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All Camps Agree: Memorable Biosimilar Names Are A Must

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The U.S. Food and Drug Administration has received comments from more than 170 groups on its proposal for naming biosimilars. Biosimilar makers, insurers and pharmacies largely oppose distinct nonproprietary names (also known as proper names) for biosimilars. By contrast, innovators (including those that develop biosimilars), health care providers and patient advocacy groups view them as critical to ensuring patient safety. However, most stakeholders in both camps urged the FDA to use meaningful suffixes to distinguish biosimilars from originator products rather than suffixes "devoid of meaning." The FDA proposed to add meaningless suffixes to the nonproprietary names of originator products to address concerns of biosimilar makers that distinguishable names will discourage adoption of biosimilar products. But biosimilar makers expressed concern that such meaningless suffixes will lead to a variety of errors and ultimately endanger public safety. The FDA may now revisit its proposal given the largely uniform preference of innovators and biosimilar makers alike for meaningful and memorable nonproprietary names, such as those that identify the manufacturer of the biologic.

Under the FDA's proposal, nonproprietary names would consist of the core nonproprietary name of the originator product plus a distinct four-letter suffix for originator products and biosimilars. For instance, the FDA proposed to assign Sandoz Inc.'s Zarxio, the only approved U.S. biosimilar, the nonproprietary name "filgrastim-bflm." Sandoz's biosimilar currently has the placeholder name "filgrastim-sndz," associating the product with Sandoz, its manufacturer. On the originator side, Zarxio is a biosimilar of Amgen Inc.'s Neupogen, currently named "filgrastim." Under the FDA's proposal, Neupogen would be assigned the name "filgrastim-jcwp" — filgrastim plus a distinct suffix of four random lowercase letters. Unlike "sndz," the suffixes proposed by the FDA would be neither meaningful nor memorable. Stakeholders, including Sandoz and Amgen, urged the FDA to reconsider its naming scheme and adopt meaningful and therefore memorable suffixes instead of random ones.

Amgen, an innovator and biosimilar maker, explained that "the suffix should be meaningful (by identifying the sponsor) and consistent across the product sponsor's portfolio." According to Amgen, "[s]uch a naming convention would help prescribers and patients with product identification, thereby avoiding inadvertent substitution and fostering accurate attribution of adverse events." Amgen also noted that assigning a meaningful suffix such as "-amgn" or "-sndz" is more appropriate since the names "will be used by people (as opposed to just machines)."

Sandoz expressed concern that "the use of random consonants will endanger public safety." Mylan NV, a biosimilar maker, said that random suffixes may have "the perverse effect of increasing medication errors and impairing pharmacovigilance." Sandoz stated that the random suffixes would "inevitably lead to adverse event reports that cannot be attributed to a specific manufacturer or are attributed to the wrong manufacturer." Sandoz also noted that a suffix such as "-sndz" does not confer any market advantage since "it will simply be interpreted to represent the company who makes the product" — information that is already associated with the product in FDA-approved packaging. Teva Pharmaceuticals, another biosimilar maker, stressed that "meaningful names also are easier to remember, both for busy health care providers and especially for patients." As a result, Teva stated that "the use of meaningful names, including ones tied to the name or ownership of the licensee, seem more likely to facilitate accurate and useful adverse event reporting."

Health care providers and patient advocacy groups stressed the importance of memorable names. The Biologics Prescribers Collaborative (BPC) and professional organizations with biologics prescribers, such as the American College of Rheumatology, Alliance for Patient Access and American Association of Clinical Endocrinologists among others, stated: "our experience as biologics prescribers tells us that the suffix must be memorable, which cannot be easily accomplished when it is meaningless." BPC explained that a "randomized four-letter code may complicate the achievement of FDA's goal to improve pharmacovigilance and prevent inadvertent substitution." BPC emphasized that the use of meaningful suffixes reflective of the name of the manufacturer of the biologic, such as "-sndz," meets the needs of "biologics prescribers in day-to-day human interactions with patients, pharmacists and other health care professionals."

Pharmacies and insurers also preferred suffixes with meaning to the ones proposed by the FDA. CVS Health stated that a "random meaningless four-letter suffix ... could increase the rate of prescribing and dispensing errors compared to use of a naming convention in which the name is composed of the same 'core name' plus a meaningful four-letter suffix." Blue Cross Blue Shield Association also favored "using a suffix with meaning, derived from the manufacturer's name." The association was concerned that "the use of suffix without meaning logic may lead to arbitrary and/or erroneous usage of biological products."

Innovator companies also urged the FDA to adopt meaningful and memorable suffixes rather than random ones. Genentech, a developer of antibody products, stressed that memorable suffixes "will increase transparency and result in more well-informed and safe use of medicines." Pfizer Inc., an innovator and biosimilar maker, explained that "although a randomly assigned letter suffix would be better than no unique identifier, Pfizer does not believe a random suffix would achieve accurate and efficient reporting as easily as a meaningful suffix." Pfizer also stated that if the FDA ultimately adopts random suffixes instead of meaningful ones, the suffix it adopts should be the same across a company's biological products "such that over time it will become associated with the company and make accurate reporting easier." Allergan PLC, an innovator and biosimilar maker, explained that "the designation of a suffix that is the same for all of a license holder's products would reduce the number of suffixes the health care professionals must remember, facilitating the appropriate and correct use of the suffixes."

Given the many practical reasons not to use random suffixes and the largely uniform preference of innovators and biosimilar makers alike for meaningful and therefore memorable suffixes, the FDA may reconsider its naming approach and adopt meaningful suffixes to distinguish biosimilar and originator products.

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