Association for Accessible Medicines

Your Generics & Biosimilars Industry

December 8, 2017

Maureen K. Ohlhausen
Acting Chairwoman
Federal Trade Commission
400 7th St., SW
Washington, DC 20024

Re: Understanding Competition in U.S. Prescription Drug Markets: Entry and Supply Chain Dynamics; Public Workshop; Request for Comments

The Association for Accessible Medicines (AAM) is pleased to provide comments to the Federal Trade Commission (FTC or the Commission) in response to the commission's request for comments on Understanding Competition in U.S. Prescription Drug Markets: Entry and Supply Chain Dynamics.

Background

AAM. AAM's core mission is to improve the lives of patients by advancing timely access to safe, effective and affordable generic medications. Our association represents the manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals and suppliers of other goods and services to the generic pharmaceutical industry. AAM is the sole association representing America's generics and biosimilar pharmaceutical sector. Our members' products are used in more than three billion prescriptions every year. Generics represent greater than 89 percent of all prescriptions dispensed in the U.S., but only 26 percent of expenditures on prescription drugs, saving patients and payers nearly $5 billion every week.[1]

Evolving Generics Drug Industry. In 1984, Congress enacted the Hatch-Waxman Act[2] which represents a model of successful, bipartisan public policy. Over its more than 30-year history, the act has produced a thriving and constantly changing pharmaceutical marketplace by balancing innovation in drug development and accelerating the availability of lower-cost generic alternatives. This has important effects on the public health, allowing patients to live longer, healthier lives. AAM applauds the FTC's attention to maintaining the balance struck in the 1984 Hatch-Waxman Act and its collaboration with the Food and Drug Administration (FDA) in this regard.

[1] $253 billion total savings in 2016, equivalent to approximately $5 billion every week. AAM 2017 Generic Drug Access & Savings in the U.S., http://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf.
[2] Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417 (1984).

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In the last decade, the U.S. health care system has saved $1.67 trillion due to the availability of low-cost generics.[3] In 2016 alone, generic medicines generated $253 billion in savings for patients and taxpayers. Savings for the two largest government health care programs, Medicare and Medicaid, totaled $77 billion and $37.9 billion, respectively, in 2016. This translates to an average annual savings of $1,883 per Medicare enrollee and an average savings of $512 per Medicaid enrollee.[4]

Today's generics industry includes a range of diverse companies that have become global leaders both in providing safe and effective medicines and in pioneering new treatment options for patients. Generic competition continues to play a vital role in improving access to pharmaceuticals and driving cost savings to American patients and the health care system. This growth in the generics industry has led to the creation of thousands of new jobs across the country and to the improvement of the quality of life for millions of people.

Despite the success of the Hatch-Waxman Act in creating a vibrant generic drug industry, there are troubling indications that the intended balance between innovation and access has become skewed in recent years. On the one hand, there is abundant evidence that the "innovation" side of this balance has been flourishing. Indeed, as of this writing, the FDA has already approved 15 more new molecular entities in 2017 than it did in all of 2016.[5] This is good news for all of us. Unfortunately, improvements to the innovation side have not been matched by similar focus or improvements on the "access" side of the Hatch-Waxman balance. As a result, while brand-drug innovation has benefited from a series of laws subsequent to Hatch-Waxman that establish incentives and development tools, the generics and biosimilar marketplace and patient access has not received an equivalent level of attention. That neglect, combined with current market and anticompetitive realities, reinforces why the FTC's work on this issue is so important.

Indeed, the sustainability of a competitive generics market and the availability of generic medicines for patients, uninterrupted by shortages, is in jeopardy. They are now threatened by (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) a failure of policy to account for the unique challenges facing generic and biosimilar medicines.

The FTC's call for comments asked a number of questions relating to the following topics: (a) incentives and disincentives for generic competition and supply; (b) tactics that have been utilized to stifle generic competition; and (c) the impact of current intermediary trends on the generic industry. Finally, the commission asked for input on ways to increase consumer access and the FTC's roles in promoting such gains. AAM's comments in response to these areas of inquiry are set forth in detail below.

A. Generic Competition and Supply Incentives

The FTC's first inquiries relate to incentives for generic competition. To address the current incentives and disincentives in ensuring generic competition and supply, it is important to

[3] Association for Accessible Medicines, *Generic Drug Access & Savings in the U.S.-2017*, at 20 (online at: http://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf).
[4] *Id.*at 42.
[5] FDA, *Novel Drug Approvals for 2017* (online at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm537040.htm).

