



February 9, 2016
Arthritis Advisory Committee Meeting
U.S. Food and Drug Administration

AMCP BBCIC Oral Statement

On behalf of the AMCP Biologics and Biosimilars Collective Intelligence Consortium (BBCIC), I would like to thank FDA for hosting this meeting today and for its consideration of the approval of biosimilars in the United States. My name is Bernadette Eichelberger, and I serve as Program Director for the BBCIC. The Academy of Managed Care Pharmacy convened BBCIC to provide active post marketing surveillance of biosimilars and their innovator biologics.

Similar to the United States experience with the introduction of generics, we expect that as biosimilars come to market, physicians, patients and other stakeholders will have questions about their safety and effectiveness. Currently in the U.S., we do not have an active post-approval surveillance system built for purpose to monitor biologics and biosimilars. To meet this need, the BBCIC was convened in May of 2015 as a public service initiative that will draw on large sets of de-identified pharmacy and medical data to provide unbiased scientific information on the safety and effectiveness of marketed biosimilars and their corresponding novel biologics.

The BBCIC is a multi-stakeholder consortium that is science-driven and leverages existing distributed research network resources to conduct research and active surveillance of biosimilars and biologics. It will supplement the country's current passive reporting systems such as FDA Adverse Event Reporting System. We believe that the public's and health care community's understanding of biosimilars will be enhanced by the BBCIC's balanced, scientific approach.

The BBCIC is the only distributed research network dedicated to monitoring biosimilars and their corresponding innovator biologic products. The BBCIC framework will apply the same scientific, analytic methods used by the FDA Sentinel initiative, a post-market surveillance system comprising more than 100 million lives that tracks the safety of pharmaceuticals and other therapies once they reach the market. The Charter, available at www.BBCIC.org, describes the transparent process used to characterize patient populations and generate evidence for biologics and biosimilars in a manner that promotes robust and relevant scientific research and exchange. BBCIC launched these research activities last month.

The BBCIC involves a collaboration of some of our country's largest managed care organizations and integrated delivery systems, as well as pharmacy benefit management firms, research institutions and pharmaceutical companies. These organizations are providing the broad financial and in-kind support needed to support our research activities. In addition, 3 public representatives from patient advocacy and

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medical societies sit on our BBCIC Planning Board.

The BBCIC initiative reflects the consortium's commitment to public safety and health. Once again, the BBCIC thanks the FDA for the opportunity to provide comments and for hosting this meeting.