

**Prepared Statement of  
Markus H. Meier  
Acting Director, Bureau of Competition  
U.S. Federal Trade Commission**

**Before the  
United States House of Representatives  
Judiciary Committee  
Subcommittee on Regulatory Reform, Commercial and Antitrust Law**

**on**

**“Antitrust Concerns and the FDA Approval Process”**

**Washington, D.C.  
July 27, 2017**

## I. Introduction

Chairman Marino, Ranking Member Cicilline, and Members of the Subcommittee, thank you for the opportunity to appear before you today. I am Markus H. Meier, Acting Director of the Federal Trade Commission's Bureau of Competition, and I am pleased to testify about one of the Commission's top priorities: stopping anticompetitive conduct in the pharmaceutical industry.<sup>1</sup>

The FTC is an independent agency charged by Congress with protecting the interests of consumers by enforcing competition and consumer protection laws.<sup>2</sup> It exercises primary responsibility for civil antitrust enforcement in the pharmaceutical industry.<sup>3</sup> The FTC has substantial experience evaluating the framework for generic drug development and competition under the Hatch-Waxman Act,<sup>4</sup> the framework for biosimilar drug development and competition under the Biologics Price Competition and Innovation Act (BPCIA),<sup>5</sup> and corresponding state laws.

Competition in the pharmaceutical industry occurs within a framework of federal and state laws that balance several important policy goals: providing appropriate incentives for research and development of innovative new drug products, facilitating entry of lower-cost generic drugs, and ensuring that prescription drugs are safe and effective.

---

<sup>1</sup> This written statement represents the views of the Federal Trade Commission. My oral presentation and responses to questions are my own and do not necessarily reflect the views of the Commission or of any Commissioner.

<sup>2</sup> See Federal Trade Commission Act, 15 U.S.C. §§ 41-58.

<sup>3</sup> For a summary of the FTC's antitrust actions in the pharmaceutical industry, see *Overview of FTC Antitrust Actions in Pharmaceutical Products and Distribution* (April 2017), [https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview\\_pharma\\_april\\_2017.pdf](https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_pharma_april_2017.pdf).

<sup>4</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355 (1994)). For a discussion of the Act's statutory background, see "Protecting Consumer Access to Generic Drugs: The Benefits of a Legislative Solution to Anticompetitive Settlements in the Pharmaceutical Industry," FTC Testimony before the Subcommittee on Trade, Commerce, and Consumer Protection, Committee on Energy and Commerce (May 2, 2007) at 8-9, <https://www.ftc.gov/public-statements/2007/05/prepared-statement-federal-trade-commission-protecting-consumer-access>.

<sup>5</sup> Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 804-821 (2010).

In many ways, the existing regulatory framework works well in furthering these objectives. However, over time, certain aspects of the existing structure have proven susceptible to strategic – and potentially anticompetitive – behavior. In brief, drug manufacturers have exploited certain features of the existing regulatory framework created by the Hatch-Waxman Act to extend exclusive rights well beyond the periods Congress provided to spur investments in innovation.

When drug companies can succeed in delaying generic entry, American consumers will pay higher prices for prescription drugs. Patent rights facilitate innovation in the pharmaceutical industry. Companies need economic incentives to invest in developing new, lifesaving medicines that benefit us all. However, extensions of exclusivity beyond the boundaries established by Congress can create private windfalls at the public's expense.

At the FTC, we've been fighting back against these efforts to keep prices artificially inflated. In the years since the Hatch-Waxman Act was enacted, the Commission has pursued numerous antitrust enforcement actions involving both branded and generic firms. Fortunately, we are not the only ones focused on these issues. Over the years, Congress has amended the Hatch-Waxman Act and the FDA has modified its regulations to address certain abuses, often with the support of the Commission.<sup>6</sup>

As we discuss in greater detail below, the problem of branded firms using so-called Risk Evaluation and Mitigation Strategies (REMS) programs to impede generic entry is, in our view, an appropriate area for Congressional focus and concern. There are several ways that branded

---

<sup>6</sup> See Prepared Statement of the Federal Trade Commission before the Committee on the Judiciary, United States Senate (June 17, 2003) (recommending changes to regulations governing patent listing in the Orange Book and eligibility for the 30-month stay of ANDA approval), [https://www.ftc.gov/sites/default/files/documents/public\\_statements/prepared-statement-federal-trade-commission-competition-pharmaceutical-industry/030617pharmtestimony.pdf](https://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-competition-pharmaceutical-industry/030617pharmtestimony.pdf).

firms can use these programs strategically to delay generic entry, and at least some of these methods will be difficult to reach effectively under the antitrust laws today.

