

September 18, 2017

Food and Drug Administration
Dockets Management Staff (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

***Re: Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access
[Docket No. FDA-2017-N-3615]***

Dear Sir or Madam:

The Academy of Managed Care Pharmacy (AMCP) thanks the Food and Drug Administration (FDA) for the opportunity to provide comments in response to the request for comments titled “*Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access [Docket No. FDA-2017-N-3615]*” as published in the *Federal Register* on June 22, 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- 2016.¹ 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

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

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 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. Furthermore, AMCP supports Congressional efforts, such as H.R. 2212 – The Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act, to give the FDA more authority to address abuses with the Risk Evaluation and Mitigation Strategy (REMS) system that result in the delay of market entry for generic medications.

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with FDA. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-684-2600 or scantrell@amcp.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Susan Cantrell". The signature is fluid and cursive, with a long horizontal stroke extending from the end.

Susan A. Cantrell, RPh, CAE
Chief Executive Officer