Robert Califf, M.D.
Commissioner Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

June 3rd, 2016

Dear Dr. Califf,

As healthcare and pharmaceutical supply chain stakeholders, we are all carefully watching the development of the biosimilars market in the United States. As policymakers look at ways to control spending growth in the healthcare sector, biosimilars offer a unique opportunity to create savings and improve patient access, similar to what the generics market has done for small-molecule therapies. We believe that developing policies that encourage biosimilars competition are critical to the growth of this important market, and critical to realizing the maximum level of savings to the health system.

For that reason, we would like to thank the Food and Drug Administration (FDA) for releasing its March 2016 guidance "Labeling for Biosimilar Products" [Docket No. FDA-2016-D-0643]. Finalizing guidances such as this are an important element of creating a predictable regulatory environment for all members of the pharmaceutical supply chain. We appreciate FDA's diligence in continuing to provide additional clarity for stakeholders.

As an initial matter we applaud FDA for taking steps in the Draft Guidance to ensure that biosimilar labeling reflects the scientific information necessary for health care providers to use a product safely and effectively, consistent with FDA regulations.

We support FDA's recommendation that biosimilar labeling should focus on information on the clinical studies for the biosimilar's reference product. In most cases, the scientific information necessary to approve a biosimilar will primarily focus on establishing biosimilarity between the two products. Therefore, the safety and efficacy information will come from studies of the reference product rather than the biosimilar. Including a biosimilar product's biosimilarity data in addition to that of the reference product would only provide unnecessary information and create confusion for readers, including prescribers and patients. We appreciate FDA's willingness to allow a biosimilar's labeling to differ when there is appropriate safety or efficacy data that distinguishes the biosimilar from its reference product.

However, we are concerned about the FDA's requirement to include a biosimilarity statement on biosimilar labeling. The biosimilarity statement is at best unnecessary. The FDA has never required any similar statement for products found to be therapeutically equivalent, and has not provided sufficient justification for its inclusion in biosimilar labeling. Moreover, the biosimilarity statement will be confusing to patients and providers who are unfamiliar with this type of unprecedented statement. This confusion could put biosimilar utilization, and savings, at risk.

This differentiation between biosimilars and their reference products risks undermining the important provider education that is being done by the FDA today. Informing providers that biosimilars have "no clinically meaningful differences in terms of safety, purity and potency (safety and effectiveness) from the reference product"[1] while requiring a differentiator on the labeling sends mixed signals to providers responsible for driving patient familiarity and comfort with these products.

We thank you for your consideration of these comments and look forward to continuing to work with FDA and other stakeholders to improve the lives of patients by providing timely access to affordable pharmaceutical and biological products.

Sincerely,
Academy of Managed Care Pharmacy (AMCP)
America's Health Insurance Plans (AHIP)
American Pharmacists Association (APhA)
Blue Cross Blue Shield Association (BCBSA)
CVS Health
Express Scripts
Healthcare Supply Chain Association (HSCA)
Pharmaceutical Care Management Association (PCMA)
Premier healthcare alliance
Prime Therapeutics
UAW Retiree Medical Benefits

[1] "FDA Overview of Biosimilar Products." FDA CDERLearn. http://fdabiosimilars.e-paga.com/