cases, the remedy prescribed to correct the underlying antitrust violation may also lower the price. The U.S. approach to antitrust enforcement targets conduct that has the potential to create anticompetitive effects. One indicator of such potential anticompetitive effects is an excessively high price. Thus, although charging a high price does not violate U.S. antitrust law in and of itself, the existence of a high price can be an important element in proving an antitrust violation.

19. The Agencies have brought a number of enforcement actions and filed amicus briefs in cases addressing unlawful conduct that harms competition and keeps drug prices artificially high.¹⁶ A few examples of these enforcement actions and amicus filings are described briefly below.

¹⁵ <https://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm#q4>

¹⁶See Overview of FTC Actions in Pharmaceutical Products and Distribution, August 2018, for an ongoing compilation of antitrust enforcement actions undertaken by the FTC in the pharmaceutical

4.1. Price Fixing and Market Allocation

20. Agreements among competitors to fix prices are *per se* illegal whether the agreed-to price is higher or lower than would otherwise prevail in a market without such restraints. In December 2016, DOJ obtained guilty pleas from two executives for conspiracies related to price fixing, bid rigging, and customer allocation of generic pharmaceuticals doxycycline hyclate delayed release and glyburide. Also in December 2016, several states filed a civil lawsuit in federal court against six of the largest generic drug producers, alleging that they conspired to fix prices, divide markets, and rig bids for doxycycline and glyburide. Since then, the suit has expanded. Plaintiffs now include 48 states, the District of Columbia, and the Commonwealth of Puerto Rico with allegations against 18 companies and involving 15 drugs, and has been consolidated with pending private lawsuits in multidistrict litigation in the Eastern District of Pennsylvania.¹⁷

4.2. Reverse Payment Patent Settlements

21. The FTC has challenged a number of reverse payment agreements (also known as “exclusion payment” or “pay-for-delay” agreements). Such agreements entail settlements of patent litigation in which the branded drug firm pays its potential generic competitor to abandon a patent challenge and delay entering the market with a lower cost, generic product. Branded manufacturers have used such agreements to buy more protection from competition than their patent rights provide, at the expense of competition and consumers. As the Supreme Court explained in *FTC v. Actavis*, “There is reason for concern that settlements taking this form tend to have significant adverse effects on competition.”¹⁸ The core concern with agreements such as these—what the Court termed “the relevant anticompetitive harm”—is that they will allow the branded drug firm to “prevent the risk of competition” by sharing its monopoly profits, which are preserved by the agreement, with the prospective generic entrant.¹⁹ The FTC has several pending cases involving allegations of anticompetitive reverse payment agreements.²⁰

4.3. Abuse of Government Processes

22. The FTC has also challenged unilateral conduct by branded manufacturers to illegally maintain a monopoly position through abuse of governmental processes, such as sham litigation, repetitive regulatory filings, or misuse of restricted drug distribution

industry. https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_pharma_august_2018.pdf

¹⁷ *In Re: Generic Pharms. Pricing Antitrust Litig.*, 2:16-md-02724.

¹⁸ *Federal Trade Commission v. Actavis, Inc.*, 570 U.S. 756 (2013).

¹⁹ *Id.* at 2236.

²⁰ *Federal Trade Commission, et al. v. Watson Pharmaceuticals, Inc., et al.*, (Generic Androgel), Case No. CV-09-00598 (C.D. Cal.), FTC File No. 0710060 (complaint filed January 27, 2009) (transferred to N.D. Ga. April 2009). *In re Androgel Antitrust Litigation (No. II)*, MDL Docket No. 2084 (All Cases), 1:09-MD-2084-TWT, 677 F.3d 1298 (11th Cir. 2012) (affirming lower court’s order granting motions to dismiss complaints), <https://www.ftc.gov/enforcement/cases-proceedings/071-0060/watson-pharmaceuticals-inc-et-al>