The Commission greatly appreciates this Committee's interest in identifying forms of conduct that may undermine the Hatch-Waxman and BPCIA frameworks and we look forward to assisting the Committee in this important work.

Finally, we note that the FDA recently held a hearing as part of an initiative to seek public comment on the administration of the Hatch-Waxman framework "to help ensure the intended balance between encouraging innovation in drug development and accelerating the availability to the public of lower cost alternatives to innovator drugs is maintained."<sup>7</sup> The Commission commends the FDA on this effort and greatly appreciates being invited to participate alongside FDA staff at that hearing. We look forward to working with Commissioner Gottlieb and the FDA, with which we have long had an excellent relationship, to identify aspects of the Hatch-Waxman and BPCIA framework that have been misused to delay the introduction of low-cost generic drugs in contravention of the careful balance struck by Congress.

## **II. The Hatch-Waxman Act Balances Innovation and Competition But Also Provides Opportunities to Impede Generic Competition**

Generic drugs play a crucial role in containing rising prescription drug costs by offering consumers therapeutically equivalent alternatives to branded drugs at a significantly reduced cost. The first generic competitor's product is typically offered at a 20% to 30% discount to the

---

<sup>7</sup> FDA, "Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access," 82 Fed. Reg. 28493 (Jun. 22, 2017).

branded product.<sup>8</sup> Subsequent generic entry creates greater price competition, with discounts of 85% or more off the price of the branded drug.<sup>9</sup>

The Hatch-Waxman Act is a carefully balanced regulatory framework designed to facilitate the introduction of lower-cost generic drugs while preserving incentives for innovation.<sup>10</sup> To encourage innovation, the Act provides several benefits to branded drug companies, including patent-term restoration provisions designed to address the lengthy timeline typically required to develop a new drug product and gain FDA approval.<sup>11</sup> Further, the Act provides for an automatic 30-month stay of generic approval if a branded firm timely files a patent infringement suit, obviating the need to seek a preliminary injunction.<sup>12</sup> Through these provisions, “patent owners received statutory assurance that there would be no generic competitor on the market unless and until their patent rights were adjudicated.”<sup>13</sup>

With the Hatch-Waxman Act, Congress also created a mechanism for accelerated approval of generic drugs through an Abbreviated New Drug Application (ANDA) based on a showing of bioequivalence.<sup>14</sup> Generally, a generic drug is considered bioequivalent or “AB-rated” if it contains the same active pharmaceutical ingredient as the brand drug, is the same

---

<sup>8</sup> FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* ii-iii (2011), <https://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission>.

<sup>9</sup> FTC, *Pay-For-Delay: How Drug Company Pay-offs Cost Consumers Billions* 8 (2010), <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf>.

<sup>10</sup> FTC, *Generic Drug Entry Prior to Patent Expiration: an FTC Study* (Jul. 2002), <https://www.ftc.gov/reports/generic-drug-entry-prior-patent-expiration-ftc-study>.

<sup>11</sup> See *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 669-71 (1990) (describing patent-term restoration provisions).

<sup>12</sup> 21 U.S.C. § 355(j)(5)(B)(iii).

<sup>13</sup> Alfred B. Engleberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 *IDEA J. L. & Tech.* 389, 402 (1999).

<sup>14</sup> The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355 (j) (2011), as amended by the Food and Drug Administration Amendments Act of 2007, Public Law 110-85, 121 Stat. 823 (Sept. 27, 2007).

dosage and form, and exhibits a similar rate and extent of absorption as the branded product.<sup>15</sup>

Allowing generic manufacturers to rely on brands' already-completed safety and efficacy studies significantly reduces generic drug development costs and expedites the FDA approval process, while ensuring that generic drugs share the same safety and efficacy profile as their branded counterparts. To conduct the bioequivalence testing needed to file an ANDA, a generic firm must obtain a limited amount of the branded product.

