

August 1, 2016

The Honorable Lamar Alexander, Chairman, Senate Committee on Health, Education, Labor, and Pensions (HELP)

The Honorable Patty Murray, Ranking Member, Senate HELP Committee

The Honorable Orrin G. Hatch, Chairman, Senate Committee on Finance

The Honorable Ron Wyden, Ranking Member, Senate Committee on Finance

The Honorable Fred Upton, Chairman, House Committee on Energy and Commerce

The Honorable Frank Pallone, Ranking Member, House Committee on Energy and Commerce

The Honorable Kevin Brady, Chair, House Committee on Ways and Means

The Honorable Sander M. Levin, Ranking Member, House Committee on Ways and Means

Dear Chairman Alexander, Ranking Member Murray, Chairman Hatch, Ranking Member Wyden, Chairman Upton, Ranking Member Pallone, Chairman Brady, and Ranking Member Levin:

We are writing to express concern about proposals by the Food and Drug Administration (FDA) and a provision included in Section 11 of the "FDA and NIH Workforce Authorities Modernization Act" (S. 2700) that would exempt certain biological products, including biosimilars, from the requirement to adhere to U.S. Pharmacopeial (USP) public standards for quality, including the naming of biologic and biosimilar medicines. We have serious reservations concerning any such possible change in law, which we believe would have a critical impact on patient safety and stray from established practices that enable health care practitioners to clearly communicate health information and protect patients from misbranded or adulterated medications.

Pharmacists and other practitioners rely on the monographs in the *United States Pharmacopeia-National Formulary (USP-NF)* to set a single standard for quality, safety, and purity of medications, but also as the primary means to identify the single non-proprietary name of medications. Approaches that deviate from using a single source to identify the non-proprietary naming impact the ability of health care practitioners to clearly communicate health information and protect patients from misbranded and adulterated medications. The current system establishes USP as the primary entity to develop and establish names in the United States consistent with global standards for nonproprietary naming. USP works with other stakeholders, nationally and internationally, to accomplish that objective. Divergence from this process in the United States could jeopardize the supply chain and make medications less safe.

The current proposals would result in FDA having sole responsibility for establishing nonproprietary names for these medicines, without allowing for adequate stakeholder discussion and input, including through full comment and rulemaking, and would represent a significant departure from the long established public process established by Congress which gave the primary authority to establish nonproprietary names for all medicines to USP.

The significance of such a potential change in law for naming of biologics, as represented by such current proposals, cannot be understated. Mandatory compliance with public quality standards, including for the identity of a medicine, ensures that medicines, including biologics, manufactured by multiple manufacturers are identified with a common name. This provides a uniform quality standard; clarity for all components of prescription communications and transactions, including prescribing and dispensing by healthcare practitioners; meaningful names for coverage and tiering decisions for insurers and benefit managers; and confidence for patients.

The undersigned organizations represent pharmacists, pharmacies, payers, pharmacy benefit managers, and other stakeholders with a key role in delivering safe and cost-effective prescription medications through a variety of ways including dispensing drugs to patients, supplying drugs to health care facilities, and managing formularies to ensure that beneficiaries have access to critical medications. We are concerned that any naming approach which would assign a unique non-proprietary name to each biological drug, including biosimilars, would create unclear and complex naming conventions that could lead to unintended consequences and barriers to access for biologic and biosimilar medications; result in practitioner and patient confusion and miscommunication relative to the appropriate use, safety, and efficacy of these medications; and impede substitutability of interchangeable products through state policies.

Unique nonproprietary names for each medicine could undermine physician and patient confidence in biosimilars and perpetuate the notion that biosimilars are not comparable to the reference biologic drug. These perceived differences may reduce the confidence patients and health care providers have in these drugs and inhibit them from using, prescribing, or dispensing these products, undermining the benefits of the Biologics Price Competition and Innovation Act of 2009.

Pharmacists and other health care practitioners are also concerned that differences in naming conventions may result in a system where various parties potentially operate under different understandings of product identities, thus leading to medication dispensing and utilization errors, potentially harming patients. While we understand and share FDA's goals of ensuring effective pharmacovigilance, we believe these goals may be achieved without disrupting the existing longstanding and well-understood approach to medication naming.

Standardized naming is also essential to ensure functioning of systems that further the electronic exchange of information and improve communication between care teams. To keep systems of medicines data collection, maintenance, transmission, and access running smoothly and functioning in real time, carefully considered standards-based practices are essential. Any move away from these standards-based practices, such as would occur with proposals for unique names for each medicine, may jeopardize patient safety.

The proposed biosimilar naming practice as advanced by FDA and others could also serve as a barrier that would inhibit market entry of follow-on competitors and potentially disrupt the current global naming system. Indeed, approximately 20 biosimilar drugs have been successfully approved and marketed in Europe under an existing system of mandatory public standards and common nonproprietary names. Improved patient outcomes and decreased overall health care costs will be enabled by the adoption, access, and affordability of biosimilar products in the United States.

In summary, our organizations share a commitment to patient safety, and as such, we believe that biologics and biosimilars should be required to have the *same* nonproprietary names based on existing standards and mechanisms. Given the broad and negative implications of such potential naming proposals, as well as their controversial nature, we are requesting that FDA not finalize current guidance and proposals and that legislation not include these provisions. We stand ready to continue to work with the Congress to help ensure that healthcare practitioners, providers and patients have access to affordable, quality biological medicines, including biosimilars.

Thank you for your consideration.

Sincerely,



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- Academy of Managed Care Pharmacy (AMCP)
 - American Pharmacists Association (APhA)
 - American Society of Consultant Pharmacists (ASCP)
 - American Society of Health-System Pharmacists (ASHP)
 - Biosimilars Council—A Division of the Generic Pharmaceutical Association (Biosimilars Council)
 - International Academy of Compounding Pharmacists (IACP)
 - National Alliance of State Pharmacy Associations (NASPA)
 - National Community Pharmacists Association (NCPA)
 - National Council for Prescription Drug Programs (NCPDP)