



Your Generics and Biosimilars Industry

August 20, 2018

Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue, NW
Suite CC-5610 (Annex C)
Washington, DC 20580

Re: Competition and Consumer Protection in the 21st Century Hearings, Project Number P181201

The Association for Accessible Medicines (“AAM”) is pleased to provide comments to the Federal Trade Commission in response to the Agency’s June 20, 2018 request for public comments in advance of the above-referenced hearings.

AAM is a nonprofit, voluntary association representing the leading manufacturers and distributors of finished generic and biosimilar medicines and bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic and biosimilar pharmaceutical industry.

AAM’s core mission is to improve the lives of patients by advancing timely access to safe, effective, and affordable prescription medicines. AAM is the sole association representing America’s generic and biosimilar pharmaceutical sector. Our members’ products are used in more than three billion prescriptions every year.

The Hatch-Waxman Act, enacted in 1984, and the Biologics Price Competition and Innovation Act of 2009 (BPCIA) have increased competition in the pharmaceutical market by balancing innovation in drug development and acceleration of the availability of lower cost generic alternatives.

However, the sustainability of a competitive generic and biosimilar drug market, the availability of alternative generic and biosimilar products, and the continuing supply of generic and biosimilar medicines for patients, uninterrupted by shortages, is in jeopardy.

Today’s Market Presents Challenges to a Thriving Generic and Biosimilar Industry

It is sobering to consider what America’s patients would face if there were no FDA-approved generic or biosimilar medicines to provide reliable access to affordable treatments. Generics do not merely deliver the most medicine at the lowest cost and greatest savings. Every day, generics cushion the significant financial impact of high brand name drug prices for patients and the health care system.

Put another way, the availability of low-cost generics helps to offset the financial impact of high brand drug prices. While prices for FDA-approved generic medicines are currently declining by



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more than 7 percent year over year¹, prices for brand drugs, especially biologics and specialty medicines, are increasing at an unsustainable rate – 62 percent from 2011 to 2015.²

However, the sustainability, competitiveness and reliability of both the generic and biosimilar markets are in jeopardy. These markets are confronted by the same destructive forces, yet face distinct challenges. Threats facing both markets include:

- (i) changing and increasingly challenging market and reimbursement frameworks, including significant and monopolistic purchaser consolidations;
- (ii) the abuse of laws and regulations by bad actors; and
- (iii) policy miscues that ignore the unique challenges facing generic and biosimilar medicines and unfairly penalize generic drugs.

As part of this, older generic medicines face aggressive price deflation and other hurdles to remaining in the market. For instance, market consolidation has winnowed the buyer side to three main purchasing consortia that buy 90 percent³ of the prescription drugs for wholesale distribution. With more than 200 multi-source manufacturers recognized by the FDA, competition is fierce, and prices decline rapidly.

In addition, newer, highly desirable generics and biosimilars face barriers to entering the market.

Purchaser Consolidation Poses Significant Challenges to a Sustainable Market & Supply of Low-Cost Generic Medicines for Patients

Increasing consolidation among pharmaceutical purchasers represents an increasing threat to maintaining a stable supply of generic medicines. In fact, today roughly 200 generic companies compete to sell to three purchasing groups that collectively control 90 percent of the market.⁴

This often leaves generic companies without contracts, and requires generic companies to suspend marketing their drugs until such contracts become available again. These challenges are particularly acute in low-margin or low-volume markets. They play an important role in companies' decisions to market FDA-approved generic drugs or even to submit an abbreviated new drug application (ANDA).

As these purchasing consortia move more and more toward single-source contracts for generic drugs, it creates a dynamic where it is possible that no more than three generic manufacturers may be able to market any given product successfully. Notwithstanding the economic principle that more suppliers of a good or service creates lower prices for consumers, it is unclear that

¹ Morgan Stanley. June 29, 2018. "Spec/Gx Trends in Pictures"

² U.S. Department of Health and Human Services Office of Inspector General. June 2018. Data Brief: Increases in Reimbursement for Brand-Name Drugs in Part D

³ Fein, A. The 2016-2017 Economic Report on Pharmaceutical Supply Chain.

⁴ Fein, A. The 2016-2017 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors, September 2016.



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the new imbalance between approximately 200 generic competitors and a handful of purchasers is sustainable. This undermines future competitive success in the generic market as generic drug manufacturers are forced to maximize economies of scale and consolidate. In fact, it poses a number of dangers — including of critical drug shortages.

Excessive consolidation of purchasing power among the consortia presents the risk of exerting undue market power over generic suppliers, driving wholesale prices below marginal costs and reducing output. In turn, this may lead to producers exiting the market, reduction of output, ceasing production of unprofitable drugs and shortages of critical medicines. Such consolidation also poses a danger of stabilizing and elevating downstream costs to end users and payors in the market.

Abuse of the Patent System Keeps Patient Costs High by Delaying Generic and Biosimilar Competition

AAM's members support and engage in innovation. Without innovation there could be no generic pharmaceutical or biosimilar medicines for patients. However, AAM is concerned that all too often some brand-name drug companies attempt to patent features of drugs that do not represent true innovation and are therefore not worthy of patent protection. Brand-name drug companies often attempt to bury competition from generic and biosimilar drugs indefinitely by finding ways to re-package existing inventions in later patents. These later patents are often not innovative, meaning they are likely invalid.

