MEDICAL MUTUAL®

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2014 OCT -6 P 1:12

October 3, 2014

Sandra Benton
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Electronically delivered: http://www.regulations.gov
Reference: Docket No. FDA-2013-D-1165

To the Food and Drug Administration:

Medical Mutual appreciates the opportunity to provide comments on "Guidance for Industry Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act" published in the Federal Register on August 4, 2014.

Medical Mutual is a mutual company that provides life and health insurance, including prescription drug benefits, to approximately 1.6M members in the State of Ohio. In 2013, Medical Mutual's drug spend of medications accessed through the medical and prescription drug benefits approached $1B. We anticipate our drug spend to increase with the growing availability and utilization of specialty drugs, which currently has limited marketplace competition and utilization management tools. As a mutual company, we have a fiduciary responsibility to protect and optimize the use of our members' healthcare dollars. The increase in biosimilars' availability and interchangeability to the reference brand biologic is critical to meeting our fiduciary responsibilities.

The FDA is in a unique position to shape the future of medicine. Your decisions toward the development of a biosimilar review pathway can positively influence the marketplace by ***increasing*** **access** to these medically necessary specialty drugs and **competition**, which is needed to help reduce the costs of these typically high cost specialty drugs.

On behalf of our Individual and Group sponsors/members, Medical Mutual urges the FDA to:

- Create and implement in early 2015 a pathway that encourages the efficient review and disposition of safe and effective biosimilars;
- Develop a framework and promulgate guidance/rules to facilitate the interchange of biosimilars, when appropriate; and
- Encourage manufacturers to develop biosimilars to treat conditions where there is limited to no treatment options through regulatory or other available means

<u>An Efficient Review of Safe and Effective Biosimilars</u>
Speed to market on biosimilars is critical given the sky-rocketing costs of many specialty drugs. The review process must be efficient and expedient while also ensuring the right balance with FDA's rigorous examination of the biosimilar's safety and effectiveness.

A Framework and Rules for Biosimilar Interchanges

The FDA should collaborate with the European Medicines Agency (EMA) to understand and learn from their experiences. Through this collaboration, our hope is that best practices from their experiences can translate into the framework for biosimilar interchanges that is yet to be developed in the United States. In addition, the FDA should provide the States guidance and/or rules by which biosimilar interchanges can occur. By providing guidance and/or rules, the FDA will promote consistency in access and interchangeability as it relates to pharmacy practices across the country. Anything less may potentially cause confusion and inconsistency in access and interchanges, which does not support good patient care.

Encourage Manufacturers to Develop Biosimilars

On behalf of Medical Mutual, our Individual members, and our Group sponsors, we support any FDA initiative to encourage market development and competition of biosimilars. This competition can potentially increase the availability of treatment options and drive the prices of specialty drugs in a downward trend; the latter, a critical need of payors across the country.

We thank you again for the opportunity to submit our comments on this draft guidance.

Please contact us if you have any questions.

Sincerely,

R. E. Rzewnicki

ABBarton

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