National Business Group on Health®

20 F Street, NW, Suite 200
Washington, D.C. 20001
202.558.3000 • Fax 202.628.9244
www.businessgrouphealth.org

Creative Health Benefits Solutions for Today, Strong Policy for Tomorrow

December 8, 2017

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

Submitted electronically via: https://ftcpublic.commentworks.com/ftc/pharmaworkshop/

RE: Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics

Dear Chairman Ohlhausen:

The National Business Group on Health (the "Business Group" or NBGH) represents 421 primarily large employers, including 73 of the Fortune 100, who voluntarily provide group health and other employee benefits to over 55 million American employees, retirees, and their families. Being mostly self-funded, our employer members as well as many other employers, have a vested interest in more effective, efficient health care, including a competitive marketplace. They promote health plan designs that encourage delivery of the right care at the right time and in the right place; emphasize health promotion and primary and preventive care; improve value while reducing the cost of care; and, deliver services to the highest level of customer satisfaction.

We thank the Federal Trade Commission (FTC) for hosting the "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics" workshop on November 8, 2017. The issue of pharmaceutical pricing remains a top priority for the Business Group, as our members increasingly cite specialty medicines as the top driver of overall medical trend in health benefits spending. With that, we are pleased to see increased attention on this topic being paid by both the FTC and, recently, the Food and Drug Administration (FDA). We commend both bodies for taking a comprehensive look at the supply side through the lens of the generic drug market, pharmaceutical intermediaries, and group purchasing organizations. At a similarly focused meeting, the Business Group previously submitted testimony to the FDA earlier this year when the Administration held its hearing on "The Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access."[1]

To aid the Commission in its exploration of this important topic, our comments below are specific to the questions posed at the November 8, 2017 workshop, listed numerically. At a high-level, our comments urge the FTC to work in partnership with sister agencies and the Congress to:

[1] Hearing Testimony: U.S. Food & Drug Administration: The Hatch-Waxman Amendments: Ensuring A Balance Between Innovation And Access. Tuesday, July 18, 2017. Accessible via: https://www.fda.gov/downloads/Drugs/NewsEvents/UCM571419.pdf

- ***Eliminate or limit additive patent extensions and exclusivity periods that serve only to extend monopoly power, especially where there is limited or no additional company investment or patient value produced.***
- ***Develop sound policy that would discourage patent abuses such as "ever-greening" and "product hopping." These policies may include financial penalties, loss of exclusivity periods and/or reduced patent terms for other products.***
- ***Reduce the market exclusivity for biologics from 12 years to 7 years.***
- ***Diligently monitor pay-for-delay arrangements and take action where jurisdiction allows. The Commission should also urge the Congress to pass legislation that would ban pay-for-delay arrangements and thus, protect payers and consumers from these costly arrangements.***
- ***Urge Congress to pass legislation to prevent the misuse of REMS and restricted distribution schemes to delay generic drug competition.***
- ***Monitor consolidation across industry sectors by:***
    - ***Increasing scrutiny of consolidation within the PBM, retailer, wholesaler and distributor markets to better understand the impact such consolidation would have on drug pricing throughout the supply chain;***
    - ***Increasing scrutiny of vertical consolidation (hospital and health system) acquisition of physician practices, particularly as they affect access to and pricing of Part B medications;***
    - ***Lowering the threshold for mandatory reporting of planned transactions involving acquisition of provider practices, given that most of these transactions fall below the current threshold, particularly if the health system has more than a 30% or other appropriate percentage of the primary care market in a given service area; and,***
    - ***Increasing monitoring and evaluation of post-merger market impacts and strengthen enforcement actions where anti-competitive harms occur.***
- ***Increase the power of transparency tools by requiring that employers and consumers are given more straight-forward information about gross and net drug pricing, which would ultimately increase competition.***

1. **Do generic drug manufacturers have sufficient incentives to enter markets where the brand drug is off-patent? Do policymakers or market participants have a role in providing incentives to encourage entry decisions that better align with the public interest?**

   The Drug Price Competition and Patent Term Restoration Act (known as the "Hatch-Waxman Act") was crafted by Congress with competing goals in mind, to both 1) spur generic drugs to market, and 2) encourage brand drug development. The legislation provides a number of incentives for generic manufacturers to enter the market where the brand drug is off patent, including:

   - The ability to file an Abbreviated New Drug Application (ANDA);
   - A 180-day exclusivity period for the first-filed generic drug product;
   - A safe-harbor from infringement when performing testing for regulatory review;
   - The ability to file declaratory judgment actions to resolve potential patent disputes; and

- The ability to file a counterclaim to a patent infringement action seeking to de-list patents from the Orange Book.

