

February 4, 2016

Rep. Joe Pitts (R-PA)
Chairman
Subcommittee on Health
Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

Rep. Gene Green (D-TX)
Ranking Member
Subcommittee on Health
Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

Re: Examining Implementation of the Biologics Price Competition and Innovation Act

Dear Chairman Pitts and Ranking Member Green:

The Academy of Managed Care Pharmacy (AMCP) appreciates the opportunity to submit comments for the record on the hearing titled “Examining Implementation of the Biologics Price Competition and Innovation Act” scheduled for February 4, 2016. AMCP supports an expedited approval process for biosimilars that encourages innovation and balances the public’s interest in ensuring safety, efficacy and affordability because of the potential for biosimilars to be an important tool for bending the health care cost curve without compromising quality. AMCP supports provisions in the *Biologics Price Competition and Innovation Act* (BPCIA) which established a new abbreviated licensure pathway at the Food and Drug Administration (FDA) for biological products determined to be “biosimilar to” or “interchangeable with” previously licensed biologics. AMCP believes that adoption and access of biosimilar products is critical in the United States to improve patient outcomes and decrease overall health care costs, however, remains concerned about the ability of biosimilars to reach their full potential in the United States because of incomplete guidance from the FDA, confusing federal and state regulatory guidance, and lack of clarity related to payment, coding, and reimbursement. AMCP urges Congress to use its oversight authority to direct FDA and the Department of Health and Human Services (HHS) to finalize and harmonize guidance documents and proposed rules related to the biosimilars pathway, including release of guidance documents for interchangeability and labeling. Furthermore, Congress should allocate funding for FDA to provide education and information related to biosimilars directed to consumers, health care providers, payers, and other stakeholders.

AMCP is a professional association of pharmacists and other practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's 8,000 members develop and provide a diversified range of clinical, educational, medication and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

Biologics play an increasingly important role in the US health care system, particularly for the prevention, treatment and cure of otherwise incurable or complex diseases. It is important for the biosimilars approval process to support an appropriate balance between bringing safe and effective drugs to market and maximizing patient access to affordable drugs. The regulatory process must be designed to rigorously examine the safety and efficacy of a biosimilar application, but not prove so burdensome in either the length of time required for review or in added costs for the manufacturer seeking the biosimilar license that manufacturers are discouraged from filing for approval. To this end, the FDA should determine on a case-by-case basis whether to require additional clinical studies prior to approval, as well as any post-marketing studies to be conducted after approval.

AMCP supports the use of the same international nonproprietary name (INN) for reference products and biosimilars. The INN has proven safe and effective globally for small molecule drugs and for biologic products in Europe, and therefore it should be the standard in the United States. AMCP is concerned that any departure from the currently accepted nonproprietary naming system will create confusion among healthcare practitioners and patients, have negative effects on the ability to ensure safe dispensing and tracking, and result in lower market adoption and cost-savings. AMCP urges Congress to require FDA to re-examine its current naming guidance and proposed rule to determine whether a hyphenated suffix attached to the INN for all biologics and biosimilars helps to ensure safety and is not an additional piece of data that will create more confusion for consumers, health care providers, and payers and thus lead to medication dispensing errors. After FDA examines and provides appropriate information, it must finalize its naming guidance as soon as possible to provide certainty to applicants pursuing approval of biosimilars.

One biosimilar is currently available in the United States and FDA will consider another application on February 9, 2016. Therefore, the time is now for FDA to finalize guidance documents to provide feedback and information related to designation of a biosimilar product as interchangeable with the reference product and labeling requirements for biosimilars.

In regard to interchangeability, the BPCIA states that “interchangeable products may be substituted for the reference product without the intervention of the prescribing healthcare provider.” (*Public Health Service Act* § 351(i)(3)). This section clearly states that the intent of Congress is to allow pharmacists to substitute interchangeable products without additional intervention by the prescriber. FDA’s guidance on interchangeability should clarify the meaning of that provision and discourage states from limiting the ability of pharmacists to automatically substitute interchangeable products.

The approval of biosimilars should occur with the knowledge that post-marketing surveillance systems are available to monitor safety and efficacy in large populations. These reporting systems will supplement the voluntary reporting systems, but minimize the unknown bias that exists with such voluntary reporting systems. AMCP believes that performing diligent pharmacovigilance for biological products post-marketing is vital and can be accomplished through the continued use of existing mechanisms, including utilizing identifying factors such as manufacturer name, national drug code, and lot numbers. AMCP has taken a proactive approach to pharmacovigilance and has launched a significant nationwide initiative to proactively monitor both biologics and biosimilars using data from millions of de-identified patients. AMCP’s approach for active post-marketing surveillance should be encouraged through funding contained in legislation such as the *Biosimilar User Fee Act* (BsUFA).

AMCP is also actively engaged in providing education to health care providers, payers, consumers, and other stakeholders about scientific, clinical, and legislative and regulatory issues impacting biologics and biosimilars targeted to many levels of understanding. These educational efforts are critical to the success of biosimilars in the United States. Therefore, BsUFA and other legislative efforts should include funding for FDA and other public and private stakeholders to provide education about biologics and biosimilars.

AMCP thanks the Subcommittee on Health for its work in examining the implementation of the BPCIA and looks forward to continuing work on this issue with the committee. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-683-8416 or mcarden@amcp.org.

Sincerely,

A handwritten signature in cursive script that reads "Mary Jo Carden". The signature is written in black ink and is positioned above the typed name.

Mary Jo Carden, RPh, JD
Vice President of Government and Pharmacy Affairs