Recent research shows the brand-name pharmaceutical industry is manipulating this system by obtaining dozens of potentially non-innovative patents to extend its market exclusivity farther than policymakers initially intended, a ploy known as building “patent thickets.”⁵ In these instances, branded biologic manufacturers are attempting to accumulate patents not because they are innovative, but rather to increase litigation and development costs for potential would-be biosimilar competitors. These patent thickets chill competition by discouraging competitors from entering a market because of the exorbitant cost of litigating meritless patents.

Sometimes, as the original patent on a lucrative drug is close to expiring, a brand-name drug company will seek a new patent for a minor change such as changing from a pill to a gelcap and call this a new innovation worthy of a new, multi-year monopoly protection from the government.

When the U.S. Patent & Trademark Office (PTO) grants pharmaceutical patents that do not represent innovation, drug costs remain high due to the prevention of generic drug competition. In this way, the PTO has an important role in the cost of prescription drugs.

Patent gamesmanship by some originator pharmaceutical companies is an enormous problem that drives up prescription drug costs to patients and consumers.

⁵ Feldman, Robin and Wang, Connie, May Your Drug Price Be Ever Green (October 29, 2017). UC Hastings Research Paper No. 256. Available at: SSRN: <https://ssrn.com/abstract=3061567>. Accessed: April 30, 2018.



FTC Should Support Congressional Action to End Anticompetitive and Abusive Restricted Access Programs that Delay Generic and Biosimilar Development

As HHS and FDA officials have noted, a significant barrier to competition is restrictions by brand manufacturers who block the sale of reference product for generic and biosimilar development. This includes simple refusals to sell reference product as well the abuse of Risk Evaluation and Mitigation Strategies (REMS) to delay and prevent generic and biosimilar development.⁶

A fundamental premise since 1984 under Hatch-Waxman and since 2010 under the BPCIA is that generic and biosimilar manufacturers must test their product in comparison to the reference product to demonstrate “sameness” for generics and “biosimilarity” for biosimilars. If purchase of the reference product is blocked by a brand manufacturer, then there is no opportunity to develop affordable medicines when exclusivity expires. This practice emerged in the last 10 years and has been highly profitable for brand companies as their peak sales (and profits) occur at the end of the life cycle and this has the effect of extending exclusivity well beyond appropriate regulatory protection and patent life. This has a major impact on drug pricing and if not stopped, will interfere with continued generic and future biosimilar savings.

In addition, brand companies are using REMS to block sales and restrict access to samples necessary for testing and approval of generic and biosimilar products as well. Congress established the REMS authority in 2007 to further assure the safety of drugs.⁷ Pursuant to a REMS, the FDA can require a sponsor to implement a broad range of risk-mitigation tools to ensure that the benefits of a drug outweigh its risks to patients. Such tools include medication guides, communication plans and other distribution and use restrictions, called “elements to assure safe use,” or ETASU. A REMS with ETASU may impose strict requirements on who may prescribe or dispense the drug, where the drug may be dispensed and on patients to whom the drug may be prescribed or dispensed.⁸ If a brand drug is subject to a REMS with ETASU, generic and biosimilar versions are subject to the same distribution and use restrictions and, unless waived by FDA, must utilize a shared system (SSRS) with the brand drug.⁹

At the time of enactment, Congress acknowledged there was the potential for the REMS tools to be gamed, and outright abused, by branded manufacturers to extend patent protection and delay robust generic competition.¹⁰ Congress specifically prohibited brand manufacturers from using any element of a REMS to “block or delay” generic competition or to interfere with adoption of an SSRS.¹¹ Contrary to the intent of Congress, however, brand companies routinely

⁶ Senate Finance Committee Full Committee Hearing on Prescription Drug Affordability and Innovation: Addressing Challenges in Today's Market. June 26, 2018.

⁷ See 21 U.S.C. § 355-1.

⁸ *Id.* § 355-1(f)(3).

⁹ *Id.* § 355-1(i)(1)(B).

¹⁰ An early version of the Food and Drug Administration Amendments Act of 2007 (“FDAAA”) would have required brand companies to sell their drugs subject to distribution restrictions to generic companies at fair market value for bioequivalence testing. Food and Drug Administration Amendments Act of 2007, H.R. 2900 § 901(f)(6), 110th Cong. (1st Sess. 2007).

¹¹ 21 U.S.C. § 355-1(f)(8).



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use REMS and other restricted access strategies to impede generic and now biosimilar competition. They do so with little fear of adverse regulatory action by FDA or other governmental authorities.

REMS and restricted access abuses generally fit into two categories, each presenting an opportunity for stronger, more effective administration and oversight by FDA. First, brand companies use their REMS with ETASU or self-imposed restricted access programs to deny generic companies' access to the brand company reference listed drug (RLD) samples needed to support ANDAs. Second, brand companies use the requirement for an SSRS¹² to forestall approval of generic drugs by delaying or refusing to agree to an SSRS. Both strategies are discussed in more detail below.

