AMCP Academy of Managed Care Pharmacy®

July 8, 2014

Ms. Jennifer Horne
Associate Director of Policy
The Council of State Governments
2760 Research Park Drive
Lexington, KY 40511

RE: Consideration of Biosimilar Legislation on the August Docket of the Committee on Suggested State Legislation

Dear Ms. Horne:

The Academy of Managed Care Pharmacy (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 more than 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.

As you know, biologic products are already playing an important role in today's health care system, both in terms of scientific improvements in the treatment of disease and in increased drug costs. The high costs of many of these products threaten patient access to important therapies and place a strain on payers trying to manage prescription drug spending. Since the introduction of biosimilars in 2006, the European Union has experienced an average price reduction of 30 percent for products with competition from biosimilars, and it is reasonable to expect a similar impact in the United States.

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) became law in March 2010. The BPCIA established an abbreviated approval pathway for biosimilars and interchangeable biologics. AMCP was supportive of the expedited approval process for biosimilar products because we believed that it would provide a needed incentive for the development of new therapeutic products that hold the promise of preventing, treating or curing otherwise inevitable, untreatable and incurable diseases. Since 2012, the U.S. Food and Drug Administration (FDA) has issued 5 Draft Guidances focused on Biosimilarity and one (1) Draft Guidance on proprietary names that will also have an impact on biosimilars:

- Guidance for Industry on Biosimilars: Q&As Regarding Implementation of the BPCI Act of 2009 (issued 02/09/12)
- Scientific Considerations in Demonstrating Biosimilarity to a Reference Product (Issued 02/09/12)
- Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product (Issued 02/09/12)
- Formal Meetings between the FDA and Biosimilar Biologic Product Sponsors or Applicants (Issued 03/29/13)
- Demonstration of Biosimilarity to a Reference Product (Issued 05/13/14)
- Guidance for Industry – Best Practices in Developing Proprietary Names for Drugs (Issued 05/29/14)

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However, to date, the FDA has not adopted any Guidance, nor has the FDA approved a biosimilar. In fact, there has been no confirmation from the FDA that a biosimilar application has even been filed.

On another front, the Federal Trade Commission (FTC) held a Follow-On Biologics Workshop in February 2014 on the Impact of Recent Legislative and Regulatory Naming Proposals on Competition. The FTC is considering, among other things, how the state laws and regulatory proposals will affect competition expected to develop between biosimilar or interchangeable biologicals and reference biologics and what the potential is for different state laws regulating follow on biologics to affect the prospects for the development of follow on biologics. The public comment period has closed, and the FTC is in the process of preparing its report for release.

On the state legislative front, AMCP has also been very involved in advocating against the enactment of state legislation as it is our belief that at this time, given the lack of FDA approved guidance, that such legislation is premature. Until those guidelines are finalized, there is no way to know if additional steps are warranted by states prior to the substitution of a biosimilar or use of an interchangeable product.

AMCP supports:

- the FDA's pathway as the mechanism to assure that safe drugs are permitted in the marketplace;
- the ability of prescribers to ensure that they are selecting the best medication for their patients and, if they are unsure about a medication, to prohibit substitution which is currently the law in all states;
- the ability of a pharmacist to rely on the FDA's determination of interchangeability;
- the patient's ability to select a biosimilar without the government legislating additional requirements not applied to other prescription selections; and
- the ability of employers, health plans and other payers to provide cost savings to their members by making available FDA approved biosimilar or interchangeable drugs.

In addition to being premature, AMCP has found state legislative laws and proposals that in some cases define the terms "biosimilar," "interchangeable," and "biologic" differently than the FDA, place undue administrative burdens on pharmacists by requiring additional patient notification prior to dispensing, and that require prescriber notification within a certain period of time following dispensing, and, for the most part, neither notification requirements are required for any other category of drug dispensed. However, our greatest concern is shared with an FDA spokesperson who stated that "efforts to undermine trust in these products are worrisome and represent a disservice to patients who could benefit from these lower cost treatments." We believe that the additional notification requirements are designed to make patients, without cause, question the safety of these prescriptions.

For these reasons, AMCP believes that this legislation will discourage substitution, which only benefits those entities offering more costly biologic drugs and, conversely, potentially increases medication costs to patients and payers, thereby, threatening patient access to more affordable

medications. The legislation does not recognize the value that biosimilars offer to patients and payers by enhancing access to safe and lower cost medications.

In closing, AMCP is aware that the Suggested State Legislation Committee deferred the discussion of biosimilar legislation from your May meeting to the upcoming August meeting. AMCP urges you to defer discussion until the FDA has finalized the regulatory guidance for submission of these products, including the naming issue. Thank you for the opportunity to share our views with you on this important issue. If you have any questions, you may contact AMCP Vice President of Government Affairs, Lauren Fuller, at (703) 683-8416 or lfuller@amcp.org.

Sincerely,

Edith A. Rosato, R.Ph., IOM
Chief Executive Officer