AMCP Academy of Managed Care Pharmacy®

August 12, 2014

The Honorable Margaret Hamburg
Administrator
Food and Drug Administration
Division of Dockets Management (HFA-305)
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Comments on Docket No. FDA-2014-D-0234: *Draft Guidance for Industry on Clinical Pharmacy Data to Support a Demonstration of Biosimilarity to a Reference Product*

Dear Administrator Hamburg:

The Academy of Managed Care Pharmacy (AMCP) appreciates the Food and Drug Administration's (FDA) release of its *Draft Guidance for Industry on Clinical Pharmacy Data to Support a Demonstration of Biosimilarity to a Reference Products* and the opportunity to provide comments on this issue. AMCP supports the development of a robust pathway using scientific and clinical data to ensure that Americans receive access to cost effective and affordable biologics, including biosimilars and interchangeable biosimilars that demonstrate safety, purity, and potency in comparison to the innovator product. To achieve this goal, FDA must apply consistent regulatory standards in the development of biosimilar agents.

AMCP is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's nearly 7,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

In regard to the specific requirements for pharmacokinetic (PK) and pharmacodynamic (PD) studies necessary to demonstrate biosimilarity to a reference product, AMCP recommends that FDA carefully review comments submitted by potential manufacturers of biosimilar products, scientists, and clinicians who provide specific recommendations regarding the information presented. Then, FDA should update and finalize the guidance to provide clear regulatory standards that also allows manufacturers to provide scientific justifications for their approach.

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As a policy matter, AMCP recommends that FDA provide information and data related to the biosimilar approval process, including PK and PD studies, on its public website. Access to this information will allow for proper analysis by health care providers, including managed care pharmacy decision makers, clinical and scientific researchers, and consumers to assess biosimilars for appropriate use. It is also critical for states to have access to this information because they are enacting legislation and adopting regulations on biosimilars.

Thank you again for the opportunity for the public to submit comments in response to this draft guidance and other documents related to creation of the pathway necessary for biosimilar adoption. AMCP looks forward to working with FDA and other stakeholders in ensuring that Americans have access to safe and effective biosimilar products. If you have questions or require additional information from AMCP please contact Lauren Fuller, Vice President of Government Affairs at 703-684-2625 or lfuller@amcp.org.

Sincerely,

Edith Rosato, RPh, IOM
Chief Executive Officer