National Business Group on Health®

20 F Street, NW, Suite 200
Washington, D.C. 20001
202.558.3000 • Fax 202.628.9244
www.businessgrouphealth.org

Creative Health Benefits Solutions for Today, Strong Policy for Tomorrow

June 3, 2016

The Honorable Dr. Robert M. Califf, MD
Commissioner, Food and Drug Administration
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2016-D-0643 regarding Labeling for Biosimilar Products; Draft Guidance for Industry; Availability

Dear Dr. Califf:

The National Business Group on Health (the Business Group) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) proposed guidance for industry on the labeling of biosimilar products. **The Business Group writes in strong support of the agency's efforts to assure a favorable regulatory environment for the robust uptake of biosimilars into evidence-based clinical practice where it is safe and appropriate, as these products could have the potential to significantly reduce the expenditure burden for both employers and employees in need of expensive biologic drug**s. The Business Group further applauds the agency for its detailed and thoughtful approach to the guidance, which seeks to clearly distinguish how and when differentiation between the reference product and the biosimilar product is needed within a product's package insert. **We believe the labeling approach set out in the guidance strikes an important and appropriate balance between provider and patient need for clinical information, and limiting confusion around critieria used to determine biosimilarity versus those used to determine clinical effectiveness for a reference product**.

The National Business Group on Health represents approximately 430, primarily large, employers (including 70 of the Fortune 100) who voluntarily provide generous health benefits and other health programs to over 55 million American employees, retirees, and their families.

We sincerely thank those at FDA for continuing to pave a responsible regulatory environment, favorable for safe, evidence-based adoption of these products into clinical practice. Regulatory clarity for biosimilars is particularly important as the rise in prices associated with specialty drugs clouds the health care expenditure outlook for nearly all employers and other payers, being both unsustainable and unaffordable if trends continue. In addition to the labeling guidance, we know FDA is hard at work on guidance related to the interchangeability of biosimilars, which may additionally facilitate competition in the biosimilar space. To date, the lack of additional federal guidelines, coupled with the efforts of some states to regulate biosimilar substitution has constrained development of biosimilar alternatives to biologics and may hamper wider adoption of biosimilars.

In addition to federal regulations, employers and other payers are monitoring the state legislative environment closely, especially as more biosimilars are approved. As of this writing, 20 states (including Puerto Rico) have enacted new laws or regulations specific to biosimilar substitution and dispensing. Additionally, at least 10 other states have proposals related to biosimilars, which are likely to be carried over or refiled in 2017.

The ability to negotiate formularies which might rely on more affordable biologics will depend largely on future FDA guidance and state legislative actions. The Business Group urges the agency to continue its thoughtful deliberation of issues related to market adoption of biosimilars, as it develops its guidance around interchangeability.

Thank you again for the opportunity to comment. Please contact me or Steven Wojcik, the National Business Group on Health's Vice President of Public Policy, at (202) 558-3012 if you would like to discuss our comments in further detail.

Sincerely,

Brian J. Marcotte
President and CEO