March 24, 2020

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852
Submitted via https://www.regulations.gov/

RE: Docket No. FDA-2019-N-6050 for FDA/FTC Workshop on Competitive Marketplace for Biosimilars

To Whom it May Concern:

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit, ANSI-Accredited Standards Developer (ASD) consisting of more than 1,700 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, professional societies and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI-accredited standards, and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

For over 40 years NCPDP has been committed to furthering the interoperable electronic exchange of information among a wide array of healthcare stakeholders. To assist in consistent and accurate identification of drugs and health-related products, NCPDP's Work Group 2 Product Identification works with product identification systems and any type of descriptive data, including naming, that serves to uniquely identify a product with the intent of establishing standards for product identification to avoid ambiguity in distinguishing one product from another.

The product information exchange procedures developed and maintained by NCPDP are used by all originator biologics and biosimilars licensed in the US. The industry expects and anticipates these procedures will also be used for all originator biologics, biosimilars and interchangeable biologics in the future. As such, NCPDP is central to developing standards by which these products are distributed and recorded, including identification of products for the purpose of pharmacovigilance.

It is NCPDP's position that biosimilars and interchangeable biologics should carry the same nonproprietary names as their respective reference products. We incorporate by reference our submission of August 20, 2012, to US FDA Commissioner Hamburg in which we stated that the International Nonproprietary Name (INN), "should not be redesigned to respond to concerns about pharmacovigilance and drug tracking."

NCPDP maintains its concerns about the downstream financial burden to the healthcare sector and patients in implementing the FDA's suffix-based naming policy for biologics, including biosimilar and interchangeable products, and to potential anti-competitive effects that distinct proper names carry for highly similar products sharing a common core name (International Nonproprietary Name, INN). Such naming distinctions carry the risk of false or misleading communications about originator products and their biosimilar or interchangeable counterparts and negative effects on public health, including safety and efficacy claims and on competition.

The FDA and the Federal Trade Commission (FTC) are right to acknowledge how false or misleading comparisons of originator products and their biosimilar and interchangeable counterparts could lead to unfair or deceptive practices that undermine the confidence in these products, particularly concerning the intent of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act).

The FTC's prescient concern raised in its October 2017 comments to the FDA about the Agency's suffix-based naming policy remains true today—assignment of different suffixes to drug substance names of biosimilars and their reference products could result in prescribers and others believing the products differ in clinically meaningful ways, particularly since drug substance naming distinctions traditionally have connoted meaningful differences. Such misinterpretation could deter clinicians from prescribing biosimilars, thereby impeding the development of biosimilar markets and the competitive intent of the BPCI Act. Thus, at the most basic level, FDA has created a naming policy that is innately anti-competitive.[1]

Unfortunately, the FDA ignored the FTC's advice to reconsider its proposed suffix-based naming system. NCPDP continues to share the FTC's position that suffix-based naming distinctions should have been abandoned and replaced by other mechanisms that were less likely to be anti-competitive while still accomplishing the agency's goal of improved pharmacovigilance and reduced inadvertent substitution of biosimilar products. In fact, one such approach was recently implemented by Health Canada in which the INN and brand names along with drug identification numbers (DINs) would provide a naming convention with strong product tracking capabilities. Unlike the FDA's approach, Health Canada's system is intuitive, simple and memorable while avoiding the anti-competitive risks that distinct proper names carry. It also achieves the pharmacovigilance needs of the FDA since evidence from both Canada and the US have shown reporting by brand name is largely successful in achieving accurate product-level attribution of spontaneously adverse effects for suspected biologics.[2]

In NCPDP's May 2019 comments to Docket No. FDA-2013-D-1543 "Nonproprietary Naming of Biological Products: Update", we raised concerns that exempting existing reference products from the FDA's suffix-based naming scheme would add further confusion in drug naming standards that are now being applied to biologics and that such an approach risks unintended anti-competitive interpretations. The two separate naming standards for related products sharing identical nonproprietary ("core") names would have to be accommodated at the data systems level, adding to the burden of an already arduous downstream implementation. Dissimilar naming standards for related products must be avoided as it amplifies