The ANDA process set forth in the Hatch-Waxman Act is complemented at the state level by drug substitution laws that allow a pharmacist presented with a prescription for a branded drug to substitute an AB-rated generic drug, unless the physician or patient specifically directs otherwise. These laws address a unique feature of prescription drug markets that can prevent effective price competition: the physician, who selects but does not pay for the drug, has little incentive to consider price when deciding which drug to prescribe. By providing a mechanism for pharmacists, health plans and patients to select drug products based on price, automatic substitution laws have helped drive widespread adoption of lower-cost generic drugs in the United States.

Although the widespread introduction of generic drugs has saved Americans hundreds of billions of dollars in drug costs, some companies have exploited the ability to delay generic entry through abuse of government processes. Since the inception of the Hatch-Waxman framework, some branded firms have employed a variety of strategies, including conduct that violates the

---

<sup>15</sup> *Id.* §§ 355(j)(2)(A)(ii), (iii), (iv). “Drug products that FDA considers to be therapeutically equivalent to other pharmaceutically equivalent products, i.e., drug products for which: (1) there are no known or suspected bioequivalence problems. These are designated AA, AN, AO, AP, or AT, depending on the dosage form; or (2) actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence supporting bioequivalence. These are designated AB.” FDA, *Preface to Approved Drug Products With Therapeutic Equivalence Evaluations* (37<sup>th</sup> Ed.), <https://www.fda.gov/drugs/developmentapprovalprocess/ucm079068.htm>.

antitrust laws, solely for the purpose of delaying generic competition and effectively extending their patent exclusivity.

### **III. REMS and Voluntary Restrictions on Distribution May Allow Branded Pharmaceutical Firms to Delay Generic Competition**

One area where the current regulatory system presents opportunities for branded firms to delay generic entry is in situations where the branded pharmaceutical is subject to either an FDA-mandated or a voluntary restricted distribution system.

In principle, there is nothing inappropriate about restricting the distribution of certain pharmaceuticals in order to safeguard the public and prevent potential abuse or diversion. Indeed, the FDA is authorized to require a REMS program when necessary to ensure that a drug's benefits outweigh its risks.<sup>16</sup> The specific program can take a variety of forms, ranging from something as simple as a medication guide or patient package insert, to safety protocols and elements to assure safe use that may limit distribution between sellers, wholesalers, and buyers. For example, a REMS might require that all pharmacies selling the drug be enrolled in the manufacturer's REMS program and that the pharmacist verify that the prescriber and patient also are enrolled in that REMS before dispensing the drug.

Alternatively, for drugs for which the FDA does not require REMS, the manufacturer can voluntarily adopt a restricted distribution policy using exclusive contracts with distributors or specialty pharmacies to limit access to the product.

Under current law, a branded manufacturer has two opportunities to delay generic entry for drugs subject to restricted distribution programs. First, on the front end, the branded company can refuse to provide samples so that the generic firm cannot perform the required

---

<sup>16</sup> The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355-1, as amended by the Food and Drug Administration Amendments Act of 2007, Public Law 110-85, 121 Stat. 823 (Sept. 27, 2007).

preclinical and clinical testing required to complete an ANDA for FDA approval. The second opportunity is on the back end of the ANDA process, by denying the generic firm access to the existing REMS distribution system so that the FDA cannot approve the generic firm's ANDA application and labelling. In either scenario, use of a restricted distribution system to exclude generic competition is especially troubling because it can potentially delay entry indefinitely. If successful, conduct of this type alters the careful balance created by the Hatch-Waxman Act between innovation and access and, more broadly, creates a competition problem.

Despite clear guidance from both Congress<sup>17</sup> and the FDA that drug firms should not use REMS programs to block or delay generic or biosimilar competition,<sup>18</sup> complaints about abuse of the regulatory process persist. Instances of extreme price hikes of some off-patent drugs and efforts to limit their distribution to prevent competition have made headlines in recent years.<sup>19</sup> The problem, however, is not confined to just a handful of drugs. One study estimates that Americans have lost \$5.4 billion in annual savings due to delays in accessing drug samples caused by REMS misuse and other non-FDA mandated restricted distribution programs.<sup>20</sup>

**a. Refusing to Supply Samples for Product Testing Undermines the Hatch-Waxman Framework and May Violate the Antitrust Laws**

To conduct the bioequivalence testing required to receive FDA approval, a generic firm must purchase sufficient amounts of the branded product. Ordinarily, generic firms obtain

---

<sup>17</sup> FDAAA subsection f(8) states that no holder of a REMS-covered drug shall use an aspect of the REMS to “block or delay approval” of an ANDA. 21 U.S.C. § 355-1(f)(8).

