

January 28, 2020

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re: Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products; Draft Guidance for Industry; Availability**

Dear Commissioner Hahn,

The undersigned groups share the Food and Drug Administration's (FDA) deep commitment to the development of a robust biosimilars market and appreciate the Agency's work to develop an efficient approval pathway for biosimilars to bring savings and access to America's patients. As such, we support the approach outlined in the "Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products" draft guidance. **Specifically, we agree with the Agency's assessment that if a manufacturer demonstrates its proposed biosimilar insulin is "highly similar" to its reference product, the Agency may waive the need for the manufacturer to conduct additional immunogenicity studies in order for the Agency to deem the product as interchangeable with its reference product.**

As the Agency highlights in the draft guidance, under the supervision of their health care practitioners, patients requiring insulin treatment regularly switch between branded insulins and have done so for decades. This extensive clinical experience has identified no meaningful clinical impact of immunogenicity on the safety or efficacy of insulin product use. Given the highly similar nature of a biosimilar to its reference product, adverse impacts are likely to be even less of a concern than those for switches between branded insulin products.

The lack of more-affordable alternatives to branded insulin products has been characterized as a "public health crisis" and highlighted as a priority by numerous members of Congress and the Administration. We believe finalizing the policy outlined in the draft guidance will help speed the availability of automatically substitutable biosimilar insulin to America's patients, thereby increasing competition and promoting more affordable access through lower prices and out-of-pocket costs—the stated goal of the Administration's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.

To that end, we support the Agency's flexibility in implementing statutory evaluation requirements for biosimilar and interchangeable products. However, we believe it is important for FDA to ensure that its approach to biosimilar and interchangeable insulin products is consistent with its approach to biosimilars and interchangeable products broadly.

As such, we are concerned with the Agency's interpretation that biosimilars that are "more complex" than insulin be subject to more rigorous approval requirements than "less complex" biologics such as insulin. We encourage the Agency to use its experience with insulin to further streamline regulatory requirements for biosimilar and interchangeable biologics broadly. We believe that providing biosimilar manufacturers as much clarity and flexibility as possible, while maintaining the FDA's high standards for patient safety, is the appropriate guiding principle for Agency decisions related to further developing biosimilar policy.

We thank you for the Agency's continued work to ensure insulin biosimilars are able to efficiently be developed and come to market post-March 2020 for the patients who need them. We thank you for your time and consideration.

Sincerely,

Academy of Managed Care Pharmacy  
America's Health Insurance Plans (AHIP)  
Association for Accessible Medicines & the Biosimilars Council  
Black Women's Health Imperative  
Blue Cross Blue Shield Association  
Citizens Against Government Waste  
Citizen Outreach  
Consumer Action  
FreedomWorks  
Healthcare Supply Chain Association  
Innovation Defense Foundation  
National Alliance of Healthcare Purchaser Coalitions  
National Association of Chain Drug Stores  
National Community Pharmacists Association  
National Taxpayers Union  
Ohio Public Employees Retirement System  
Pacific Business Group on Health  
PCMA  
Prime Therapeutics  
Vizient