programs, such as Risk Evaluation and Mitigation Strategies (REMS). For instance, in *Federal Trade Commission v. AbbVie Inc.*,²¹ the FTC charged several major pharmaceutical companies with illegally blocking consumers' access to lower-cost versions of the blockbuster drug AndroGel, a brand-name testosterone replacement therapy for men with low testosterone. The complaint alleged that the AbbVie Defendants (AbbVie Inc., Unimed Pharmaceuticals, LLC (now a wholly-owned subsidiary of AbbVie), and Abbott Laboratories) and Besins Healthcare Inc., filed baseless patent infringement lawsuits against potential generic competitors Teva Pharmaceuticals USA, Inc. and Perrigo to unlawfully maintain and extend their monopoly power in the supply of AndroGel by delaying the introduction of lower-priced versions of the drug. Under federal law, these lawsuits triggered an automatic 30-month stay of the FDA's authority to approve the generic competitors' applications to market their testosterone gel products, regardless of the merits of the infringement claims. The complaint further alleged that while the lawsuits were pending, the AbbVie Defendants entered into an anticompetitive settlement agreement with Teva to further delay generic drug competition. According to the complaint, Teva concluded that it would be better off sharing in the AbbVie Defendants' monopoly profits from the sale of AndroGel than by competing. Thus, Teva settled the baseless infringement lawsuit by entering an agreement with the AbbVie Defendants to delay launching its alternative to AndroGel. In return, the AbbVie Defendants paid Teva in the form of a highly profitable authorized generic deal for another product, executed on the same day as the AndroGel patent litigation settlement. In May 2015, the district court dismissed claims that the patent settlement agreement with Teva was an anticompetitive reverse payment. The FTC is appealing that decision.

23. On September 15, 2017, the district court awarded partial summary judgment to the FTC, ruling that the patent infringement lawsuits filed by the AbbVie Defendants and Besins were objectively baseless. In February 2018, the FTC tried its case in the court on the remaining issues: (1) whether the AbbVie Defendants and Besins used their objectively baseless lawsuits as anticompetitive weapons; (2) whether they had market power; and (3) the appropriate relief, if any.

24. On June 29, 2018, the court found in the FTC's favor and held that the AbbVie Defendants and Besins violated Section 5(a) of the FTC Act. The court held that the FTC established that Defendants illegally and willfully maintained their monopoly power through the filing of sham litigation. The sham litigation delayed the entry of generic AndroGel to the detriment of consumers. The court awarded equitable monetary relief of \$448 million to be refunded to consumers and also awarded \$46 million in prejudgment interest. The parties have appealed the decision.

25. In another case, *Federal Trade Commission v. Shire ViroPharma Inc.*,²² the FTC alleged that Shire ViroPharma Inc. (ViroPharma) abused government processes to delay generic competition to its branded Vancocin Capsules. Vancocin Capsules are used to treat a potentially life-threatening gastrointestinal infection. Specifically, the complaint alleged that ViroPharma waged a campaign of serial, repetitive, and unsupported filings with the

²¹ *Federal Trade Commission 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>.

²² *Federal Trade Commission v. Shire ViroPharma Inc.*, Civil Action No. 1:17-cv-00131-RGA (D. Del.), FTC File No. 1210062 (complaint filed February 7, 2017), <https://www.ftc.gov/enforcement/cases-proceedings/121-0062/shire-viropharma>.

FDA and the courts to delay the FDA's approval of generic Vancocin Capsules. ViroPharma submitted 43 filings with the FDA and filed three lawsuits against the FDA between 2006 and 2012. According to the complaint, ViroPharma's filings lacked supporting clinical data, which ViroPharma understood it needed to have any chance of persuading the FDA for approval. ViroPharma also allegedly knew that its petitioning was obstructing and delaying the FDA's approval of generic Vancocin Capsules. The Commission sought a court order permanently prohibiting ViroPharma from submitting repetitive and baseless filings with the FDA and the courts, and from similar and related conduct as well as any other necessary equitable relief, including restitution and disgorgement. On March 20, 2018, the district court dismissed the FTC's complaint for failure to sufficiently allege that ViroPharma "is violating or about to violate" the law under Section 13(b) of the FTC Act. The FTC appealed the ruling to the Third Circuit Court of Appeals on June 19, 2018.

26. In some instances, generic firms have encountered difficulty in obtaining drug samples from branded manufacturers. To receive approval from the FDA, generic firms are required to conduct bioequivalence testing to demonstrate that a generic formulation is therapeutically equivalent to the brand drug. This testing process requires a limited amount of the brand product. Certain brand drugs are subject to distribution restrictions that can be used to prevent generic firms from obtaining samples of the brand product for testing purposes. In many instances, these restricted distribution programs are implemented as part of FDA-mandated risk management programs known as Risk Evaluation and Mitigation Strategies (REMS). When Congress authorized the FDA to require REMS programs, it directed that the FDA was not to use such programs to block or delay approval of generic drug products.