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understand the market in which generic drugs are offered, as the generic drug marketplace has changed dramatically in recent years. The generic drug industry is proud to be able to deliver great savings for patients, employers, insurers, the federal government and the states. However, it is operating in a rapidly changing marketplace with significant and unique pressures that distinguish it from the monopolized branded sector.

While brand drugs see steady price growth over time, the price of a generic drug falls precipitously as competitors enter the market, often settling at 80 percent less than that of the brand. This creates a volatile marketplace in which many generic manufacturers make decisions on market entry and exit more quickly and more often than a brand manufacturer.

Such decisions can be influenced by a range of factors and challenges including ambiguous or burdensome regulatory requirements, rapidly evolving competition and difficult market conditions. These hurdles include delays in approval; the inability to acquire the active pharmaceutical ingredient (API); ingredient cost and supply fluctuations; a low potential for return on investment driven by extensive consolidation in the wholesale and retail markets for generics; and wide-scale annual price deflation.

For instance, generic companies are impeded by efforts by brand companies to "lock-up" API manufacturers, resulting in unnecessary delays to identify new API manufacturers. Even when generic companies are able to bring generic drugs to market, they often must intermittently market their drugs because, particularly in low-volume markets, ongoing manufacturing may not be warranted. Moreover, as discussed further in Part B, purchaser consolidation often leaves generic companies without contracts, and requires generic companies to suspend marketing their drugs until such contracts become available again. In fact, because of tremendous consolidation among purchasers, today roughly 200 generic companies compete to sell to three purchasing groups that collectively control 90 percent of the market. 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).

A generic company considers a range of factors when determining whether to pursue development of a generic version of an approved drug, including:

- Product development capability (whether the company has the scientific know-how to develop the product or whether it can outsource development);
- Manufacturing capability (whether the company has the manufacturing capabilities to manufacture the product or whether it can outsource manufacturing);
- Regulatory capability (whether the company has the regulatory expertise to compile and file a marketing application or whether it can outsource the regulatory work);
- Ability to acquire the API (whether the API is readily available or if it is contractually "locked-up," and, if it is locked-up, whether the company can source the API from another qualified API manufacturer); and
- Business development (whether the company's cost and profit analysis for the product is favorable compared to other potential product candidates).

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Assuming the evaluation for each of the criteria above is favorable, the timeline to bring a generic version of the product candidate is roughly 30 months at the earliest. A range of factors may delay development and push market entry to upwards of 48 to 60 months. An example of a generic development timeline is presented below:

Pre-Submission Activity	Time
Determine development feasibility (per the criteria set forth above)	2-3 months
Secure API	1-3 months (if readily available)
	12-24 months (if new API source needed)
Product development	6-12 months
Manufacture exhibit batches; perform stability and bioequivalence testing; file application	9-12 months

Post-Submission Activity	Time[6]
FDA review	8 months (priority review)
	10 months (standard review)
Response to deficiency	3 months (minor)
	6 months (major, priority review)
	8 months (major, standard review)

In its request for comments, the FTC specifically requested information regarding incentives to enter markets where the brand drug is off-patent. To consider the market effect on the decision to submit an ANDA, AAM performed an assessment of the products identified in the FDA's List of Off-Patent, Off-Exclusivity Drugs Without an Approved Generic.[7]

AAM's assessment of the FDA's List of Off-Patent, Off-Exclusivity Drugs Without an Approved Generic revealed that the list contains 264 products,[8] and consists of 83 products that are often deemed inappropriate development candidates due to their product type and the capital investment required (for example, radiopharmaceuticals, amino acid/electrolyte replacements). Of the remaining 181 potential products, 144 products have low volume sales, which reduces the attractiveness of developing the product. Generic companies evaluate potential product candidates

[6]These post-submission times are based upon FDA's GDUFA II commitments and reflect FDA action on the submission, not necessarily FDA approval.
[7] FDA List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic, *available at* https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/UCM564441.pdf. List current as of FDA release on June 27, 2017.
[8] One product is an OTC drug, and therefore is outside of the scope of AAM's research. Two products are listed twice in the list.

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with low sales; however, the drugs often treat small patient populations or are no longer the standard of care.

The balance created by Hatch-Waxman established a new and different market for generic drugs – separate from brand drugs – that has supported growth in generic utilization and its attendant savings for patients. Although brand manufacturers often criticize pharmacy benefit managers (PBM) and health plan formulary and rebate practices, the supply chain and pricing models they criticize do not represent the vast majority of prescription drugs distributed in this country. The 89 percent of prescriptions filled by generic medicines are subject to a different set of economic incentives and arrangements – the result of multiple manufacturers marketing identical products and competing exclusively on price, in a commodity-style market.