These abuses are significant. According to a recent study,¹³ as of May 2017, 74 drugs are subject to restricted access programs (that is, drugs that are either subject to REMS or self-imposed restricted distribution programs) with total sales of \$22.7 billion in 2016. Of these, 41 drugs are restricted by REMS programs, with \$11.5 billion in sales in 2016. The remaining 33 drugs are restricted by the brands in a voluntarily imposed non-REMS program, with \$11.2 billion in sales in 2016.

Brand abuse of restricted access and the REMS process imposes substantial costs on consumers and other participants in the health care system. A 2014 study concluded that REMS abuse costs the U.S. health care system \$5.4 billion annually.¹⁴ Consumers bear \$960 million of that cost while Medicare and Medicaid incur \$1.8 billion; private insurers bear the remaining \$2.4 billion.¹⁵ This estimate is conservative "and should not be construed as the entirety of the lost savings from REMS misuse, either currently or going forward."¹⁶

Moreover, the opportunities for abuse are growing. This is due, in part, to the fact that (a) FDA increasingly is requiring REMS as a condition for new drug approvals, and (b) these REMS programs increasingly include ETASU. In 2014, it was estimated that nearly 40 percent of new FDA approvals are subject to REMS.¹⁷ While only approximately 25 percent of REMS programs included ETASU in 2009,¹⁸ now nearly 60 percent of REMS programs (42 of 71) include the types of distribution and use restrictions that can be used by brand companies to delay generic and biosimilar competition.¹⁹

¹² *Id.* § 355-1(i)(1)(B).

¹³ Alex Brill "REMS and Restricted Distribution Programs: An Estimate of the Market (June 2017),)" Available at http://www.gphaonline.org/media/cms/Alex_Brill_REMS_Study_June_2017.pdf. Accessed: July 5, 2018.

¹⁴ Alex Brill, "Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry, at 5 (2014),). Available at: http://www.gphaonline.org/media/cms/REMS_Studyfinal_July2014.pdf. Accessed: July 5, 2018.

¹⁵ *Id.*

¹⁶ *Id.* at 5.

¹⁷ *Id.* at 6

¹⁸ *Id.* at 3.

¹⁹ Alex Brill, *REMS and Restricted Distribution Programs: An Estimate of the Market*, p. 2.



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The FTC and senior FDA officials have identified restricted access and REMS abuse as a significant problem that impairs generic competition and increases drug costs. Specifically, the FTC has warned that REMS abuse “threatens to undermine the careful balance created by the Hatch-Waxman Act and potentially preserve a brand company’s monopoly indefinitely.”²⁰ In his recent testimony to Congress, FDA Commissioner Gottlieb stated that statutory and regulatory requirements established to ensure the safety and quality of drugs approved by FDA, such as the REMS requirements, can be “gamed ... in an effort to delay generic drug approvals beyond the timeframe the law has intended. *This can serve to thwart expected competition.*”²¹ Likewise, in earlier testimony to Congress, FDA Center for Drug Evaluation and Research (CDER) Director Janet Woodcock, M.D., stated that REMS abuse “can delay timely consumer access to less expensive generic medicines.”²²

While AAM commends the FDA and FTC for seeking to address REMS and restricted access abuses, as well as to publicize these abuses and seek additional support from stakeholders, they are limited in their capacity as federal agencies. The Federal Food Drug & Cosmetic Act’s penalties are insufficient to effectively deter bad behavior by the brands. Ultimately, the FDA lacks the ability to compel brand companies to sell samples to generic manufacturers.

AAM encourages HHS to support enactment of the CREATES Act.²³ This bipartisan bill would prevent the misuse of REMS and voluntarily imposed restricted access programs to delay generic drug competition.

In light of the myriad of competitive threats to the generic and biosimilar pharmaceutical market identified herein and elsewhere, AAM urges the FTC to make a key focus of its upcoming hearings the issue of competitive threats in this industry. AAM stands ready to assist in any way in terms of providing additional information, including the testimony of a representative of our industry or membership. Thank you in advance for your consideration.

Respectfully submitted,

/s/

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²⁰ FTC Amicus Brief, *Actelion Pharmaceuticals LTD. v. Apotex Inc.*, Case No. 1:12-cv-05743 (D.N.J.).

²¹ FDA Commissioner Scott Gottlieb, M.D., Congressional Testimony before House Committee on the Judiciary, Subcommittee on Regulatory Reform, Commercial and Antitrust Law, at 2 (July 27, 2017). (emphasis added).

²² Janet Woodcock, M.D., Congressional Testimony before House Committee on Oversight & Investigations (Mar. 22, 2017). In addition, in 2015, Dr. John Jenkins, then-Director of FDA’s Office of New Drugs stated that brand companies are aggressively using REMS to block generic competition. Gingery, Derrick. REMS That Block Generics Are “Major” Problem for FDA, Jenkins Says. The Pink Sheet Daily. January 8, 2015. [random capitalization]

²³ Creating and Restoring Equal Access to Equivalent Samples Act of 2017, S. 974, 115th Cong. (2017).