<sup>18</sup> See Center for Drug Evaluation and Research, FDA, Risk Evaluation and Mitigation Strategy (REMS) Public Meeting (July 28, 2010), at 270-71 (statement by Jane Axelrad, Associate Director of Policy, Center for Drug Evaluation and Research), <http://www.fda.gov/downloads/Drugs/NewsEvents/UCM224950.pdf>; FDA, Risk Evaluation and Mitigation Strategies; Notice of Public Meeting; Reopening of Comment Period, 75 Fed. Reg. 34453, at 34456 (June 17, 2010) (noting FDAAA subsection f(8) and requesting input on steps FDA could take “to ensure that REMS are not used to block or delay generic competition”).

<sup>19</sup> U.S. Senate, Special Comm. on Aging, “Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System” (Dec. 2016), at 36-41.

<sup>20</sup> Brill, Alex, Lost Prescription Drug Savings from the Use of REMS Programs to Delay Market Entry, Matrix Global Advisors (July 2014).

needed samples of a branded product from wholesale distributors. However, branded firms have used restrictions on distribution to prevent generic firms from purchasing the requisite amount of branded drugs from wholesale distributors or directly from the branded firm. Simply by refusing to sell the quantity needed for bioequivalence testing, despite the product being generally available for sale and the generic firm offering to pay the market price for samples, a branded company can preclude generic firms from ever obtaining FDA approval.<sup>21</sup>

To address the problem of generic companies obtaining reference product samples, the FDA has issued letters clarifying that a generic firm's testing protocol is safe and that a particular branded firm may sell drugs subject to REMS programs to particular generic firms for bioequivalence testing without violating the terms of the REMS.<sup>22</sup> In December 2014, the FDA published draft guidance detailing how generic firms could obtain a letter validating the bioequivalence study protocol in order to seek product samples.<sup>23</sup> According to the FDA, despite these efforts, generic companies continue to report to the FDA that they face long delays and incur substantial cost to obtain sufficient quantities of reference branded drugs for testing.<sup>24</sup>

Withholding the samples necessary to gain regulatory approval from generic producers has spawned several antitrust cases. For instance, Mylan Pharmaceuticals alleged that Celgene Corporation violated the Sherman Act by using its REMS to prevent generic firms, including

---

<sup>21</sup> Under the *Bolar* Amendment to the Hatch Waxman Act, Congress clarified that it “shall not be an act of infringement to make, use, offer to sell, or sell . . . a patented invention . . . solely for uses reasonably related to the development and submission of information” for FDA approval. 35 U.S.C. § 271(e)(1). This provision overruled *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984), in which the Federal Circuit had held that testing conducted to develop a generic drug was an act of infringement.

<sup>22</sup> See Verified Complaint, Exh. A, *Lannett Co. v. Celgene Corp.*, No. 08-cv-3920 (E.D. Pa. Aug. 15, 2008) (letter from FDA to brand manufacturer stating “it is not the agency’s intention to permit the restrictions of the [applicable REMS program] to prevent manufacturers of generic drugs from obtaining [the brand product] for use in the bioequivalence testing necessary to obtain approval of an [ANDA]”).

<sup>23</sup> U.S. Dep’t of Health and Human Services, FDA Center for Drug Evaluation and Research, “How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD: Guidance for Industry” (Dec. 2014), <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm425662.pdf>.

<sup>24</sup> 82 Fed. Reg. at 28495.

Mylan, from acquiring samples necessary for bioequivalence testing of two blockbuster branded cancer drugs, Thalomid and Revlimid, even though the FDA had determined that Mylan's testing protocols for the proposed generics were sufficient.<sup>25</sup> While taking no position on the outcome of the case, the Commission filed an *amicus* brief in this matter explaining that, although the Supreme Court has expressed caution about imposing antitrust liability based on a monopolist's unilateral refusal to deal, the Court has recognized that such conduct may violate Section 2 of the Sherman Act. Moreover, vertical agreements, such as those between a manufacturer and its distributors, may also violate Section 1 of the Sherman Act.<sup>26</sup>

