May 7, 2019

Dr. Norman Sharpless
Acting Commissioner
U.S. Food and Drug Administration (FDA)
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Sharpless:

As stakeholders that support patient access to affordable medicines and competition in the pharmaceutical marketplace, we applaud the Food and Drug Administration's (FDA) efforts to foster the development of biosimilar medicines for America's patients. However, we are concerned that as recently updated, the FDA policy for the naming of biological products could harm the development of a robust biosimilars market in the United States, putting access and savings for patients in jeopardy.

We share the FDA's commitment to patient safety, and as such, we believe that biologics and biosimilars should be required to have the same International Nonproprietary Name (INN), devoid of a suffix. The FDA's current system of requiring random suffixes for biosimilars and not for their approved reference products fails to confer any safety benefits and ultimately leads to confusion for patients, prescribers, pharmacists and other healthcare providers. Moreover, this approach creates the perception that there are meaningful differences between FDA-approved biologics and biosimilars, when, in fact, agency approval explicitly indicates they have "no clinically meaningful differences."

As the FDA noted in the January 2017 final guidance "Nonproprietary Naming of Biological Products":

> "Applying this [suffix] naming convention only for products licensed under section 351(k) of the PHS Act—but not for the reference product licensed under 351(a) of the PHS Act—could adversely affect health care provider and patient perceptions of these new products. ***Specifically, such an approach could be misinterpreted as indicating that biosimilar products differ from their reference products in a clinically meaningful way or are inferior to their reference products for their approved conditions of use."***[1]

FDA's Current System is Ineffective and Other Identification Mechanisms are Sufficient

We believe that requiring a random suffix provides little to no value. A recent study using the FDA's Adverse Event Report System (FAERS) Public Dashboard reveals that the number of biosimilar safety reports provided to the FDA that contain the suffix is almost negligible, at 0.9 percent. In 99.1 percent of the time, biosimilar adverse events were reported by their brand

[1] https://www.fda.gov/downloads/drugs/guidances/ucm459987.pdf

name. [2] This point was also affirmed by Dr. Janet Woodcock[3], Director of the FDA Center for Drug Evaluation and Research (CDER) and is likely due to the fact that a random four-letter suffix is difficult to remember for patients and providers while the brand name is memorable.

To that end, while we agree with the FDA that it is important to gather data that allows providers to better understand how biologics and biosimilars are performing among various patient groups and to assist in the tracking of adverse events, we believe that the current mechanisms in place (e.g., NDC code, lot number, brand name, manufacturer, etc.) are sufficient.

FDA's Approach Creates Two Distinct Standards for Biologic Medicines

The FDA's updated draft guidance proposes to add a random four-letter suffix to newly approved biologic products and all biosimilars. The updated proposal is counter to the FDA's prior policy of adding suffixes retroactively to previously approved biologics that may serve as reference products. This change results in creating two distinct standards for the same class of products.

Previously approved biologics and many "transitional" biologics that will be regulated under the Public Health Services Act (PHSA) as of March 2020 will not be required to have a suffix, despite the fact that many transitional products share a non-proprietary name. Concerningly, by adding a suffix to newly approved biologics and biosimilars, the FDA is also creating the perception that there are two different classes of biologic medicines-- those with a suffix and those without. This will cause confusion amongst patients, prescribers, pharmacists, payers, and pharmacy benefit managers, especially as biosimilars are approved for the transitional products that share a non-proprietary name. This is contrary to the FDA's stated goal of creating "a framework for safe use and optimal pharmacovigilance for biosimilar products and interchangeable products that is informed by current experience and industry best practices."[4]

FDA's Updated Draft Guidance Will Slow the Adoption of Interchangeable Biologics

The updated draft guidance proposes to add a suffix to the non-proprietary name for interchangeable biologics. If a product is approved and marketed prior to applying and receiving the interchangeability designation, that product will retain the original suffix assigned at the time of the original approval even after gaining the interchangeable designation. This may create confusion about when a product can be interchanged. For instance, a product may be on the market and not automatically substitutable during the pharmacy dispensing process, and then later gain the interchangeable designation allowing for automatic substitution. These types of scenarios could introduce unnecessary barriers and will require re-education of healthcare professionals for specific products.

Further, pharmacy substitution laws vary from state to state, and in some instances, a product with a different non-proprietary name than its reference product cannot be automatically

[2] https://pink.pharmaintelligence.informa.com/PS124042/Biosimilar-Suffixes-Appear-Superfluous-In-Adverse-Event-Reporting

[3] https://pink.pharmaintelligence.informa.com/PS124962/Woodcock-Concerns-About-US-FDAs-Biosimilars-Suffix-Policy-Detached-From-Reality

[4] https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM632806.pdf

substituted by law or may be perceived by pharmacists to be unsuitable for substitution, given the ambiguity of such laws in states such as Michigan, Nebraska, and Nevada.

Conclusion

The FDA's draft guidance on the naming of biologic products creates an artificial barrier to the uptake of these medicines. Current experience with biosimilars makes clear that the mechanisms already in place, besides the suffix, are sufficient in tracking the FDA's concern on pharmacovigilance. We ask that the agency change course on this policy, which is misaligned with the FDA's own Biosimilars Action Plan and the Trump Administration's stated goal of lowering drug prices and enhancing the efforts to foster biosimilar competition to improve access to affordable treatments for America's patients. We stand ready to work with you to address these concerns.

Thank you for your time and consideration.

Sincerely,

AARP
Academy of Managed Care Pharmacy
Allergy & Asthma Network
America's Health Insurance Plans (AHIP)
American Pharmacists Association (APhA)
Association for Accessible Medicines & Biosimilars Council
Blue Cross Blue Shield Association
Campaign for Sustainable Rx Pricing (CSRxP)
Cancer*Care*
Caregiver Action Network
Coalition to Reduce Spending
Consumer Action
CVS Health
Employers Health
Global Healthy Living Foundation
Healthcare Supply Chain Association (HSCA)
Marti Nelson Cancer Foundation
National Association of Chain Drug Stores (NACDS)
National Business Group on Health
National Coalition on Health Care
Ohio Public Employees Retirement System
Pacific Business Group on Health
Pharmaceutical Care Management Association (PCMA)
Premier healthcare alliance
Prevent Cancer Foundation
Prime Therapeutics
Public Sector HealthCare Roundtable
Rite Aid
Vizient