American Enterprise Institute for Public Policy Research

1789 Massachusetts Ave. NW | Washington, DC 20036

Maureen K. Ohlhausen
Acting Chairman
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

December 8, 2017

Re: Understanding Competition in U.S. Prescription Drug Markets: Entry and Supply Chain Dynamics

Dear Ms. Ohlhausen:

I am a resident fellow at the American Enterprise Institute, a public policy think tank in Washington, DC. Thank you for the opportunity to comment on the important goal of understanding competition, including market entry and supply chain dynamics, in U.S. prescription drug markets. The United States faces an increasingly sophisticated pharmaceutical marketplace, and it is vital that the FTC keep abreast of changing dynamics. I commend the Commission for organizing its November 8, 2017, workshop on this topic. I agree with the view you expressed at that meeting that the FTC and FDA should work in partnership on this matter, and I commend the FDA for its recent focus on ensuring a balance between innovation and access in administering the Hatch-Waxman amendments. This letter is based on comments I made at the July 18, 2017, public meeting that FDA held on the topic of balancing innovation and access, where I endorsed the FDA's periodic reevaluation of the appropriateness and effectiveness of innovation policies and competition policies.

It is my view that sound competition policy is not always in direct conflict with an innovation policy agenda. Just as Samsung spurs Apple to innovate better iPhone technology and Ford spurs GM innovation in the auto industry, the "threat" of either generic competition or a new competing brand drug can spur additional pharmaceutical innovation. For policymakers seeking a balance between innovation and competition, it is critical to recognize that this is not a zero-sum game.

In broad terms, public policy geared toward balancing innovation and competition has two objectives. On the one hand, innovators need appropriate protections over their intellectual property and from untimely market entry that will undermine their ability to recoup fixed investment costs. On the other hand, competitors must not be unduly hindered in their pursuit of delivering customers more choice in the marketplace. Over

time, changes with respect to marketplace dynamics across the supply chain means that the balance may shift even if the statutes remain constant. Moreover, new pricing strategies, new legal strategies, and other more fundamental changes in the cost of development and cost to manufacture products can result in a tilting of this balance. I would argue that, at the present moment, there is a need to rebalance regulatory policy toward the fair promotion of competition.

Before I offer specific recommendations to encourage competition in prescription drug markets, I would like to comment on one broader issue examined at the recent FTC workshop – that is, the alleged role of intermediaries in driving up drug prices. I urge the Commission to continue to exercise caution, as it has done, in taking action that would interfere with pharmacy benefit managers (PBMs), group purchasing organizations (GPOs), and other pharmaceutical supply chain intermediaries. Rightly or wrongly, drug pricing involves great complexity and opacity, and unintended consequences of broad-stroke interventions could be detrimental to consumer welfare. In addition, there are valid arguments to consider regarding the benefits and savings that GPOs and PBMs bring to consumers and payors.

With that said, the main point of my letter is that, in crafting policy to encourage competition, it is important to recognize that there are different types of competition among pharmaceuticals. Below, I offer a few suggestions for encouraging competition in each of these spheres.

Policy Recommendations for Encouraging Different Types of Drug Competition

Policies geared toward promoting competition must take into account that there are different types of competition in the pharmaceutical space, including:

1. Generic-to-brand competition, where generic drugs compete with their brand counterparts;
2. Generic-to-generic competition, where generics compete with each other;
3. Brand-to-brand competition, where brand drugs compete with other brands in the same drug class; and
4. Biologic-to-biosimilar competition, where biosimilars compete with their reference products.

My recommendations – which are by no means comprehensive – for improving competition in each of these arenas are targeted toward policy changes (statutory and regulatory) for the FDA. As I have written previously, though the FDA's primary role is ensuring the safety and efficacy of products, its actions (or inaction) can play a major role in encouraging or discouraging healthy competition.[1]

[1] Alex Brill, "How the Next FDA Commissioner Can Address Drug Prices by Promoting Drug Competition," April 2017.

