Comment on Section 11 of S. 2700

June 13, 2016

Dear Chairman Alexander and Ranking Member Murray:

Commending your bipartisan sponsorship of Section 11 of S. 2700, the undersigned organizations strongly support the provisions of S. 2700 (as amended) that assure full FDA authority over the identity (name) and quality standards for biologic products, including biosimilars. Absent this assurance, the unique regulatory framework Congress designed exclusively for the approval and safe use of biosimilars could be severely undermined.

Our nation's biosimilar regulatory framework – as set forth in the Biologics Price Competition and Innovation Act (BPCIA) – accounts for the very significant differences between large-molecule biologics produced by living cells and small-molecule, chemically made drugs. Incompatible with these differences are the official compendia standards for identity and quality, which are configured for small-molecule drugs.

Section 11 will ensure official compendia standards are not applied to biologics, including biosimilars, thereby making explicit Congress' intent when it passed BPCIA as part of the Patient Protection and Affordable Care Act in 2010.

Since then, FDA has worked to establish the appropriate regulatory framework for what is likely to be a $50-100 billion market in biosimilars.[1] FDA has proceeded cautiously, declaring that it will make decisions on a case-by-case basis until it has the knowledge to impose a comprehensive regulatory framework for the approval and safe use of biosimilars.

Now, after considerable, specialized work and the approval of two biosimilars, the agency feels ready to propose, and soon finalize, guidance that will set the course for biosimilars. Potentially interfering with this biologics-based approach is the traditional, small-molecule drug role granted to official compendia, specifically that of the United States Pharmacopeia (USP), to define the official nomenclature and common quality standards.

This involvement of the USP has made sense for small molecule drug products. However, it is not appropriate for biosimilars, where each product relies on a unique cell line and manufacturing process and requires unique specifications. Section 11 will ensure that FDA sets biosimilars policy, not USP.

Along with many other stakeholders, we believe that Section 11 of S. 2700 is the right step to usher in the era of biosimilars. We thank you for introducing and actively supporting it.

Sincerely,

Alliance for Patient Access
American Association of Clinical Endocrinologists
American College of Rheumatology
Biologics Prescribers Collaborative
Coalition of State Rheumatology Organizations
Endocrine Society

[1] Rader, R. A. (2013). An analysis of the US biosimilars development pipeline and likely market evolution. *BioProcess Int*, *11*(6).