When brand manufacturers leverage the pricing power granted by their patents and regulatory exclusivities, PBMs, distributors and payers rely on formulary management and rebate agreements to control costs.

However, upon generic entry, payers typically shift away from rebate models of reimbursement and rely on distribution channels to effectively lower the price of the medicine. Rather than providing rebates to lower the cost, generic manufacturers must compete for sales to wholesalers. Because the products are virtually identical, the primary leverage manufacturers have is their ability to lower the price and provide the necessary volume. With more than 200 generic manufacturers recognized by the FDA, competition is fierce and prices decline rapidly. The wholesalers, often in collaborative purchasing agreements with pharmacies across the country, then distribute generic medicines to various retail pharmacies. Generic manufacturers may also have to negotiate separate payments to pharmacies to stock their product.

The different business model in the generic industry leads to a different type of business planning by generic and biosimilar manufacturers. As part of this process, the decisions by which generic and biosimilar manufacturers select which products to develop can take into account multiple variables. Considerations include: the complexity in engineering the original product, the state of the intellectual property claimed by the brand manufacturer over the product, the size of the patient population served, the number of likely competitors for that product and the product development and manufacturing capabilities and costs.

Generic drug reimbursement is also different. Rather than relying on per-transaction rebates, PBMs and insurers typically establish a Maximum Allowable Cost (MAC) list that sets a specific reimbursement rate for the product, regardless of the generic product cost to the pharmacy. These MAC lists create additional incentives for pharmacies to maximize their dispensing margins by finding the lowest cost source for generic products.

The result is a business model that differs significantly from the brand business model. While brand companies typically market a small number of high-margin products, many generic manufacturers market hundreds of products with varying levels of profitability or loss.

These differences in the generic and brand marketplaces create vastly different incentives for the various manufacturers, wholesalers, distributors, pharmacy benefit managers (PBM), insurers and retail pharmacies that make up the supply chain. To put it simply, virtually all other actors in the supply chain enjoy significant financial benefits from the manufacture of generic medicines.

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This phenomenon was most recently examined by a group of researchers at the USC Leonard D. Schaeffer Center for Health Policy & Economics. That analysis, The Flow of Money Through the Pharmaceutical Distribution System, identified two items relevant to this topic:

- First, for every sale of a brand-name drug to a patient, the brand manufacturer captures approximately 76 percent of the revenue. Meanwhile, even though generic prices are only a fraction of brand prices, generic manufacturers keep only half of their much lower revenues. Moreover, generic manufacturers cannot rely on capturing the total volume within the market as the brands do, and therefore individual generic manufacturers are forced to rely on much smaller revenue streams. To put it simply, brand drugs capture a higher percentage of the "spend" of a higher-value market.

- Second, the supply chain captures significantly more of the revenue spent on generic medicines than on brand-name drugs. For every $100 spent on dispensing generic medicines in this country, approximately $65 goes to the distribution and reimbursement of those products by the members of the supply chain. PBMs make nearly three times as much on generics as they do on brands. Wholesalers make about eight times more. Pharmacies make more than 10 times for every $100 spent on generics than brands. [9]

B. Abusive Tactics Hindering Generic Competition

The commission's second area of questions relates to strategies being employed to reduce generic competition. As noted above, the "access" side of the Hatch-Waxman equation has faced significant barriers in combating brand manufacturer abuses. Brand tactics take advantage of existing regulatory requirements, such as drug safety protections, in an attempt to stifle legitimate generic competition. Unfortunately, these games have been extremely effective at blocking competition and therefore patient access to lower-priced, safe and effective generic and biosimilar medicines. The result is that patients and payers are forced to pay monopoly prices for much longer than Congress intended when it passed the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act (BPCIA), thereby impeding access and impairing the public health. Given the increasing reliance on higher-priced biologics, the use of these tactics to block competition to biosimilars is likely to be even greater in the years to come.

As the FTC's own history of weighing in against such tactics makes clear, one of the most problematic tactics is the abuse of Risk Evaluation and Mitigation Strategies (REMS) restricted distribution systems and restricted distribution systems that brand companies create on their own (without any mandate from FDA) as a means to forestall generic competition.

Congress established the REMS authority in 2007 to give the FDA a new tool to further assure the safety of drugs.[10] 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

[9] Sood, et al., "The Flow of Money Through the Pharmaceutical Distribution System." June 2017. http://healthpolicy.usc.edu/documents/USC%20Schaeffer_Flow%20of%20Money_2017.pdf
[10] *See* 21 U.S.C. § 355-1.