Similarly, in March 2013, the FTC filed an *amicus* brief in another antitrust case involving the restricted distribution of two drugs, only one of which was subject to a REMS. In *Actelion Pharmaceuticals Ltd. v. Apotex Inc.*, generic firms Actavis, Apotex, and Roxane alleged that Actelion imposed distribution restrictions preventing them from buying samples of Actelion's branded drugs through customary distribution channels, and that Actelion refused to sell the drugs directly.<sup>27</sup> Actelion, meanwhile, sought a broad declaration that it is under "no duty or obligation" to sell its products to potential competitors. Actelion contended that its distribution restrictions were required by the FDA, but that in any event its right to refuse to sell to the generic firms would apply even without an FDA mandate. The Commission's *amicus* brief, which took no position on the merits, explains that the generic firms' antitrust claims are not barred as a matter of law and notes that the Hatch-Waxman regulatory framework cannot

---

<sup>25</sup> *Mylan Pharms. v. Celgene Corp.*, Case No. 2:14-cv-2094 (D.N.J.).

<sup>26</sup> Fed. Trade Comm'n Brief as *Amicus Curiae*, *Mylan v. Celgene Corp.* (Jun. 17, 2014), <https://www.ftc.gov/policy/advocacy/amicus-briefs/2014/06/mylan-pharmaceuticals-inc-v-celgene-corporation>.

<sup>27</sup> *Actelion Pharms Ltd. v. Apotex Inc.*, Case No. 1:12-cv-05743 (D.N.J.). This case was settled in 2014.

function as Congress intended if generic firms are unable to obtain samples of branded products.<sup>28</sup>

We further note that even if a generic firm is ultimately able to prevail in an antitrust action and all subsequent appeals therefrom, such litigation can create substantial delays in obtaining the needed samples and a corresponding delay in generic approval. Accordingly, even a successful antitrust challenge is unlikely to provide immediate redress.

**b. Failure to Reach Agreement on FDA-mandated Shared REMS Programs Can Delay Entry for Ready-to-Approve Generics**

For drugs with an approved REMS in place, the FDA generally prefers for the branded and generic to share the same distribution system.<sup>29</sup> But if the branded and generic firms cannot reach agreement over the terms of a shared REMS, the generic will not be approved unless the FDA grants a waiver for the generic to establish its own REMS distribution system. In practice, the FDA has rarely granted a waiver of the shared REMS requirement, which can create a strategic incentive for the branded firm to refuse to cooperate with the generic entrant, since lack of cooperation can delay generic entry.

Generally, antitrust laws do not impose a duty on firms to cooperate or share resources with competitors. Under some circumstances, courts have found firms with market power liable under the antitrust laws for refusing to deal with competitors, such as when a monopolist refuses to sell a product to a competitor that it makes available to others. This is an unsettled area of antitrust law, however, which limits the ability of antitrust enforcement to address these situations. We note that at least one court has dismissed allegations that a branded firm violated

---

<sup>28</sup> Fed. Trade Comm'n Brief as *Amicus Curiae*, *Actelion Pharms Ltd. v. Apotex Inc.* (Mar. 11, 2013), [http://www.ftc.gov/sites/default/files/documents/amicus\\_briefs/actelion-pharmaceuticals-ltd-et-al.v.apotex-inc./130311actelionamicusbrief.pdf](http://www.ftc.gov/sites/default/files/documents/amicus_briefs/actelion-pharmaceuticals-ltd-et-al.v.apotex-inc./130311actelionamicusbrief.pdf).

<sup>29</sup> 21 U.S.C. § 505-1(i)(1)(B).

the antitrust laws by failing to cooperate with generic firms seeking to distribute their product in a shared REMS. In 2011, the FDA approved a REMS for Suboxone, a prescription drug used for the maintenance treatment of opioid dependence. After two companies filed ANDAs for generic Suboxone tablets, the FDA determined that all branded and generic Suboxone products would be subject to a single shared REMS program, and the would-be generic suppliers were expected to collaborate with Reckitt Benckiser, the branded firm, on the creation of a shared REMS system. However, the firms failed to reach an agreement, and antitrust litigation ensued.

In ruling on a motion to dismiss, the district court let stand various antitrust claims that the branded firm had improperly maintained its monopoly in violation of Section 2 of the Sherman Act, but specifically dismissed allegations that the branded had an antitrust “duty to deal” with generic competitors to establish a shared REMS program.<sup>30</sup> In that court’s view, recent Supreme Court decisions provide a distinction between a refusal to supply samples – which can violate the antitrust laws – and a refusal to cooperate in a shared REMS – which the court thought likely would not violate the antitrust laws. The court relied on the regulatory option for the generic firms to obtain a waiver from the FDA that would allow them to establish their own shared REMS program.

