National Business Group on Health®

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July 12, 2016

Arthritis Advisory Committee (AAC)
FDA White Oak Campus
Building 31 Conference Center
The Great Room (Rm. 1503)
10903 New Hampshire Avenue
Silver Spring, Maryland

RE: July 12, 2016 meeting to discuss biologics license application (BLA) 761024, for ABP 501, a proposed biosimilar to AbbVie Inc.'s HUMIRA (adalimumab)

Distinguished members of the Arthritis Advisory Committee, Dr. Woodcock, and other esteemed representatives of the Food and Drug Administration, thank you for the opportunity to comment today.

My name is Tiffany McCaslin and I am Senior Policy Analyst at the National Business Group on Health. Our members would like to thank the committee for holding this important meeting on biologics license application 761024 for ABP 501.

The National Business Group on Health represents approximately 425 primarily large employers, including 72 of the fortune 100, who voluntarily provide group health plan coverage and other health programs to over 55 million American employees, retirees, and their families.

The Business Group and our members appreciate the opportunity to state for the public record that we strongly support a regulatory environment which favors the robust uptake of high quality, safe, and efficacious biosimilars. While we appreciate that the complexity of competition among large molecules differs from that of small molecules, we support the notion that, in general, competition fosters innovations that have the potential to redefine markets. We know that the availability of generic drugs has reduced drug prices and increased patient access to medicines, and we believe that competition among biosimilars may be able to do the same, as biosimilars competing for market share with each other, could be expected to lead to lower prices, as well as potentially greater access to these products. To this end, we support the direction the FDA has laid out with regard to biosimilar development, requiring demonstration that a biosimilar demonstrate biosimilarity to a reference product, and believe the FDA has put in place the appropriate patient safeguards to permit data extrapolation to inform biosimilar use.

Again, we thank the committee for holding this important meeting today, as well as all of those at FDA, CDER, OND, and other sister agencies – we recognize the significant challenges associated with your work and appreciate your continued commitment to a clear pathway by which manufacturers may bring biosimilars to market. Additionally, we thank the sponsor for its commitment to innovating in the biosimilar space, which we hope will lead to lower prices of and increased access to both live-improving and life-saving medicines for patients, payers, public programs, and other consumers.

Sincerely,

Tiffany McCaslin

Tiffany L. McCaslin
Senior Policy Analyst, Public Policy