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whom the drug may be prescribed or dispensed.[11] If a brand drug is subject to a REMS with ETASU, generic 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.[12]

At the time of enactment, Congress knew there was the potential for the REMS tools to be gamed, and outright abused, by branded manufacturers to extend monopolies and delay robust generic competition.[13] Congress therefore, 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.[14] Contrary to the intent of Congress, however, brand companies routinely use REMS and other restricted access strategies to impede generic competition. They do so with little fear of adverse regulatory action by FDA or other governmental authorities. Today's well-intentioned, but widely abused system thus defies congressional intent.

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 SSRS[15] to forestall approval of generic drugs by delaying or refusing to agree to an SSRS. Both strategies are discussed in more detail below.

The problem with REMS abuse and voluntarily imposed "safety" programs is significant and has the potential to grow. According to a recent study,[16] 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 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.[17] Consumers bear $960 million of that cost while Medicare and Medicaid incur $1.8 billion; private insurers bear the remaining $2.4 billion.[18] This estimate is conservative "and should not be construed as the entirety of the lost savings from REMS misuse, either currently or going forward."[19]

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[11] *Id.* § 355-1(f)(3).
[12] *Id.* § 355-1(i)(1)(B).
[13] 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).
[14] 21 U.S.C. § 355-1(f)(8).
[15] *Id.* § 355-1(i)(1)(B).
[16] 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 .
[17] 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.
[18] *Id.*
[19] *Id.* at 5.

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Moreover, the opportunities for brand companies to abuse the REMS system 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.[20] While only approximately 25 percent of REMS programs included ETASU in 2009,[21] 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 competition.[22]

The FTC and senior FDA officials have identified 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."[23] In another amicus brief, the FTC reiterated that REMS abuse could harm generic competition and potentially extend a brand's monopoly into perpetuity.[24]

In his recent testimony to Congress, FDA Commissioner Dr. Scott 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*."[25] Likewise, in earlier testimony to Congress, FDA Center for Drug Evaluation and Research (CDER) Director Dr. Janet Woodcock, stated that REMS abuse "can delay timely consumer access to less expensive generic medicines."[26]

While AAM commends the FTC for its efforts to address REMS and restricted access abuses, as well as efforts to publicize these abuses and seek additional support from stakeholders, there is a limit to what the FDA or FTC can do on their own. One of the key deficiencies in the current FDC Act is that the penalties available to the FDA to stem the kinds of anticompetitive tactics by the brands 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.

C. Supply Side Consolidation Threats to Generic Competition

The third main subject of the commission's inquiries involved intermediaries and, specifically, whether consolidation has affected generic competition. The increasing consolidation in the supply chain is certainly another key threat to sustainable generic markets. Compared to the fragmented generic drug market, consolidation in the wholesale market and contractual arrangements between pharmacy chains and wholesalers have left generic manufacturers with only a small number of

[20] *Id*. at 6
[21] *Id*. at 3.
[22] Alex Brill, *REMS and Restricted Distribution Programs: An Estimate of the Market,* p. 2.
[23] FTC Amicus Brief, *Actelion Pharmaceuticals LTD. v. Apotex Inc.*, Case No. 1:12-cv-05743 (D.N.J.).
[24] FTC Amicus Brief, *Mylan Pharmaceutical, Inc. v. Celgene Corp.*, Case No. 2:14-CV-2094-ES-MAH (D.N.J.).
[25] Gottlieb Congressional Testimony, p. 2 (emphasis added).
[26] 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.

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purchasers. The result is a market where three purchasers account for more than 90 percent of all wholesale revenue.[27]

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 successfully market any given product. This dynamic risks future competitive success in the generic market as generic drug manufacturers may be forced to maximize economies of scale and consolidate.

It is clear the significant benefits for patients of reliable access to affordable generic medicines are at risk. Notwithstanding the economic principle that more suppliers of a good or service creates lower prices for consumers, it is unclear that the new imbalance between 200 generic competitors and a handful of purchasers is sustainable. Some industry analysts have already begun to forecast consolidation among generic manufacturers.