Under current law, it seems unlikely that the prospect of antitrust liability alone will create the proper incentives for branded and generic firms to reach agreement on a shared REMS program.

---

<sup>30</sup> *In re Suboxone Antitrust Litigation*, 64 F. Supp. 3d 665, 685-688 (E.D. Pa. 2014). Relying on *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko*, 540 U.S. 398 (2004) and *Pacific Bell Telephone Co. v. linkLine Communications, Inc.*, 555 U.S. 438 (2009), the court determined that “the antitrust laws do not create a duty for competitors to work together. Statutes and regulations requiring cooperation between rivals do not alter this analysis; in fact, regulation indicates that antitrust scrutiny is not necessary or prudent.”

### **c. The FTC’s REMS Concerns Extend to Biologic and Biosimilar Competition**

With the BPCIA, Congress created an abbreviated regulatory pathway for FDA to license biosimilar products that are “highly similar” to branded biologic drugs.<sup>31</sup> Congress also balanced the interest of innovation and access by granting branded biologic firms twelve years of regulatory exclusivity from biosimilar competition.<sup>32</sup>

The FTC has extensive policy experience studying the emerging biosimilar marketplace.<sup>33</sup> While this testimony focuses primarily on anticompetitive conduct related to generic drugs since passage of the Hatch-Waxman Act in 1984, the Commission has similar concerns about the potential for anticompetitive conduct designed to suppress biologic competition since the 2009 passage of the BPCIA. In particular, the FTC is concerned that branded firms could frustrate the timely entry of biosimilar competitors by restricting access to product samples, erecting roadblocks to the biosimilar firms’ efforts to meet the BPCIA requirements relating to preclinical and clinical testing using reference biologic samples. The Commission is also concerned that restrictive distribution systems, both in and outside of REMS, could be misused to exclude biosimilar competition in ways that parallel those discussed above.

### **IV. H.R. 2212, the CREATES ACT, May Reduce Incentives for Strategic Behavior**

House Bill 2212, the “Creating and Restoring Equal Access to Equivalent Samples Act of 2017” (CREATES Act), seeks to reduce incentives for regulatory abuse for both the so-called

---

<sup>31</sup> 42 U.S.C. § 262(i)(2).

<sup>32</sup> 42 U.S.C. § 262(k)(7) (Currently, there are four biosimilars approved by the FDA).

<sup>33</sup> See, e.g., FTC Public Workshop: Follow-On Biologics: Impact of Recent Legislative and Regulatory Naming Proposals on Competition, 78 Fed. Reg. 68840, 68841 (Nov. 15, 2013), [https://www.ftc.gov/sites/default/files/documents/federal\\_register\\_notices/2013/11/131115biologicsfrn.pdf](https://www.ftc.gov/sites/default/files/documents/federal_register_notices/2013/11/131115biologicsfrn.pdf); FED. TRADE COMM’N. EMERGING HEALTHCARE ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION (2009), <https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf>.

“front-end” problem of obtaining samples, and the “back-end” problems with shared REMS programs.

The bill creates a cause of action in federal court for a generic or biosimilar applicant to obtain sufficient samples to perform bioequivalency studies on commercially reasonable, market-based terms (except for drugs in shortage) from the branded manufacturer. The bill also amends the law to make it easier for a generic drug to get FDA approval for a separate REMS program.

The Commission supports the goal of the CREATES Act to protect the competitive process by eliminating incentives and opportunities for branded manufacturers to engage in manipulation of the REMS process to delay generic entry. For instance, rather than relying on the outcome of lengthy antitrust litigation to obtain needed samples, a generic firm could initiate legal action and obtain samples after establishing that it had complied with the requirements of the statute.

In addition, by providing a clearer path for a generic firm to establish a separate FDA-approved REMS program, the bill, if enacted, would reduce incentives for the branded firm to impede a shared REMS program merely to delay or block the introduction of a lower-cost generic version. As a result, the bill likely would result in fewer incidents of REMS abuse. The bill has the additional advantage that it does not compel the branded company to share its REMS program with the generic. Rather it simply removes the strategic advantage to avoid sharing created by the current regulatory system and then allows the generic and branded firms to determine both whether they will share a REMS program and the commercial terms for that arrangement on their own.