However, the above noted incentives were included in Hatch-Waxman along with arguably equal incentives for brand preservation in the pharmaceutical market:

- A patent term extension based on the length of FDA's regulatory review;
- A definition of the scope of rights under the extended patent;
- Non-patent-based exclusivities;
- A mechanism for increasing the public notice of patents and patent challenges; and
- An automatic injunction precluding premature FDA approval of a generic drug.

Similar to the Hatch-Waxman Act, the Biologics Price Competition and Innovation Act (BPCIA) passed in 2010. The BPCIA established a pathway for the development of biosimilar drugs to compete with branded biologics – often specialty drugs – to introduce competition in the biologics market and thus, put downward pricing pressure on the expanding market of these complex and expensive drugs.

As Chairman Ohlhausen pointed out at the November 8 workshop, when a branded drug's patent expires, the first generic drug entry into the market generally offers a 20-30% discount, with subsequent entries lowering the price up to 85% or more. This data underscores the importance of ensuring that market forces are working and that there are no undue barriers that exist to prevent competition, which were foundational visions of the above noted pieces of legislation.

However, after a generic or biosimilar is approved by the FDA, in many cases, it may still take years for the cheaper versions come to market. This is largely because of litigation brought by the manufacturer of the original drug, based on outstanding legal questions about whether the patents can be extended through various secondary approvals for the original drug. For example, the original patent for Humira, a biologic used to treat various types of arthritis, Crohn's Disease and other ailments, was set to expire in 2016, but its manufacturer has indicated that it has add-on patent protection from 70+ ancillary patents, which can extend the patent through 2022, and potentially beyond. These claims, however, seem to be unsubstantiated following an evaluation of the Patent Application Information Retrieval (PAIR) database housed at the Patent Trademark Office (PTO).[2]

Why the discrepancy? Deciphering and understanding patent and exclusivity terms of pharmaceutical products is complicated because the two are intertwined and work in complementary, yet distinct, ways. And as these product protection terms have become increasingly important to market share and profitability, they are fiercely protected by the pharmaceutical industry, resulting in "patent estates," or "patent blockades," on top-grossing products.[3] These are multiple patents for one product, covering different indications, delivery

[2] Evaluation of image file wrapper for Humira, patent 08/599,226, at http://portal.uspto.gov/pair/PublicPair
[3] Stanton D. AbbVie: Humira's patent maze will keep US biosimilars away until at least 2022. BioPharma-Reportercom. 2015. http://www.
biopharma-reporter.com/Markets-Regulations/AbbVie-Humira-s-patent-maze-to-keep-US-biosimilars-at-bay-until-2022.

methods, and/or combinations of the product. Thus, coming to an accurate determination of when a patent term expires often requires specialized legal expertise. A publication by the Center for Drug Evaluation and Research (CDER), part of the FDA, states that "patent" and "exclusivity" are two of the most commonly searched terms on the FDA website,[4] which underscores both the complexity and value of these product protections to drug manufacturers, as well as interest from outside stakeholders.

In a nutshell, market exclusivity is driven by 1) monopoly rights awarded following the FDA's approval of a new drug product and 2) the patents associated with the product.[5] Thus, drug makers' ability to sustain high prices in the United States hinges on the monopolistic character of the pharmaceutical market, driven by these patent and exclusivity protections, which insulate products from competition and artificially boost the industry's negotiating power.[6]

Apart from the above statutory extensions, the life of a drug's overall patent protection can additionally be extended by applying for secondary patents through new formulations of the drug, new routes of administration, new indications, or uses of the drug in combination with another drug. NBGH agrees that an appropriate period of protection is essential to promoting investment in innovation and the discovery of new medicines, but we also believe a balance must be struck between both the right to enjoy the benefits as a creator of intellectual property and society's right to have affordable, adequate health and medical care. As mentioned previously, patents and exclusivity periods afforded to drug manufacturers by the PTO and the FDA are intended to reward innovators for their contributions. The expiration of patents theoretically yields generics and biosimilars, which benefit consumers.

Unfortunately, what we sometimes see is repeated and anticompetitive exploitation of the patent system, in which some drug makers game the process, thereby extending their monopoly market terms, which directly contributes to the unaffordable and unsustainable high-priced prescription drug market. While these practices do not in effect extend an original patent, they do create patent estates, which increase the probability of litigation between branded and generic manufacturers and permit the branded manufacturer to continue to promote its product. Additionally, building these patent estates tends to run in congruence with applications for additional market exclusivity from the FDA.

