

May 31, 2019

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

***Re: The Future of Insulin Biosimilars: Increasing Access and Facilitating the Efficient Development of Biosimilar and Interchangeable Insulin Products[FDA-2019-N-1132]***

Dear Acting Commissioner Sharpless:

The Academy of Managed Care Pharmacy (AMCP) thanks the Food and Drug Administration (FDA) for the opportunity to comment on its public hearing on *Increasing Access and Facilitating the Efficient Development of Biosimilar and Interchangeable Insulin Products [FDA-2019-N-1132]*. AMCP appreciates FDA's efforts to address the rising costs of insulin and focuses our comments on the naming of biosimilar insulin products and efforts for training and development of educational resources for biosimilar and interchangeable insulin products.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of healthcare dollars. Through evidence- and value-based strategies and practices, the Academy's 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

According to a National Diabetes Statistics Report from the Centers for Disease Control and Prevention (CDC), there are over 30 million Americans with diabetes<sup>1</sup>, many of them requiring insulin to manage their disease. In fact, over 7 million Americans with diabetes use at least one form of insulin, and almost one-fourth (24%) of adults with diabetes under the poverty level use insulin.<sup>2</sup> Access to insulin can mean life or death, and it can keep patients out of the hospital and in better health. Unfortunately, insulin prices are rapidly increasing, threatening access to this medication for many patients. In an analysis conducted from 2012 to 2016, the Health Care Cost

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<sup>1</sup>Centers for Disease Control and Prevention (2017). National Diabetes Statistics Survey, 2017. Available at: <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>. Accessed May 29, 2019.

<sup>2</sup> Cefalu WT, Dawes DE, Gavlak G, et al. Erratum. Insulin Access and Affordability Working Group: Conclusions and Recommendations. *Diabetes Care* 2018;41:1299-1311. *Diabetes Care*. 2018;41(8):1831.

Institute (HCCI) found that the average point-of-sale price of insulin nearly doubled from \$0.13 to \$0.25 per unit and the wholesale acquisition cost (WAC) increased by 15% to 17% every year.<sup>3</sup> Additionally, the Kaiser Family Foundation found that the total Medicare Part D spending on insulin rose from \$1.4 billion to \$13.3 billion between 2007 and 2017 – an 840% increase.<sup>4</sup>

Biological products are certain to play an increasingly important role in the country's health care system for many chronic conditions in addition to diabetes and have resulted in scientific improvements in the treatment of disease but also contributed to the rising costs of pharmaceuticals. Our members are strong supporters of biosimilars and reducing barriers to them to include reduction of cost. In December 2018, AMCP applauded former FDA Commissioner Scott Gottlieb's statement to reclassify insulin as a biologic by 2020, which would allow for biosimilar substitution that can contain the cost of treatment and create space to drive innovation and increase competition for biosimilar insulin products.<sup>5</sup>

AMCP shares the FDA's commitment to patient safety and recently addressed our concerns with FDA's updated draft guidance on Nonproprietary Naming of Biological Products in May 2019.<sup>6</sup> In the updated draft guidance, the FDA proposed that it will no longer retroactively modify the legacy names of biological products that have already been licensed or approved without an FDA designated suffix. However, FDA will continue to assign suffixes to newly approved innovator biologics, all biosimilars, and interchangeable biosimilar products. Consequently, two separate naming conventions for the same class of products will be established. AMCP is concerned with the FDA's proposed updates to its naming convention and believes that it may negatively impact patients as well as impede biosimilar adoption.

Utilizing a different naming approach for a biosimilar or interchangeable product, including insulin products, is likely to lead to confusion amongst prescribers and pharmacists. For example, inconsistent naming could result in clinicians incorrectly believing that the biosimilar is clinically different than its reference product. There may also be confusion as to what insulin products can be interchanged, especially when interchangeable designation is gained for an

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<sup>3</sup> Biniek JF, Johnson W. 2019. Health Care Cost Institute. Spending on Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices. Available at: <https://www.healthcostinstitute.org/research/publications/entry/spending-on-individuals-with-type-1-diabetes-and-the-role-of-rapidly-increasing-insulin-prices>. Accessed May 29, 2019.

<sup>4</sup> Cubanski J, Neuman T. Kaiser Family Foundation. April 1, 2019. How Much Does Medicare Spend on Insulin? Available at: <https://www.kff.org/medicare/issue-brief/how-much-does-medicare-spend-on-insulin/>. Accessed May 29, 2019.

