

December 8, 2017

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

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

Dear Acting Chairman Ohlhausen:

The Academy of Managed Care Pharmacy (AMCP) thanks the Federal Trade Commission (FTC) for the opportunity to provide comments in response to the request for comments titled “*Understanding Competition in U.S. Prescription Drug Markets: Entry and Supply Chain Dynamics*” released on October 18, 2017. The introduction of generic medications in the United States marketplace has saved the United States healthcare industry billions of dollars in annual expenditures, estimated at \$253 billion in 2016 alone, and \$1.67 trillion over a ten year period from 2007- 2016.<sup>1</sup> AMCP recognizes the importance of maintaining the balance between innovation and access, and supports the implementation of a robust generics pathway and competitive generics marketplace to ensure that Americans continue to receive access to safe, effective, and affordable generic medications.

AMCP is the nation’s leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of health care dollars. Through evidence- and value-based strategies and practices, the Academy’s 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

The Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act,” P.L. 98-417) streamlined the process by which the FDA approved generic versions of brand name medications and in many cases expedited the introduction of generic medications in the marketplace. However, certain provisions of the law are susceptible to strategies that can delay the entry of generic medications into the marketplace for reasons other than safety and efficacy. While AMCP realizes that appropriate incentives must be retained in order for

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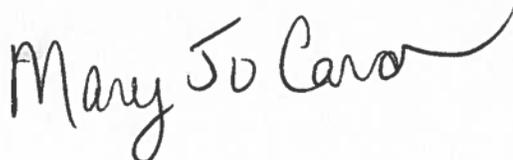
<sup>1</sup> Association for Accessible Medicines, 2016 Generic Drug Savings & Access in the United States Report, June 8, 2017.

brand name manufacturers to recoup their investment in research and development of brand name medications, the use of strategies that can unnecessarily delay the entry of generic medications into the marketplace for reasons other than safety and efficacy must be prohibited. AMCP supports efforts to prohibit patent settlement agreements between brand name and generic manufacturers that result in the generic manufacturer delaying market entry of a generic drug, as well as authorized generics, which are intended to discourage generic competition. AMCP believes these strategies must be addressed in order to streamline the generic approval process and allow patients greater access to generic medications.

AMCP requests an opportunity to meet with FTC leadership to further discuss potential solutions to ensure a competitive generic marketplace in the United States, as well as strategies for ensuring a competitive biosimilars marketplace.

AMCP appreciates your consideration of the concerns outlined above and looks forward to meeting with FTC leadership to discuss potential solutions and strategies to address these issues. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-684-2603 or [mcarden@amcp.org](mailto:mcarden@amcp.org).

Sincerely,

A handwritten signature in black ink that reads "Mary Jo Carden". The signature is written in a cursive, flowing style.

Mary Jo Carden, RPh, JD

Vice President of Government and Pharmacy Affairs