27. The FTC filed an amicus brief in a pending private suit, *Mylan Pharmaceuticals, Inc. v. Celgene Corporation*. Without taking a position on the factual merits of the case, the Commission's brief explained that Mylan's antitrust claims are not barred as a matter of law.²³ This case involves allegations that Celgene prevented Mylan from offering competing generic versions of Celgene's brand drug products, Thalomid and Revlimid, by precluding it from obtaining samples of those drugs to perform necessary testing even though the FDA had determined that Mylan's testing protocols for the proposed generics were sufficient. Both drugs treat several forms of cancer, as well as other serious conditions. In this private antitrust action, Mylan alleged that Celgene stalled Mylan's efforts to obtain samples of the drugs by imposing voluminous and unnecessary requests for information, requests that were a pretext to allow Celgene to delay providing samples with an intention of foreclosing potential competition. Defendant Celgene sought dismissal of the case. Celgene argued that, as a matter of law, a private firm is ordinarily free to choose with whom to do business and that vertical agreements, such as the ones between a manufacturer and its distributors, rarely raise antitrust concerns.

28. The FTC brief described how Mylan's allegations in this case fit within established Supreme Court precedent holding that a monopolist's refusal to sell products to its potential competitors may, under certain circumstances, violate Section 2 of the Sherman Act. It also explained that a distribution agreement between a brand drug manufacturer and its distributors may violate Section 1 of the Sherman Act, and that under established law a

²³ *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.

brand name drug manufacturer's patents do not reach activities undertaken in connection with bioequivalence testing.

5. Market Research, Competition Policy, and Advocacy Initiatives

29. The FTC uses research and market reports to protect and promote competition in the pharmaceutical industry by advocating for regulatory policies that encourage more competition. For example, the current U.S. pharmaceutical distribution system at the pharmacy level was significantly influenced by a January 1979 FTC Report entitled Drug Product Selection.²⁴

30. In 1985, staff of the FTC's Bureau of Economics found that generic substitution on eligible prescriptions rose after the passage of generic substitution laws, and that generic substitution reduced consumer expenditures.²⁵ The Commission also concluded that the 1984 Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act increased generic drug entry,²⁶ but that two provisions governing generic drug approval prior to the brand drug's patent expiration (the 180-day generic exclusivity and the 30-month stay of generic approval provisions) were susceptible to anticompetitive strategies.²⁷

31. In July 2002, the FTC issued a report summarizing a lengthy study of allegedly anticompetitive agreements between brand and generic drug companies that took advantage of one or the other of the two provisions,²⁸ and advocated strongly for the elimination of the multiple 30-month stays blocking generic entry that branded drug companies were obtaining by filing multiple patents on a single drug. In 2003, Congress amended the Medicare Modernization Act and eliminated the loophole.

32. In July 2004, following 27 days of hearings, an FTC workshop, and independent research, the FTC and the Antitrust Division issued a report examining competition issues in health care, including markets relating to prescription drugs. This report included a

²⁴ The Report concluded that state anti-substitution laws that prohibit pharmacists from dispensing a lower-cost generic drug for a prescription written for a brand name unduly restricted price competition for multisource prescription drugs and imposed unwarranted costs on consumers. The Report further advised that the repeal of anti-substitution laws would produce significant consumer benefits without compromising the quality of health care. The Report proposed that states facilitate pharmacists' selection of drug products therapeutically equivalent to, but less expensive than products prescribed by brand name by adopting a model statute, the Model Drug Product Selection Act. FTC, Drug Product Selection Report January 1979, *available at* <http://www.bookprep.com/book/mdp.39015008517792>. Five years later, all states had enacted laws allowing pharmacists, when filling a prescription for a specific branded drug, to dispense an equivalent generic version unless the prescribing physician instructs otherwise.

²⁵ *Id.*

²⁶ For a more in-depth description of the Hatch-Waxman Act, *see generally* <http://www.fda.gov/newsevents/testimony/ucm115033.htm>.

²⁷ Alison Masson and Robert L. Steiner, Federal Trade Commission, "Generic Substitution and Prescription Drug Prices: Economic Effects of Drug Product Selection Laws" (Oct. 1985), *available at* <http://www.ftc.gov/reports/generic-substitution-prescription-drug-prices-economic-effects-state-drug-product-selection>.