## **V. The FTC Continues to be Active in Antitrust Enforcement in Pharmaceutical Markets**

Aside from REMS abuses, the FTC continues to identify and investigate other potential anticompetitive conduct in the pharmaceutical industry. Below we discuss our long-standing efforts to combat reverse payment patent settlements, also known as pay-for-delay agreements, and our recent actions to prevent monopolization by branded firms through abuse of governmental processes, including sham citizen petitions.

### **a. FTC Efforts to Combat Pay-for-Delay and Agreements Not to Compete**

Pay-for-delay agreements (also known as “exclusion payment” or “reverse payment” agreements) are 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 agreement to buy more protection from competition than their patent rights provide, at the expense to 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.”<sup>34</sup> The core concern with agreements such as these – what the Court termed “the relevant anticompetitive harm” – is that they will allow the branded to “prevent the risk of competition,” by sharing its monopoly profits, which are preserved by the agreement, with the prospective generic entrant.<sup>35</sup>

The Commission has long recognized that stopping pay-for-delay deals was a matter of pressing national concern. Since this issue first arose in 1998, every single member of the Commission, past and present – whether Democrat, Republican, or Independent – has supported the Commission’s challenges to these anticompetitive agreements. The Commission remains united today in its determination to end these deals.

---

<sup>34</sup> *Federal Trade Commission v. Actavis, Inc.*, 133 S.Ct. 2223, 2231; 570 U.S. 756, \_\_\_ (2013).

<sup>35</sup> *Id.* at 2236.

In our high-profile *Actavis* case, the FTC challenged two patent settlements involving AndroGel, a multi-billion dollar testosterone replacement drug. As alleged by the FTC, Solvay Pharmaceuticals, Inc.<sup>36</sup> agreed to pay generic drug makers Watson Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc., to delay generic competition. Applying the “scope-of-the-patent” test, the Eleventh Circuit, affirmed a dismissal of the suit because the settlement did not delay competition beyond the patent’s expiration date.

Shortly after the Eleventh Circuit decision, the Third Circuit in *K-Dur*, rejected the scope-of-the-patent approach and held reverse-payment settlements presumptively anticompetitive.<sup>37</sup> The Supreme Court granted certiorari in *Actavis* to resolve the resulting conflict between the circuit courts. The Court found no basis in statutes or case law to support the scope-of-the-patent standard. Instead, the Supreme Court ruled that pay-for-delay agreements are appropriately subject to rule of reason scrutiny, the standard applied in most antitrust actions. The Supreme Court’s decision in *Actavis* serves as an important victory for consumers and the goals underlying the Hatch-Waxman framework.

Since the Supreme Court ruling in *Actavis*, the FTC has had other successes in our long-standing effort to combat anticompetitive brand-generic agreements that undermine competition and the Hatch-Waxman framework. For instance, the FTC obtained a settlement in another pay-for-delay case involving Provigil, a prescription drug used to treat sleep disorders. In *FTC v. Cephalon*,<sup>38</sup> the Commission alleged that Cephalon entered into anticompetitive pay-for-delay agreements to prevent generic competition to Provigil, its leading product. In May of 2015,

---

<sup>36</sup> Due to subsequent acquisitions, many of names of the original parties to this litigation have changed. Solvay Pharmaceuticals, Inc. is now AbbVie, Inc., Watson Pharmaceuticals, Inc. is now owned by Allegan, while Par Pharmaceutical Companies, Inc. is now owned by Endo Pharmaceuticals. To avoid confusion, we use the original party names here.

<sup>37</sup> *In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir. 2012).

<sup>38</sup> *FTC v. Cephalon, Inc.*, No. 08-cv-2141 (E.D. Pa. complaint filed Feb. 13, 2008), <https://www.ftc.gov/enforcement/cases-proceedings/061-0182/cephalon-inc>.

Cephalon's new owner, Teva Pharmaceuticals, agreed to settle the FTC's charges by making a total of \$1.2 billion available to compensate purchasers, including drug wholesalers, pharmacies, and insurers, who overpaid because of Cephalon's anticompetitive conduct.<sup>39</sup> Teva also agreed to refrain from entering into various types of reverse payment agreements for any of its other products for 10 years.

