Waxman

MEMORANDUM

DATE: December 7, 2017

TO: Acting Chairman Maureen K. Ohlhausen, Federal Trade Commission

FROM: Former Congressman Henry Waxman, Chairman of Waxman Strategies

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

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Dear Acting Chairman Ohlhausen,

Thank you for the opportunity to allow the public to submit ideas on how to facilitate increased competition in the pharmaceutical drug market, and in doing so, to better balance innovation in drug development with increased patient access to affordable drugs. I applaud your leadership in hosting the Federal Trade Commission's (FTC) workshop to better understand competition and the obstacles in generic drug markets, pharmaceutical supply chains, and contractual relationships between manufacturers and various intermediaries. During the workshop, you heard how the high price of prescription drugs affects patients every day, often leaving them without access to the medicines they need, and there was a great discussion around how we can improve the policies set several decades ago.

As an author of the Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the Hatch-Waxman Act), I am deeply concerned about Americans' access to affordable prescription drugs. The intent of the Hatch-Waxman Act was to achieve a balance between innovation in pharmaceutical development and price competition. The legislation achieved that goal. However, for several reasons, including regulatory "gaming" and misuse by various brand name manufacturers, the balance of incentives and competition has become distorted over time. The workshop highlighted several examples of this. Further, the Food and Drug Administration (FDA) Commissioner Gottlieb cautioned the industry against the "shenanigans" of the misuse of FDA-approved Risk Evaluation and Mitigation Strategies (REMS) to delay or defeat generic entry efforts. Further, he cautioned brand name manufacturers not to delay or defeat generic entry by using private distribution restrictions in their commercial contracts, which make it hard for wholesalers in the drug supply chain to sell the drugs to generic manufacturers working to develop a generic version of the drug.

I would like to bring to your attention a recently published report, *Getting to the Root of High Prescription Drug Prices,* that my team and I wrote with support from the Commonwealth Fund and the Laura and John Arnold Foundation in partnership with the Johns Hopkins Bloomberg School of Public Health. Our report

identifies the many problems and drivers of high prescription drug prices and the actions that could restore the balance between innovation and vigorous price competition. Specifically, from the supply side factors, our report describes the barriers that impede robust generic and biosimilar entry and the potential actions federal agencies and this Administration could take to lift those barriers and encourage greater competition in prescription drug and biologic markets. Here are some of those actions:

- Require brand name manufacturers to make their approved drug product available to generic and biosimilar manufacturers seeking to submit applications to FDA. Prohibit any REMS or limited distribution network for the brand name drug from being used to block such access.

- Require federal agencies, including the FDA, FTC, and the DOJ to proactively monitor, assess, and report on how the pharmaceutical markets are performing, including identifying anticompetitive behaviors, concentrated markets, and other conditions that lead to significant increases in price. FDA should proactively conduct monitoring in regular coordination with the FTC and DOJ as they monitor for potential anti-competitive behavior. As highlighted at the workshop by some of the panelists, this type of increased market monitoring should address issues related to vertical and horizontal consolidation and encompass monitoring of manufacturers, various intermediaries, and any relationships among those intermediaries that lead to anti-competitive practices.

Furthermore, looking at demand-side factors, our report included a few other actions, including:

- Eliminate practices that obscure pricing to patients and encourage industry to engage in more straightforward, front end-discounts and open-pricing practices. The use of non-transparent, backend rebates and consumer coupons provided by manufacturers and intermediaries could be disfavored and eliminated through Administration regulations prohibiting the use of coupons and rebates in Medicare and Medicaid. The use of rebates between manufacturers and intermediaries should also be discontinued, and replaced by upfront discounts. Recently the Department of Health and Human Services (HHS) published a proposed rule in November 2017 (CMS-4182-P) that requests information on potential policy approaches for applying some manufacturer rebates and all pharmacy price concessions to the price of a drug at the point of sale in Medicare Part D. Addressing the driver of high drug prices, such as anti-competitive practices, is key, but we should also focus on reducing the impact of high drug prices on patients. Approaches like the one in the HHS proposed rule can shine light on obscure pricing practices, reduce out-of-pocket burdens for patients, and save the Federal government money.

The report also includes other actions that could be taken to ensure greater price competition and that require new authority to be implemented. The full report follows this cover note. I am encouraged by the open dialogue you are promoting on this issue and hope that the FTC will take into consideration what is outlined in our report as you move forward.

A pharmaceutical drug market is most efficient when appropriate incentives for innovation are balanced with vigorous price competition. U.S. prescription drug pricing over the past decade reflects a distortion of the policies enacted by Congress to balance innovation and price competition and to enable access to affordable medicine. Policymakers, such as yourself, can establish a more efficient and effective pharmaceutical market that functions to meet the needs of all stakeholders: patients and consumers, public and private health care purchasers, health care providers, and the pharmaceutical industry. While the discovery and development of innovative medicines is one cornerstone of the U.S. health care system, it should not be at a price that leaves patients without access.

We hope to continue our conversations with you, your staff, and other federal agencies involved in this difficult issue resolving the imbalances that affecting competition in the prescription drug and biologic markets, as well as the issues that impact drug pricing overall.

Regards,

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