[1] Federal Trade Commission. Comment of the staff of the Federal Trade Commission. Submitted to the Food and Drug Administration in response to a request for comments on its guidance for industry on the "Nonproprietary Naming of Biological Products; Draft Guidance for Industry; Availability". [Docket No. FDA-2013-D-1543] https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-submitted-food-drug-administration-response-fdas-request-comments-its-guidance/151028fdabiosimilar.pdf (accessed 2018 Mar 20)

[2] Health Canada, Office of Policy and International Collaboration, Biologics and Genetic Therapies Directorate. Notice to stakeholders: Policy statement on the naming of biologic drugs. Ottawa, ON: 2019 Feb 14. https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/biosimilar-biologic-notice-to-stakeholders-drugs-naming-of-biologics.html (accessed 2020 Mar 9)

confusion and error potential. In addition, such naming distinctions would add to the complexity of maintaining clinically relevant drug relationships in data systems and applications.

Such an exemption also risks favoring the innovator product by creating a false sense of superiority by the absence of any modifying suffix relative to competitive products. For products with identical core names, it also will favor alphabetical listing and probable product selection of the reference (originator) product in listings organized by nonproprietary names. Therefore, NCPDP strongly opposes application of two distinct naming policies for reference products versus competitive products sharing identical core names from both an implementation standpoint as well as from the unintended anti-competitive risks that distinct naming standards for reference products versus their biosimilar and interchangeable counterparts can cause.

By definition, biosimilarity means, "that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components," and that, "there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product," (see section 351(i)(2) of the PHS Act). As such, the FDA and the FTC must ensure communications about biosimilar products do not portray the originator product as superior to its biosimilar counterparts and vice versa. In their 2017 comments to the FDA, the FTC noted a number of concerns about the ability of follow-on biologics (biosimilars) to gain market share in contrast to the history with small molecule generics. Recognizing these existing barriers, it becomes even more important that the FDA and the FTC establish effective communications to improve understanding of biosimilars among patients, clinicians and payers and to dispel misunderstandings about their potential substitutability.

One important area in naming convention that remains unresolved within the FDA is how best to handle the naming of biologics once they are determined to be interchangeable. To be interchangeable, there must be sufficient data to show that the biosimilar product can be expected to produce the same clinical result as the reference product in any given patient; and, if it is administered more than once to the same patient, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the product and the reference product is not greater than the risk of using the reference product without such alternation or switch (see section 351(k)(4) of the PHS Act). Because interchangeable products may be substituted for the reference product without the intervention of the prescribing healthcare provider (see section 351(i)(3) of the PHS Act), it is critical a "proper" nonproprietary naming practice that avoids portraying any dissimilarity among the products be adopted.

A principal goal of the BPCI Act was to stimulate the development and successful marketing of potentially interchangeable biosimilars aimed at price-lowering competition within the US biologics marketplace. The communication of any misinformation that portrays biologic products as being inferior or superior to their biosimilar or interchangeable counterparts must be aggressively addressed by these federal agencies. In the spirit of the BPCI Act, the FDA and the FTC should take the necessary steps to prevent misleading communications about biosimilar products and to clarify any misunderstandings by patients, clinicians and payers that may result.

NCPDP's position on the FDA's suffix-based naming policy has not changed despite ongoing efforts by the agency to continue to implement this new US naming approach. In fact, in many ways, NCPDP's opposition has only strengthened because of the resultant confusion that has already occurred in the electronic drug information and standards industries as well as in many other sectors (e.g., prescribers, dispensers, prescription processors, drug knowledge bases) faced with implementing and interpreting this policy and because of the anti-competitive risks of the FDA's naming policy.

We thank you for your openness in continuing to value NCPDP's input on the issues of biosimilars and interchangeability and look forward to our continued close work in agreeing to an unambiguous path forward.

For direct inquiries or questions related to this letter, please contact
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Sincerely,

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cc: NCPDP Board of Trustees

Enclosure

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