May 28, 2019

The Honorable Lamar Alexander
Chairman
Senate Committee on Health, Education, Labor and Pensions
455 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Patty Murray
Ranking Member
Senate Committee on Health, Education, Labor and Pensions
154 Russell Senate Office Building
Washington, DC, 20510

Dear Chairman Alexander and Ranking Member Murray:

On behalf of the undersigned organizations, we write to express urgent concern about a proposal[1] in the President's budget request that would undermine trust in the quality of biologic medicines with healthcare practitioners and patients, including for medicines widely prescribed to treat diabetes, rheumatoid arthritis, cancer, Crohn's disease and colitis, and other diseases. The proposal, contained in the HELP discussion draft, would exclude biologic medicines from the requirement that all medicines marketed in the United States adhere to quality standards established by the United States Pharmacopeia (USP). We believe that USP standards have been, and should remain, a foundational element in the framework ensuring that the medicine supply in the United States is among the safest in the world.

In the last Congress, a similar proposal was rejected after robust engagement from numerous stakeholders during consideration of the 21st Century Cures Act. We are alarmed that the proposal is being reexamined and could find its way into legislation to be considered by the HELP or Appropriations Committees this year. We respectfully urge that this proposal not be further considered and not be included in any legislation amending the Public Health Service Act (PHSA) or any other provision of law or appropriations legislation.

The proposal set forth in the President's budget request is framed as one that will lower drug costs by accelerating the development of biologic medicines, including biosimilars, with no data or rationale to support such a statement. We urge Congress to focus on resolving issues that could accelerate the availability of affordable, quality medicines for patients rather than reexamining this proposal, which poses a risk to the quality of medicines and could potentially hinder patient access.

Public quality standards are essential for ensuring the quality of medicines for patients and the practitioners who prescribe, dispense, and administer them. USP's public quality standards are established by independent, scientific experts from government, academia, industry, and the healthcare practitioner and patient communities. USP standards also go through a transparent public comment process. They provide manufacturers with key attributes of a quality medicine, as well as tests, methods, and other information that supports medicine development and manufacturing, and therefore contribute to a more efficient and reliable medicine supply.

[1] https://www.whitehouse.gov/wp-content/uploads/2019/03/FY20-Fact-Sheet_Lowering-Drug-Pricing-and-Payment_FINAL.pdf

USP, and the independent science experts on USP standard-setting committees, work in close collaboration with industry, government agencies, and healthcare practitioners. **USP's commitment to a collaborative process and its assurances that it will not publish a new biologic product monograph standard as official (and thereby enforceable) without FDA support, is well documented (www.usp.org/biologics/development-process).**

If enacted, the proposal to eliminate the requirement that biologic products comply with USP quality standards would have broad negative consequences to public health. Product developers would no longer be able to rely upon USP standards for product development, public health authorities would not have access to a publicly available standard to utilize in crisis situations, the pharmacy community would not have access to information that is important to the practice of pharmacy, and patients' trust in the quality of their medicines would be undermined.

We note that in Europe, where compliance with public quality standards is required for biosimilars, as well as for the original biologics, there have been 58 biosimilars approved to date, compared to only 19 approved in the US. In Europe, biosimilars have enabled more patients to be treated, often earlier in their disease, with no change in clinical outcomes.

There is no compelling or credible reason to change the law to remove USP from the framework that has protected Americans for 80 years. To remove USP would handicap future leaders across government who may have a perspective that is different than current Agency leadership, and who may wish to leverage USP standards in the future. We encourage continued collaboration on establishing relevant standards to ensure the quality of the medicine supply in the United States and support public health overall. We look forward to working with Congress and stakeholders on constructive solutions to ensure that Americans have access to affordable quality medicines.

Sincerely,

Academy of Managed Care Pharmacy
American Cancer Society Cancer Action Network, Inc.
American Diabetes Association
American Pharmacists Association
American Society of Consultant Pharmacists
Arthritis Foundation
ASHP (American Society of Health-System Pharmacists)
Association for Accessible Medicines
National Community Pharmacists Association
National Council for Prescription Drug Programs
United States Pharmacopeia