

May 23, 2016

The Honorable Lamar Alexander
Chairman
U.S. Senate
Senate Committee on Health, Education,
Labor and Pensions
727 Hart Senate Office Building
Washington, DC 20510

The Honorable Patty Murray
Ranking Member
U.S. Senate
Senate Committee on Health, Education,
Labor and Pensions
428 Dirksen Senate Office Building
Washington, DC, 20510

Dear Chairman Alexander and Ranking Member Murray:

On behalf of the undersigned organizations, we are writing to express our serious concerns regarding the inclusion of Section 11, Biological Product Innovation in the FDA and NIH Workforce Authorities Modernization Act (S. 2700)—part of the Senate Innovations legislation marked up in the HELP Committee.

This provision is unrelated to the other sections of the legislation and appears not to have received meaningful discussion with the broader stakeholder community prior to its inclusion. It would exempt biological medicines from the requirement to adhere to U.S. Pharmacopeial (USP) public standards for quality. **If enacted, this provision would have potentially grave consequences for public health and would hinder, rather than support, our shared goal of getting safe and effective biosimilars to market.**

We respectfully request that the provision be omitted from any legislation that proceeds to floor debate during the remainder of this Congress. Any consideration of removing longstanding and publicly recognized standards and patient protections should include a robust and transparent discussion. Such a review should be evidence-based and include an evaluation of the validity of assertions driving the proposed provision. Indeed, we have yet to identify any actual examples of the problem that the provision purports to address.

It is imperative that measures to address specific concerns be appropriately tailored—rather than annulling an important and longstanding element of the statutory framework that has ensured patient safety, marketplace competition, and patient access to good quality medicines for so long.

Since 1906, USP quality standards—benchmarks that consist of tests and other measures—have set the requirements for a drug or biologic's purity, potency, identity and quality. These standards are developed by expert committees, which include scientists and public health stakeholders, and utilize an unbiased, scientific process to establish public standards that help ensure the quality and integrity of medicines. While USP standards are designed to evolve to keep pace with scientific advances, they have also remained a constant element of the complementary safeguards that for over a century have helped make American medicines the safest and best quality in the world.

As impacted stakeholders, we want to ensure that all Americans have access to high quality drugs, including biologics and biosimilars. Public standards for quality are available to anyone, provide both a benchmark of quality for product developers (including biosimilars manufacturers) and a tool relied upon by public health officials to test the quality of products across the supply chain. With over 80% of the US medicines supply originating outside the US, the ability to utilize a public quality standard to ensure product quality is especially important in our increasingly globalized economy.

In addition, transparent public quality standards provide practitioners, such as pharmacists, physicians and nurses, as well as patients, with confidence in the quality of medicines. **This provision would undo an important component of the medicine quality safety net, create an unknown and potentially significant risk to patient safety, and undermine confidence in biological medicines, including biosimilars.**

Furthermore, the provision may hinder the development of biologics, including biosimilars. Data shows that USP's reference standards are extensively utilized by biosimilars manufacturers in the research and development process. They provide a benchmark for quality in drug development. Without them, biologics manufacturers would incur additional expense and delays by having to develop individual quality standards without a public benchmark. This would slow development, reduce predictability and increase costs. **Contrary to its stated purpose, the provision would frustrate the intent of Congress in enacting the Biologics Price Competition and Innovation Act of 2009.**

By supporting biosimilars product development, USP public quality standards promote competition among multiple manufacturers and support broader patient access to affordable biosimilars. As more biologics have come to market over the past few decades, USP has continuously worked with manufacturers and stakeholders to ensure that the development of standards remains transparent and flexible, to accommodate new products and new testing methods. USP's work to develop a public quality standard for Filgrastim, one of the two biosimilars approved by FDA, is an example of USP's effective process in action.

Thank you for your consideration. We look forward to working with you and FDA to help ensure that health care providers and patients continue to have access to biological and biosimilar medicines and can be confident that they are of the highest quality.

Sincerely,

