



Academy of
Managed Care
Pharmacy®

**Food and Drug Administration Oncologic Drugs Advisory Committee Meeting
FDA-2017-N-1063**

May 25, 2017

**Remarks by Academy of Managed Care Pharmacy
Mary Jo Carden, RPh, JD
Vice President, Government and Pharmacy Affairs**

Good morning, I am Mary Jo Carden, Vice President of Government and Pharmacy Affairs at the Academy of Managed Care Pharmacy. I thank you for the opportunity to present AMCP's perspective on the biosimilar pathway. 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.

AMCP supports the implementation of a robust biosimilars pathway to ensure that Americans continue to receive access to safe, effective, and affordable biologics and biosimilars. AMCP has been working extensively with the Food and Drug Administration and other stakeholders on federal and state legislation and regulations that impact the biosimilars pathway. Recently, AMCP has made biosimilars education for health care providers a key priority. AMCP applauds the FDA for releasing draft guidance on interchangeability, and has finalized guidance on naming and labeling. While we continue to have concerns with some provisions in the draft and final guidance documents, AMCP is generally pleased that FDA has provided additional clarity on the implementation of the biosimilars pathway.

AMCP generally supports the flexible, step-wise, and totality of the evidence approach to demonstrating interchangeability. AMCP also commends the FDA for not being too prescriptive and for recognizing that a one-size-fits-all approach is not feasible, given the complexity of biological and biosimilar products. In comments, AMCP noted several factors that should be considered by FDA before finalizing the guidance. AMCP supports the ability of applicants seeking interchangeable designation to use switching studies for non-U.S.-licensed reference products. There is no scientifically justifiable distinction between reference products acquired in the United States and those licensed in other comparable markets. AMCP encourages FDA to align the final interchangeability guidance with existing requirements for reference products, which permit the use of non-U.S. licensed reference product when a bridging study to the U.S. product exists.

AMCP also urges the FDA to consider the following issues as it finalizes the interchangeability guidance:

- Whether new or expanded indications for a reference product would also be considered interchangeable—including the manner in which the labels will be harmonized;
- Naming of interchangeable biologic products;
- Possibility of interchangeability from biosimilar to biosimilar; and,
- Whether “follow-on” products approved under the 505 pathway will be considered interchangeable or biosimilars when incorporated into 351(k) pathway.

AMCP is pleased that the draft interchangeability guidance included the possibility of using postmarketing surveillance and pharmacovigilance for purposes of making interchangeability determinations. AMCP has taken a proactive approach to pharmacovigilance; for example, the AMCP Biologics and Biosimilars Collective Intelligence Consortium (BBCIC), proactively monitors both biologics and biosimilars using data from distributed research networks for millions of de-identified patients. BBCIC research protocols are currently in progress and initial research findings are anticipated to be presented in the fall of 2017. BBCIC will serve as a valuable resource to address important questions about the use, impact, safety, and clinical effectiveness of biologics and biosimilars on human health.

The final guidance documents for naming and labeling have helped provide additional clarity on the requirements of the biosimilars pathway. Although AMCP is concerned about the final naming guidance’s use of a randomized 4-letter suffix for all biologics and biosimilars, AMCP does support the use of a shared nonproprietary name for biosimilars, reference biologics and interchangeable biologic products—as well as a requirement to use the National Drug Code on all claims to identify product, lot number, and package size. AMCP believes that the use of the random four-letter suffix does not ensure easy product identification. Rather the suffix adds an additional unnecessary data element that a) may result in medication errors because of transcription errors in databases associated with the additional characters added by the suffix, and b) may lead to disincentives to use certain biosimilars of reference products because they appear unrelated to each other.

Last but not least, AMCP has made a significant commitment to educating health care providers, including pharmacists, physicians and nurses. In 2016, AMCP launched the Biosimilars Resource Center (www.biosimilarsresourcecenter.org), to provide an unbiased, policy-neutral repository of educational resources and information on biosimilars. AMCP is joined in these efforts by the American Association of Colleges of Pharmacy, America’s Health Insurance Plans, the American Pharmacists Association, the American Society of Consultant Pharmacists, the Hematology/Oncology Pharmacists Association, the National Alliance of State Pharmacy Associations, and the National Community Pharmacists Association. AMCP believes that in addition to robust pathway to facilitate the adoption of biosimilars in the United States, education

of health care providers and consumers is equally as important. AMCP also supports FDA's initiatives on biosimilars education.

Thank you again for this opportunity. AMCP looks forward to continuing its work with FDA and other stakeholders on implementing the biosimilars pathway and providing education to stakeholders.