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Submitted via the Federal eRulemaking Portal: http://www.regulations.gov

Acting Commissioner Norman E. Sharpless, M.D.
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Nonproprietary Naming of Biological Products: Update; Draft Guidance for Industry; Availability [Docket No. FDA–2013–D–1543]

Dear Dr. Sharpless:

Vizient, Inc., respectfully submits our comments to The Food and Drug Administration (FDA or the Agency) regarding "Nonproprietary Naming of Biological Products: Update; Draft Guidance for Industry" as published on March 8, 2019 in the Federal Register (Vol. 84, No. 46).

Background

Vizient is the nation's largest health care performance improvement company. Our mission is to strengthen our members' delivery of high-value care by aligning cost, quality and market performance. Vizient is member-driven and member-minded, working tirelessly to amplify each organization's impact by optimizing every interaction along the continuum of care. We serve a diverse membership including academic medical centers, pediatric facilities, community hospitals, integrated health delivery networks and non-acute health care providers. Vizient is headquartered in Irving, TX with locations in Chicago, Washington, D.C., and other cities across the country.

Recommendations

Vizient appreciates the Food and Drug Administration's ongoing development and implementation of the provisions of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). We applaud the FDA's thoughtful approach, ongoing commitment to increased awareness of biologic manufacturing and regulatory principles, and furthermore the application of scientifically based decision-making in the introduction of biosimilar medications.

Vizient supports the introduction and adoption of biosimilars as safe and effective alternatives to originator biologics, and continues to provide education to physicians and other providers to remove barriers to product acceptance. We strongly believe that biosimilars are a critical component of the ongoing efforts to minimize health care costs and mitigate increasing drug expenditures to preserve access to care. In our support of promoting and encouraging a sustainable market for the continued growth and adoption of biosimilars, Vizient would like to provide the following comments to the recently published draft guidance on the nonproprietary naming of biological products.

Remove Suffix Requirements for all Biologics Including Biosimilars

Vizient previously expressed serious administrative and safety concerns regarding the Agency's naming framework for biologics and biosimilars in our comments on its draft guidance on "*Nonproprietary Naming of Biological Products*." Additionally, on behalf of Vizient, Steven Lucio, PharmD, BCPS, Associate Vice President, Center for Pharmacy Practice Excellence participated in the FDA's public hearing on September 4, 2018, "Facilitating Competition and Innovation in the Biological Products Marketplace", and Vizient responded to the request for comments. We continue to believe that the application of a differentiating, "devoid of meaning", suffix to biosimilars and originator reference products is an unnecessary and potentially dangerous approach – which serves only to increase the complexity of managing medication information throughout the transitions of care process.

Vizient applauds the FDA's decision not to require the addition of suffixes to the nonproprietary names of previously approved originator biologics as well as transitional biological products. We further recommend that FDA simplify the approach to nonproprietary naming by discontinuing the requirement of differentiating devoid of meaning suffixes for all biologics, including biosimilars.

Vizient and its members recognize the absolute necessity of adequate pharmacovigilance for all medications, small molecule and biologic, branded, generic, and biosimilar alike. While the FDA's approval process has continued to yield biosimilars of equivalent safety and efficacy to their originator predecessors, the continued documentation of that comparability will support sustained clinician and prescriber confidence. Additionally, we strongly believe that success in pharmacovigilance can be delivered via use of other available identifiers without the inclusion of an additional suffix.

Existing identifiers such as the national drug code, the product's proprietary name, and the unique serialization (as defined under the Drug Quality and Security Act[1]), now provide multiple mechanisms to differentiate biosimilars from each other and from their originator reference biologics.

Medication safety organizations have documented the potential for abbreviations and suffixes to contribute to medication errors, particularly when there is no standard interpretation of a suffix to provide a clear meaning[2]. The use of suffixes for which meaning is deliberately avoided adds unnecessary complexity to the medication management process. Vizient has heard, through formal queries, from many of our member organizations that they disagree with the Agency's current approach and believe that the inconsistent application of the naming requirements will contribute to provider reluctance to prescribe biosimilars.

Vizient recognizes that the biosimilar market remains in a formative stage. We also understand that other challenges, including reimbursement considerations and ongoing patent litigation, may presently be negatively affecting the uptake of biosimilars to a greater degree than

[1] Drug Supply Chain Security Act of 2013. Title II of Pub. L. 113-54 amending the FDC Act, (21 U.S.C. 351 et seq.). Pub.L. 113–54
[2] National Coordinating Council for Medication Error Reporting and Prevention. Promoting the Safe Use of Suffixes in Prescription Drug Names. www.nccmerp.org/promoting-safe-use-suffixes-prescription-drug-names. Accessed March 2018.

decisions related to naming[3]. However, Vizient recommends that the FDA consider steps to address all barriers, both large and small, that could limit uptake of biosimilars and the opportunity for the realization of greater value for the U.S. healthcare market and our members. As such, we respectfully request the FDA reevaluate its approach to biosimilars so that comparability is sustained for all facets of biologics.

Conclusion

Vizient welcomes the FDA's discussion and its emphasis on stakeholder involvement, which provides a significant opportunity for the health care industry to inform the Agency on nonproprietary naming of biologicals. We look forward to continuing to work with the FDA to support strategies that increase biosimilar adoption, minimize health care costs and mitigate increasing drug expenditures to preserve access to care. In addition, Vizient continues to implement sourcing strategies to support members in their efforts to lower costs through biosimilar adoption.

Vizient membership includes a wide variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. Additionally, many are specialized, including academic medical centers and pediatric facilities. Individually, our members are integral partners in their local communities, and many are ranked among the nation's top health care providers. In closing, on behalf of Vizient, I would like to thank the FDA for providing us this opportunity to comment on this important guidance. Please feel free to contact me at (202) 354-2600 or Chelsea Arnone, Director of Regulatory Affairs and Government Relations (chelsea.arnone@vizientinc.com), if you have any questions or if Vizient can provide any assistance as you consider these issues.

Respectfully submitted,

Shoshana Krilow
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[3] Cipriano M. Woodcock: concerns about US FDA's biosimilars suffix policy detached from reality. The Pink Sheet, March 20, 2019.