1. **Recommendations for Generic-to-Brand Competition**

   - ***Stop the Use of REMS to Block Generic Entry.*** As you are well aware, the FDA sometimes requires REMS programs to ensure the safety of certain prescription drugs. Brand drug manufacturers have been accused of using REMS and other restricted access programs to block generic manufacturers' access to drug samples. According to my research, in 2016, the restricted access drug segment comprised 74 drugs with total sales of nearly $23 billion.[2] In a separate analysis, I estimated that there could be $5.4 billion in annual pharmaceutical savings if generics for forty drugs being restricted by REMS or REMS-like programs were allowed to come to market; of this, $1.8 billion would accrue to the federal government.[3]

   - ***Encourage ANDAs for Brand Products with Expired Patents.*** More than 200 brand drugs lack patent protection and exclusivity but do not have an approved generic competitor. I commend the FDA for releasing a list of these drugs to allow generic manufacturers to more easily identify these products. By removing some of the uncertainty about recouping development costs, a targeted period of generic exclusivity could encourage generic entry for certain brand products that lack patent protection and exclusivity.

2. **Recommendations for Generic-to-Generic Competition**

   - ***Encourage More ANDAs to Maximize the Competitive Market Dynamic.*** Research shows that when there are more than four generic manufacturers for a given product, prices decline significantly.[4] I commend the FDA for offering expedited review to ANDAs until three generics are available for a given product. I encourage policymakers to look closely into other ways to facilitate more robust competition in drug markets with few generic competitors.

3. **Recommendations for Brand-to-Brand Competition**

   - ***Dedicate More FDA Resources to Brand-to-Brand Competition.*** Existing expedited approval pathways for brand drugs favor products addressing unmet needs or offering significant clinical advancement. These are worthwhile objectives, but should not come at the expense of brand products that would compete directly with existing products. More resources for FDA to review NDAs that would be competitors to single-source drugs would be advisable.

---

[2] Alex Brill, "REMS and Restricted Distribution Programs: An Estimate of the Market," June 2017.
[3] Alex Brill, "Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry," July 2014.
[4] See, for example, David Reiffen and Michael R. Ward, "Generic Drug Industry Dynamics," *The Review of Economics and Statistics* 87, no. 1 (February 2005): 37–49.

4. Recommendations for Biosimilar-to-Biologic Competition

- ***Remove Superfluous Barriers to Entry for Biosimilars.*** As I have written previously, balancing incentives for innovation and competition in the biologic sphere is unique compared to traditional small-molecule drugs.[5] Biosimilar manufacturers have much higher R&D costs – and thus face much greater risk – than manufacturers of small-molecule generic drugs. In addition, regulatory and market constraints further limit the potential for biosimilar market share. In my estimation, only the largest biologics will attract biosimilar competition under current constraints.[6] In order to encourage robust competition among these typically high-priced products, it is important to keep regulatory barriers to entry at a minimum. The recent decision by the Centers for Medicare and Medicaid Services to give each biosimilar a separate billing code in Medicare Part B is an important step. Ending the misuse of REMS programs, as I discussed above, would be another move in the right direction. But there remain superfluous hurdles impeding biosimilar entry, including unnecessarily laborious requirements for biosimilars to prove interchangeability with a reference product.

Conclusion

The FTC has an active and critical impact on pharmaceutical competition and innovation. Inadequate incentives for innovation may deter new and efficacious products. But competition brings benefits of its own – not only by lowering prices, but also by encouraging additional pharmaceutical innovation. In the current environment, policymakers must make greater efforts to facilitate competition in order to right the balance that Hatch-Waxman intended to strike between competition and innovation.

Thank you for the opportunity to comment on this important issue. I would be happy to answer any questions. I can be reached at

Sincerely,

Alex Brill
Resident Fellow

[5] My research was cited extensively in the June 2009 FTC study on biosimilar competition, "Emerging Health Care Issues: Follow-on Biologic Drug Competition." See Alex Brill, "Proper Duration of Data Exclusivity for Generic Biologics: A Critique," November 2008.
[6] Alex Brill, "The Economic Viability of a U.S. Biosimilars Industry," February 2015.