December 5, 2017

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

The Honorable Scott Gottlieb, M.D.
Commissioner
U.S. Food & Drug Administration (FDA)
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Federal Trade Commission Workshop on "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics"

Dear Acting Chairwoman Ohlhausen and Commissioner Gottlieb:

The American Pharmacists Association (APhA) is pleased to submit these comments to the FTC Workshop on "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics." We applaud the cooperation between the FTC and FDA to work together to increase competition, remove regulatory burdens that inhibit competition and increase patients' access to safe and affordable medications.

APhA, founded in 1852 as the American Pharmaceutical Association, represents 64,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians' offices, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

Congress intended to strike a balance between encouraging innovation in drug development and patient access to affordable alternatives to innovator drugs when it passed the *Drug Price Competition and Patent Term Restoration Act* of 1984, otherwise known as Hatch-Waxman Act.[1] Since the law passed, the pharmaceutical industry, FDA and United States health care system have evolved in many ways, including in the areas of drug development and patient safety efforts.[2] APhA believes components of FDA's current drug approval policies can be improved to better achieve Congress' intended goals related to the Hatch-Waxman Act.

I. REMS Programs

APhA has been made aware of concerns that manufacturers may be using Risk Evaluation and Mitigation Strategy (REMS) programs inappropriately to delay generic drug

[1] *See* H.R. Rep. No. 98-857 (Part I), 98th Cong, 2d Sess. At 14-15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647-48; see also, *e.g., Teva Pharmaceutical Industries Ltd.* v. *Crawford,* 410 F.3d 51, 54 (D.C. Cir. 2005)
[2] FDA. A Brief Overview of Risk Evaluation & Mitigation Strategies (REMS), available at: https://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM328784.pdf, last accessed: August 19, 2017.

development and marketing. Certain REMS programs' limited distribution requirements and patenting of REMS programs can make it more difficult for drug developers to bring generics to market. In 2007, the *Food and Drug Administration Amendments Act* (FDAA) gave FDA authority to require REMS from manufacturers to ensure the benefits of a drug or biological product outweigh its risks.[3] REMS programs vary by drug or class of drug to account for unique safety risks, and some drugs would not be able to be approved, or stay approved, unless a REMS with elements to assure safe use was required. APhA believes modifications to FDA's REMS policies and other solutions may need to be adopted to prevent REMS programs from serving as a barrier to generic drug development, without creating loopholes that may meaningfully detract from patient safety and clinical benefit.

II. Product Hopping

APhA also has concerns with the practice of product hopping or evergreening[4]—a brand-name company introducing minor changes to a drug's formulation to limit substitution and shift patients to the new drug before a generic comes to market. APhA opposes practices which circumvent the intent of drug product review laws and negatively impact the pharmacist's ability to substitute medications to safe, effective, lower-cost alternatives. APhA supports pharmacist collaboration with the prescriber and patient to design cost-effective treatment regimens or identify effective lower-cost alternative products or therapies.[5] Product hopping limits the effectiveness of these collaborations and pharmacists' efforts to optimize patient medications and cost-effectiveness. APhA encourages FTC and FDA to consider methods to prevent or discourage drug sponsors from engaging in such activity and consider alternative policies to better utilize pharmacists to limit the impact of product hopping and other practices that circumvent the intent of the Hatch-Waxman Act.

III. Biological Products

APhA believes it is equally important to balance innovation and access for biological products, including interchangeable biosimilars. As FDA is aware, there has yet to be an interchangeable biosimilar approved in the United States. Many states have passed legislation allowing the pharmacist to substitute interchangeable biosimilars independently. APhA encourages FDA to develop and implement a framework for determining biologic product interchangeability and continue to update the Purple Book to serve as a comprehensive resource for providers for approved biologic products and their interchangeability.

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[3] *See* Food and Drug Administration, FDA Basics Webinar: A Brief Overview of Risk Evaluation and Mitigation Strategies (REMS), available at: https://www.fda.gov/AboutFDA/Transparency/Basics/ucm325201.htm, last updated July 27, 2017, last accessed September 1, 2017.

[4] *See* Brief for the FTC as Amicus Curiae, Mylan Pharmaceuticals, Inc. v. Warner Chilcott plc, et al. U.S. 3d Cir. (2016), describing a typical product-hopping scheme, "A brand-name pharmaceutical company expects generic rivals to win FDA approval to compete with the company's profitable brand-name drug using automatically substitutable AB-rated equivalents. To thwart such substitution, the brand-name company introduces minor changes to the drug's formulation, such as therapeutically insignificant tweaks to dosage levels or to the form of administration (e.g., capsules vs. tablets). Before generic equivalents have a change to enter, the brand-name manufacturer then takes various steps to extinguish demand for the original version… The shift in prescriptions is generally a one-way street: once doctors prescribe a medicine and find that it works, they are generally reluctant to switch users back to the original formulation even if a cheaper generic version of it later becomes available."