FDA Commissioner Gottlieb has discussed the FTC and FDA's shared goal of ensuring that consumers benefit from greater competition in the prescription drug market and has made commitment to explore exclusivity and patent abuses, and we commend both agencies for this collaborative work because there is a limit to what any single entity can do on its own. We further encourage both FTC and FDA to partner with the PTO and work with members of Congress to:

[4] Lal R. Patents and Exclusivity. CDER Small Business Chronicles.2015.
[5] Kesselheim AS, Avorn J, Sarpatwari A. The high cost of prescription drugs in the united states: Origins and prospects for reform. JAMA. 2016;
316(8):858-871.
[6] Ibid.

- ***Eliminate or limit additive patent extensions and exclusivity periods that serve only to extend monopoly power, especially where there is limited or no additional company investment or patient value produced.***
- ***Develop sound policy that would discourage patent abuses such as "ever-greening" and "product hopping." These policies may include financial penalties, loss of exclusivity periods and/or reduced patent terms for other products.***
- ***Reduce the market exclusivity for biologics from 12 years to 7 years.***

2. Some report strategies to reduce generic drug competition when the branded drug is off-patent. Are these reports accurate? If so, what steps are taken to reduce competition? If not, are there other reasons why generic entry is not seen as robust? What can be done?

The FTC itself has identified other strategies that exist to reduce generic drug competition. In addition to those outlined in the previous question/response related to Hatch-Waxman, the Business Group agrees with the FTC's identification of the following additional impediments to generic entry:

- Pay-for-delay deals; and
- Abuse of the Risk Evaluation and Mitigation Strategies (REMS) program through the FDA.

- We commend the FTC for prioritizing pay-for-delay deals, a costly legal tactic that some brand manufacturers have been using to delay market entry of lower-cost generic alternatives. According to one study, these anticompetitive deals cost consumers and taxpayers $3.5 billion in higher drug costs every year. ***We encourage the Commission to continue to diligently monitor pay-for-delay arrangements and take action where jurisdiction allows. The Commission should also urge the Congress to pass legislation that would ban pay-for-delay arrangements and thus, protect payers and consumers from these costly arrangements.***

Another 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 a restricted distribution system. The FDA is authorized to require REMS programs, which restrict distribution of certain pharmaceuticals in order to safeguard the public and prevent potential abuse or diversion. But, even if the FDA does not require REMS for a particular drug, the manufacturer can voluntarily adopt a restricted distribution policy using exclusive contracts with distributors or specialty pharmacies to limit access to the product.

Some branded manufacturers have used these restricted distribution programs to delay generic entry in two ways: by refusing to provide samples to the generic manufacturer, leaving it unable to perform the preclinical and clinical testing the FDA requires to establish that the generic version is biologically equivalent to the branded drug; or by preventing the generic from joining the existing REMS distribution system, so the FDA cannot approve the generic manufacturer's Abbreviated New Drug Application (ANDA).

One study estimates that Americans have lost $5.4 billion annually due to higher prices for prescription drugs because of REMS manipulation by branded drug companies.[7] ***We encourage FDA to take action limiting the ability for these rules to be gamed, and we commend FTC's engagement and encourage continued oversight of potentially anticompetitive actions. However, FDA or FTC cannot remedy this failure on their own. The agencies should also urge Congress to take action by passing legislation to prevent the misuse of REMS and restricted distribution schemes to delay generic drug competition.***

3. **What role do intermediaries, such as pharmacy benefit managers (PBMs) and group purchasing organizations (GPOs) play in prescription drug pricing, consumer access, and quality? What are the benefits and costs of intermediaries in the pharmaceutical supply chain? Has consolidation affected price, access, or quality?**

PBMs and GPOs play important roles in keeping prices low for prescription drugs and other health care services. However, the concentration of the PBM market – notably, the three largest PBMs have approximately 75% market share – has raised important antitrust and drug pricing concerns for large employers. Moreover, the 15 largest firms generated more than $270 billion in revenue in 2015 through retail and mail-order pharmacy, compared to $48 billion in revenue for independent pharmacies. As a related topic, the FTC should also consider other players within the supply chain and the impact that consolidation in those spaces has on drug pricing as well. For example, the three largest U.S. distribution companies account for more than 85% of the market share, with an estimated combined drug distribution revenues of $378 billion in 2015. As well, the top tier of dispensing pharmacies account for about 62% of U.S. prescription dispensing revenues in 2016.[8]

The financing and distribution of pharmaceuticals in the United States is complex, involving manufacturers, distributors, retailers, payers, pharmacy benefit managers, and, most importantly, patients. ***Given the substantial consolidation and vertical integration of many sectors of this system over the past decade, the FTC should:***