An unfortunate yet foreseeable consequence of fewer generic manufacturers is a significantly increased risk of drug shortages. Evidence suggests that generic drugs are particularly susceptible to drug shortages, potentially related to existing market incentives as well as low reimbursement.[28] Such shortages have a serious effect on patient care. Responding to a series of drug shortages in 2011, Dr. Scott Gottlieb testified before Congress that many such shortages were a direct result of low reimbursement for older, low-margin products and that "many hospitals are being forced to ration key medicines and patients must sit on waiting lists for vital drugs."[29]

Accordingly, government agencies, Congress and the public should be vigilant concerning the potential anticompetitive effects that may result from increasingly powerful purchasing consortia. This buyer consolidation poses a number of dangers — including smaller companies being locked out of the marketplace and critical drug shortages.

Practices that may hinder competition include exclusionary long-term contracts, administrative fees, tying and bundling of product lines, obstacles for smaller suppliers, forced compliance programs for members, and interlocking most-favored nation clauses.

Excessive consolidation of power among the purchasing 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. Such consolidation also poses a danger of stabilizing and elevating downstream costs to end users and end payers in the market.

Moreover, the savings achieved by purchasing consortia may not be passed on to end users, including patients and insurers. In short, the ever-increasing market power of large purchasers may lead to higher prices for consumers.

D. Proposals to Increase Generic Competition

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[27] Fein, Adam J. Fein. The 2016-2017 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors, September 2016.

[28] Stromberg, C. (May 2014). Drug Shortages, Pricing, and Regulatory Activity. National Bureau of Economics Working Paper. http://www.nber.org/chapters/c13102.pdf

[29] Gottlieb, Scott. "Drug Shortages: Why they happen and what they mean" Testimony before the Senate Finance Committee. December 2011. https://www.finance.senate.gov/imo/media/doc/Gottlieb%20Testimony1.pdf

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Finally, the commission inquired how stakeholders should evaluate proposals to increase consumer access and the role the FTC should play.

First, AAM believes that actions should be taken to prevent monopolistic behavior by powerful purchasing organizations. The FTC and Department of Justice should consider updates to the Statements of Antitrust Enforcement Policy in Health Care and otherwise monitor and seek restriction of consolidation in the purchaser market that bestows anticompetitive market power on purchasing organizations, endangering competition and risking drug shortages.

Second, the agencies and Congress should work to eradicate abusive delaying tactics that hinder generic competition. For example, with respect to abuse of restricted distribution programs, AAM encourages Congress to take immediate action by passing the CREATES Act.[30] This bipartisan bill would prevent the misuse of REMS and voluntarily imposed safety programs to delay generic drug competition. Until this becomes law, however, AAM urges the FTC to continue to monitor this issue and consider (ii) investigating all complaints regarding REMS and restricted distribution agreements; (ii) bringing an action under Section 5 of the FTC Act challenging such practices; (iii) expressing support for any and all legislative initiatives designed to address REMS and restricted distribution abuse; and (iv) participate in joint task force activities with the FDA to help expedite the purchase and approval of generic products covered by REMS or restricted distribution programs.

Finally, in all of the above, AAM believes that it is critical that the FTC maintain a focus on the impact of anti-competitive tactics in the area of biologics. By most accounts, biologics represent the future of medicine. This is an exciting development for patients and the health care system. However, the price of new biologics has increased dramatically, and these medicines are of no use to patients if they cannot afford them. Biosimilars hold great potential to bring savings to the health care system overall. Current estimates suggest biosimilars will create anywhere between $54 billion and $250 billion in savings in the next decade.[31] Given the high price demanded by brand biologic companies, anti-competitive tactics in this area are likely to increase in future years.

Conclusion

AAM commends the FTC for its leadership in addressing the anticompetitive tactics that have distorted the balance struck by Hatch-Waxman. For the reasons discussed here, AAM urges the FTC to recognize the very different dynamics that exist between branded and generic drug business models and marketplaces, including the widespread use of abusive tactics by brand manufacturers, and adopt policies to enhance competition, prevent drug shortages and ensure both patient access and system savings.

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

[31] Andrew W. Mulcahy, Jakub P. Hlavka, Spencer R. Case, *Biosimilar Cost Savings in the United States: Initial Experience and Future Potential* (online at: https://www.rand.org/pubs/perspectives/PE264.html); ExpressScripts, *Biosimilars: Progress Today, Billions in Savings Tomorrow* (online at: http://lab.express-scripts.com/lab/insights/drug-options/biosimilars-progress-today-billions-in-savings-tomorrow).

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We look forward to continuing to work collaboratively with the commission to ensure that patients benefit from safe, effective and low-cost FDA-approved generic and biosimilar medicines at the earliest possible date.

Respectfully submitted,

Chester "Chip" Davis, Jr., J.D.
President and CEO

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