In addition to our active litigations, we also continue to monitor private actions involving possible pay-for-delay deals and other anticompetitive agreements. These can provide opportunities for the Commission to file *amicus* briefs on a variety of issues raised by pay-for-delay settlements and other issues. We can use our significant experience and expertise regarding competition in pharmaceuticals to provide necessary background that may assist a court in deciding a matter and help to shape antitrust law for the benefit of consumers and competition.<sup>40</sup>

#### **b. FTC Actions to Prevent Illegal Monopolization through Abuse of Citizens Petitions and other Governmental Processes**

Similarly, the Commission has long-standing concerns about unilateral conduct by branded manufacturers to illegally maintain a monopoly position through abuse of governmental processes in violation of the Sherman Act.<sup>41</sup> Earlier this year, the FTC charged that Shire

---

<sup>39</sup> FTC Press Release, "FTC Settlement of Cephalon Pay for Delay Case Ensures \$1.2 Billion in Ill-Gotten Gains Relinquished; Refunds Will Go To Purchasers Affected By Anticompetitive Tactics" (May 28, 2015), <https://www.ftc.gov/news-events/press-releases/2015/05/ftc-settlement-cephalon-pay-delay-case-ensures-12-billion-ill>.

<sup>40</sup> For example, the First Circuit accepted the FTC's distinction laid out in our *amicus* brief between an antitrust violation and injury-in-fact. See *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 59-60 (1st Cir. 2016); Brief of *Amicus Curiae* Federal Trade Commission in Support of No Party, *In re Nexium (Esomeprazole) Antitrust Litig.*, Nos. 15-2005, 15-2006, & 15-2007 (1st Cir. Feb. 12, 2016), [https://www.ftc.gov/system/files/documents/amicus\\_briefs/re-nexium-esomeprazole-antitrust-litigation/160212nexiumbrief.pdf](https://www.ftc.gov/system/files/documents/amicus_briefs/re-nexium-esomeprazole-antitrust-litigation/160212nexiumbrief.pdf).

<sup>41</sup> See, e.g., Statement of the Federal Trade Commission before the Committee on Commerce, Science, and Transportation, United States Senate, (Apr. 23, 2002) (discussing "second generation" FTC litigation aimed at improper Orange Book listings), [https://www.ftc.gov/sites/default/files/documents/public\\_statements/prepared-statement-federal-trade-commission-pharmaceutical-industry/pharmtestimony.pdf](https://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-pharmaceutical-industry/pharmtestimony.pdf). See also FTC Staff Report, "Enforcement Perspectives on the Noerr-Pennington Doctrine (2006),

ViroPharma illegally maintained its monopoly over Vancocin Capsules by filing 43 repetitive and unsupported (or sham) petitions with the FDA, as well as three lawsuits, between 2006 and 2012, all in an effort to obstruct and delay approval of a generic version of its branded drug.<sup>42</sup> Even after a panel of 16 independent scientific and medical experts convened by the FDA considered and rejected ViroPharma's unsupported arguments, ViroPharma continued to repeat its rejected arguments, the complaint alleges. The FTC alleged that ViroPharma's conduct significantly delayed the FDA approval of a generic, costing consumers hundreds of millions of dollars. This matter is pending in federal court in Delaware.

## **VI. Conclusion**

For over twenty years, the FTC has dedicated significant resources to prevent branded and generic pharmaceutical companies from engaging in anticompetitive conduct that undermines the Hatch-Waxman regulatory framework. Today, the Commission remains vigilant in this important area of the U.S. economy. The Commission likewise will remain vigilant in protecting against anticompetitive abuses that undermine the BPCIA.

Thank you for this opportunity to share the Commission's views. The Commission looks forward to working with the Subcommittee to protect consumers from anticompetitive conduct in the pharmaceutical industry.

---

<https://www.ftc.gov/sites/default/files/documents/reports/ftc-staff-report-concerning-enforcement-perspectives-noerr-pennington-doctrine/p013518enfperspectnoerr-penningtondoctrine.pdf>.

<sup>42</sup> FTC Press Release, "FTC Charges That Shire ViroPharma Inc. Abused Government Processes Through Serial, Sham Petitioning to Delay Generics and Maintain its Monopoly over Vancocin HCl Capsules" (Feb. 7, 2017), <https://www.ftc.gov/news-events/press-releases/2017/02/ftc-charges-shire-viopharma-inc-abused-government-processes>.