<sup>5</sup> FDA Statement. December 11, 2018. Statement from FDA Commissioner Scott Gottlieb, M.D. on New Actions Advancing the Agency's Biosimilars Policy Framework. Available at: <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-actions-advancing-agencys-biosimilars-policy>. Accessed on May 29, 2019.

<sup>6</sup> AMCP. May 7, 2019. Nonproprietary Naming of Biological Products: Update; Draft Guidance for Industry; Availability (Docket – FDA-2013-D-1543). Available at: <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=24397>. Accessed May 29, 2019.

existing product that is already on the market. This may lead to delays in patient care at the pharmacy counter and high cost for patients if they cannot access a more cost-effective interchangeable product.

AMCP has previously expressed concern that the establishment of a suffix will create confusion among healthcare practitioners and patients, have negative effects on the ability to ensure safe dispensing and tracking, and result in lower market adoption and cost-savings.<sup>7</sup> Therefore, AMCP supports the use of the international nonproprietary name for biosimilar and interchangeable biosimilar insulin products with no suffix. This naming convention will allow for the FDA strive to ensure consistency in the naming process and avoid any additional confusion, safety concerns, and delays in patient care.

The introduction of biosimilar and interchangeable insulin products to the market will require strong educational efforts to address any concerns regarding efficacy and safety, among other factors, from patients and clinicians. AMCP supports efforts for training and development of education resources, including the adoption and dissemination of existing education resources, such as AMCP's Biosimilars Resource Center (BRC)<sup>8</sup> to provide neutral, unbiased education resources to pharmacists, physicians, nurses, and other health care providers. AMCP appreciates FDA's previous education efforts and believes that it should continue to build upon those efforts and use its resources and influence to enhance its current education campaign on biosimilar and interchangeable insulin products. We continue to recommend that FDA utilizes AMCP and other organizations as a resource and to increase awareness.

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<sup>7</sup> AMCP. October, 2015. Nonproprietary Naming of Biological Products (Docket – FDA-2013-D-1542) Designation of Official Names and Proper Names for Certain Biological Products (Docket – FDA-2015-N-0648). Available at: [http://www.amcp.org/uploadedFiles/Production\\_Menu/Policy\\_Issues\\_and\\_Advocacy/Letters,\\_Statements\\_and\\_Analysis\\_-](http://www.amcp.org/uploadedFiles/Production_Menu/Policy_Issues_and_Advocacy/Letters,_Statements_and_Analysis_-)

[\\_docs/2015/AMCP%20Letter%20to%20FDA%20Re%20Biosimilar%20Naming%20Draft%20Guidance%20and%20Proposed%20Rule\\_October%202015\\_Final.pdf](http://www.amcp.org/uploadedFiles/Production_Menu/Policy_Issues_and_Advocacy/Letters,_Statements_and_Analysis_-docs/2015/AMCP%20Letter%20to%20FDA%20Re%20Biosimilar%20Naming%20Draft%20Guidance%20and%20Proposed%20Rule_October%202015_Final.pdf). Accessed April 18, 2019.

<sup>8</sup> The Biosimilars Resource Center (BRC) provides educational resources and information on biosimilars to health care providers and other stakeholders in a policy-neutral and non-promotional manner. Biosimilars have the potential to significantly decrease health care costs in the United States and improve access to treatment for patients. The need for education of health care providers on how to prescribe and dispense cost effective biosimilars is critical to driving adoption and maximizing their use in a safe and effective manner for patients. The BRC provides access to educational tools and training materials for biosimilars, including one-pagers, web-based educational seminars, continuing education and journal articles. The BRC was launched in 2016 by the Academy of Managed Care Pharmacy in partnership with the American Association of Colleges of Pharmacy, America's Health Insurance Plans, the American Pharmacists Association, the American Society of Consultant Pharmacists, the Hematology/Oncology Pharmacists Association, the National Alliance of State Pharmacy Associations, and the National Community Pharmacists Association. For more information on the BRC, please visit <https://www.biosimilarsresourcecenter.org/>.

## Conclusion

AMCP appreciates your consideration of the recommendations and concerns outlined above and looks forward to continuing work on these issues with FDA. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-684-2600 or [scantrell@amcp.org](mailto:scantrell@amcp.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Susan Cantrell". The signature is fluid and cursive, with a long horizontal line extending from the top of the "t" in "Cantrell".

Susan A. Cantrell, RPh, CAE  
Chief Executive Officer