IV. Impact of Limited Distribution Requirements on Pharmacies and Patients

APhA also believes limited distribution at the pharmacy level, including that associated with REMS programs and manufacturer-imposed policies, may have additional negative impacts on the patient and create an unfair playing field for supply chain stakeholders. As more costly and complex medications are being developed, some manufacturers, clinics, practitioners' offices and pharmacies have entered into contracts that effectively limit retail or community pharmacy distribution of certain medications, even if a specialty pharmacy or other entity is willing to meet manufacturer imposed standards to enable distribution. Accordingly, APhA is concerned limited distribution policies are used to restrict the number of entities providing certain medications which may effectively dictate the pharmacy the patient attends and ultimately, limit patient access and choice. In addition, APhA is concerned limited distribution requirements also increase the cost of care by forcing patients to attend multiple pharmacies which deprives patients the benefits of a strong pharmacist-patient relationship, such as improved medication adherence. Accordingly, APhA encourages FTC to examine the consequences of limited distribution requirements to determine whether these practices limit competition and harm consumers.

V. Drug Pricing and Other Supply Chain Impacts

As noted by the FTC, "Generic drugs play an important role in disciplining drug pricing and controlling drug costs."[5] Because the Hatch-Waxman Act encourages greater access to generic drugs and pharmaceutical innovation, drug pricing and costs to patients is directly impacted by policy changes related to Hatch-Waxman. Therefore, FDA should consider these factors when evaluating new policies related to innovation and access.

APhA has also encouraged state- and federal-level agencies, like the Centers for Medicare and Medicaid Services (CMS) and FDA, when considering policy changes, to look beyond isolated components of health care to determine cost and value. Policies cannot continue to consider drug and medical coverage, and their related costs and outcomes, separately if we are to achieve true value in health care. Current policies related to prescription drugs place incentives on the short-term, focusing on cost containment for the product rather than weighing the overall clinical benefit to the patient and the impact to their medical costs. Breaking down the many silos within our health care system will help address that $300 billion dollars spent on medication-related problems—many of which are preventable.[6]

Decisions along the entire drug supply chain impact patients' medication costs and affect competition, including arrangements between manufacturers, wholesalers, insurers, and pharmacy benefit managers, or PBMs. For example, intermediaries, such as PBMs, frequently use post point-of-sale fees, known as retroactive Direct and Indirect Remuneration (DIR) fees, which are often assessed weeks or even months after a prescription has been filled and prevent pharmacies from knowing at the time of dispensing what their actual reimbursement will be for a

[5] Federal Trade Commission Bureau of Economics (2013). The Effect of Generic Drug Competition on Generic Drug Prices During the Hatch-Waxman 180-Day Exclusivity Period, available at: https://www.ftc.gov/sites/default/files/documents/reports/estimating-effect-entry-generic-drug-prices-using-hatch-waxman-exclusivity/wp317.pdf, last accessed: September 13, 2017.

[6] NEHI. Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Adherence for Chronic Disease. *August 2009. Available at:* http://www.nehi.net/writable/publication_files/file/pa_issue_brief_final.pdf

product. CMS has acknowledged a notable growth in DIR fees, which have more than tripled in recent years.[7] These policies generally result in higher prices at point of sale which result in the beneficiary paying more because cost-sharing is based on sales prices and such hidden arrangements negatively impact competition. In addition, APhA is concerned with the inability of pharmacies to enter into contracts with health plans due to the growth of narrow networks. We encourage FDA and FTC to work with CMS to look broadly at policies which negatively impact competition and artificially inflate patient drug costs.

Thank you for your leadership and work on this issue. APhA urges our federal agencies to focus on increasing competition and access to generic medications as part of a larger strategy to improve patients' health care. We look forward to supporting FTC's and FDA's efforts and working to improve patients' access to affordable and safe medications. If you have any questions please contact, Michael Baxter, Director, Regulatory Affairs, by email mbaxter@aphanet.org or phone (202) 429-7538.

Sincerely,

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

cc: Stacie Maass, BSPharm, JD, Senior Vice President, Pharmacy Practice and Government Affairs

[7] *See,* Wakely Consulting Group analysis of S. 413/H.R. 1038. 2017. Available at: http://www.ncpa.co/pdf/wakely-report.pdf