- ***Increase scrutiny of consolidation within the PBM, retailer, wholesaler and distributor markets to better understand the impact such consolidation would have on drug pricing throughout the supply chain;***
- ***Increase scrutiny of vertical consolidation (hospital and health system) acquisition of physician practices, particularly as they affect access to and pricing of Part B medications;***
- ***Lower the threshold for mandatory reporting of planned transactions involving acquisition of provider practices, given that most of these transactions fall below the current threshold, particularly if the health system has more than a 30% or other appropriate percentage of the primary care market in a given service area; and,***
- ***Increase monitoring and evaluation of post-merger market impacts and strengthen enforcement actions where anti-competitive harms occur.***

[7] 0 Brill, Alex, Lost Prescription Drug Savings from the Use of REMS Programs to Delay Market Entry, Matrix Global Advisors (July 2014).
[8] "The Top 15 U.S. Pharmacies of 2016." February 2, 2017. Accessed via http://www.drugchannels.net/2017/02/the-top-15-us-pharmacies-of-2016.html on November 30, 2017.

4. **How do companies assess the benefits, costs, and risks of contracting with intermediaries? How well do consumers understand intermediaries' roles? Is more information necessary?**

   At a high level, when contracting with intermediaries, Business Group members want to ensure that they are acting in the best interests of plan participants, as is legally required by the Employee Retirement Income Security Act of 1974 (ERISA); that services will integrate with existing plan design, administration, and goals; and that benefits and delivery match plan documents. From our perspective, consumers have very little insight into the role of intermediaries. For this reason, the Business Group has previously submitted comments to CMS to urge its continued implementation of transparency tools, to provide meaningful information on price and quality for beneficiaries.

   In that vein, we've argued that publicly disclosing information about the price and quality of care at the provider and facility levels will enable beneficiaries to use this information to make more informed decisions about healthcare and become better consumers of health care. ***Similarly, public disclosure of list prices and discounted/rebated prices is an important issue for the FTC to consider.*** At present, consumer tools to shop for health care are only as good as the data that power them. Tools are limited by insufficient, unclear and difficult-to-interpret data on the quality of providers and the prices they charge. Congruently, employers are equally handicapped in securing the best prices for their pharmacy benefit to employees, due to the lack of transparency in drug pricing and negotiated rebates that occur in back-room discussions with pharmaceutical manufacturers. ***The FTC can play a role in increasing the power of transparency tools by requiring that employers and consumers are given more straight-forward information about gross and net drug pricing, which would ultimately increase competition.***

5. **How should stakeholders evaluate proposals to reduce drug prices and increase consumer access in prescription drug markets? What role can the FTC play in addressing these issues?**

   While employers and other payers support policy changes that encourage market-oriented solutions for managing high-priced specialty drugs, we are equally sensitive to resisting the urge for quick fixes. As consumers find themselves paying more of their drug costs, it's tempting to be lured into new policies, which would only further contribute to the anticompetitive climate. These policies may include specialty drug price caps, out-of-pocket payment caps, limitations on utilization management tools and mandated disclosure of propriety information. These types of polices could induce various unintended consequences, including overpayments for mediocre drugs, drug shortages, making drugs less responsive to price, stifling innovation, undermining payer abilities to negotiate lower prices shifting higher prices to other payers, and raising premiums and health plan costs. More importantly, short-sighted approaches aimed only at immediate patient affordability miss the mark on establishing a long-term, sustainable pricing model.

   Ultimately, employers are seeking a more rational, transparent and market-oriented approach to drug pricing, which will require an assessment of and modifications to a dysfunctional pricing process that undermines competition and inflates drug expenditures. Stakeholders should evaluate proposals to reduce drug prices cautiously and focus on ensuring that market forces are working as intended. The FTC can assist in this process by ensuring that anticompetitive

practices are reduced or eliminated. Market forces and competition are remarkably effective at driving down prices. Government policies should facilitate and reinforce competition. When the do not, they need to be reexamined and modified. Specifically, where we see that the framework laid down by Hatch-Waxman is failing to deliver on its objectives, we need to understand the causes and implement appropriate policy responses, and there is arguably no entity better equipped to investigate this area than the FTC.

In closing, we commend the Commission for its efforts to focus on this important issue and to monitor a market where competition is fundamental to its sustainability. Please contact me or Steven Wojcik, the National Business Group on Health's Vice President of Public Policy, at (202) 558-3012, if you want to discuss our comments in further detail.

Sincerely,

Brian Marcotte
President and CEO