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August 2, 2016

Dr. Robert Califf
Commissioner of Food and Drugs
Food and Drug Administration (FDA)
10903 New Hampshire Ave.
Silver Spring, MD 20993

Submitted via www.regulations.gov

Re: Draft Guidance for Industry on Labeling for Biosimilar Products [Docket No. FDA- 2016-D-0643]

Dear Dr. Califf:

Thank you for the opportunity to comment on the Draft Guidance on Labeling for Biosimilar Products and the ongoing implementation of the Biologics Price Competition and Innovation Act. The Pacific Business Group on Health (PBGH) strongly supports the creation of a biosimilar approval pathway that will provide access to safe, effective and more affordable biosimilar products. PBGH is a not-for-profit organization that leverages the strength of its 60 members – who collectively spend $40 billion a year purchasing health care services for more than 10 million Americans – to drive improvements in quality and affordability across the U.S. health system.

PBGH members are aware that biosimilars can provide a more affordable option to biologic drugs. We are also aware that FDA approval of a biosimilar drug is based on a finding that there are no clinically meaningful differences in terms of safety and effectiveness from the reference product, i.e., the original biologic drug. The use of biosimilars can create a healthy competitive marketplace for medications, which will help to improve affordability while maintaining high quality outcomes.

It is vitally important that access to FDA-approved biosimilars is not impeded by unnecessary regulatory obstacles or labeling requirements. Based on this principle, we offer the following comments on the proposed guidance on labeling:

- We support FDA's proposal that biosimilar labels include a statement about the safety and efficacy of the reference product rather than the biosimilar drug itself.
- We oppose FDA's proposal that the labels include a statement that the product is "biosimilar" to the original biologic. This statement is unnecessary, and it is more likely to create confusion among consumers. It may also discourage the use of biosimilars by inappropriately raising concerns about the safety and efficacy of biosimilars.

We appreciate your attention to the concerns of patients, consumers and purchasers as you finalize the FDA's guidance on labeling of biosimilars, and we hope that this will lead to better access to and broader

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adoption of biosimilars that can improve clinical outcomes and affordability. If you have any questions about our comments, please contact me at wkramer@pbgh.org or 503-679-8390 (cell).

Sincerely,

William E. Kramer
Executive Director for National Health Policy