²⁸ <https://www.ftc.gov/reports/generic-drug-entry-prior-patent-expiration-ftc-study>.

number of recommendations for private payors, governments, and providers to lower costs, improve quality, and enhance innovation in health care markets.²⁹

33. The extremely high prices of many biologic medicines is cause for concern as more patients are treated with these critical therapies. The FTC examined potential competition issues presented by expected entry of follow-on biologics, anticipated to be lower priced than the innovator products, in a roundtable workshop on November 21, 2008,³⁰ and in an FTC report in June 2009.³¹ The FTC conducted a public workshop on February 4, 2014, entitled Follow-On Biologics: Impact of Recent Legislative and Regulatory Naming Proposals on Competition. The purpose of the workshop and subsequent study was to collect additional and updated information concerning the expected entry of biosimilars and interchangeable biologics into the pharmaceutical distribution chain and how certain legislative proposals and naming conventions may affect follow-on biologics competition.³²

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

34. Productive working relationships with industry regulators, such as Health and Human Services (HHS) and the U.S. Food & Drug Administration (FDA), are increasingly important as the Agencies strive to improve access to affordable drugs. Working together, the U.S. health care regulators and antitrust enforcers are formulating policy and implementing strategies to increase competition, promote innovation, and lower drug costs.

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

35. 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.³³ The four strategies contemplated in the blueprint are: (1) increased competition; (2) better negotiation; (3) incentives for lower list prices; (4) and

²⁹ Improving Health Care: A Dose of Competition, *available at* <http://www.ftc.gov/reports/improving-health-care-dose-competition-report-federal-trade-commission-department-justice>.

³⁰ November 2008 Roundtable: Competition Issues Involving Follow-on Biologic Drugs, *available at* <http://www.ftc.gov/news-events/events-calendar/2008/11/emerging-health-care-competition-and-consumer-issues>.

³¹ Emerging Health Care Issues: Follow-on Biologic Drug Competition, *available at* <http://www.ftc.gov/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report>.

³² Notice of December 10, 2013 Workshop to Explore Competition Issues Involving Biologic Medicines and Follow-On Biologics; Request for Comments, *available at* <http://www.ftc.gov/policy/federal-register-notice/public-workshop-follow-biologics-impact-recent-legislative>; https://www.ftc.gov/sites/default/files/documents/public_statements/emerging-health-care-issues-follow-biologic-drug-competition/090611fobtestimony.pdf.

³³ <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf>.

reducing out-of-pocket costs. The FTC filed public comments regarding HHS's 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.³⁴

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

36. Also in May 2018, the FDA announced its Drug Competition Action Plan, designed to remove barriers to generic drug development and strengthening competition that would result in greater access and lower drug costs for patients.³⁵ In June 2018, the FDA announced important steps toward increasing competition in the market for prescription drugs, such as publishing off-patent branded drugs without generic counterparts and implementing a policy to expedite the agency's review of generic drug applications.³⁶

37. The FTC and 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," FDA Commissioner Scott Gottlieb discussed the importance of the 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.

"And we're going to be taking new steps to challenge some of the gaming tactics I talked about earlier. This includes new efforts to coordinate with the Federal Trade Commission (FTC) to address anti-competitive behavior. We look forward to participating in additional forums with the FTC to jointly identify ways that we can deter anticompetitive behavior in this space. Stay tuned."³⁷

7. Conclusion

38. U.S. antitrust law does not recognize excessive pricing as an antitrust violation in and of itself, thus allowing legitimate market participants acting independently to set their prices as high as they choose. This policy choice stems from the legislature's determination that ultimately competition will produce not only lower prices, but also better goods and services. Additionally, the policy reflects the difficulty in identifying what prices are excessive and concerns that antitrust enforcement against excessive pricing may chill incentives to compete and innovate in the first place and interfere with the proper functioning of markets.

39. Market participants who violate the antitrust laws, however, may be subject to remedies that affect their ability to charge supra-competitive prices. In addition, high or

³⁴Statement 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>.

³⁵ <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm607495.htm>

³⁶ <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm564725.htm>

³⁷ <https://www.fda.gov/NewsEvents/Speeches/ucm613452.htm>.

rapidly increasing prices often play an important role in the Agencies' antitrust investigations because they may constitute evidence of anticompetitive effects of potential antitrust violations.

40. There are many tools available to U.S. antitrust agencies today to address high drug prices, including law enforcement; competition advocacy before the legislature and the courts; reports, studies, hearings, and workshops; and working with other governmental entities and sector regulators to promote consumer access to affordable medicines.