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Robert M. Califf, M.D.
Commissioner Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Considerations in Demonstrating Interchangeability With a Reference Product: Update (FDA-2017-D-1054)

Dear Dr. Califf:

Vizient, Inc. appreciates the opportunity to respond to the Food and Drug Administration (FDA) draft guidance *Considerations for Demonstrating Interchangeability with a Reference Product: Update* (hereinafter the "Draft Guidance").[1] Vizient thanks FDA for reconsidering prior guidance as we believe certain elements, particularly the need for a switching study or studies, were excessively burdensome and unnecessary, as noted in our prior comments.

Background

Vizient, Inc., the nation's largest provider-driven healthcare performance improvement company, serves more than 65% of the nation's acute care providers, which includes 97% of the nation's academic medical centers, and more than 35% of the non-acute market. Vizient provides expertise, analytics and consulting services, as well as a contract portfolio that represents $140 billion in annual purchasing volume. Solutions and services from Vizient improve the delivery of high-value care by aligning cost, quality and market performance. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Recommendations

In the Draft Guidance, FDA intends to revise the May 2019 interchangeability guidance, *Considerations in Demonstrating Interchangeability With a Reference Product*, to provide new recommendations for applicants for proposed interchangeable biosimilar products. Based on these recommendations, an applicant would no longer need to provide a switching study or studies to show that a product is interchangeable with a reference product. Rather, under the Draft Guidance, if finalized, an applicant could rely on comparative analytical and clinical data, in addition to other relevant data to demonstrate interchangeability. Vizient strongly supports this modification as we agree that the switching study requirement is not necessary to provide assurances related to immunogenicity risks associated with alternating between the reference

[1] https://www.fda.gov/media/179456/download

product and proposed interchangeable product. In addition, comparative analytical data is particularly helpful when assessing products. Based on this information, Vizient urges FDA to promptly finalize the Draft Guidance.

Conclusion

While Vizient recognizes that FDA is not positioned to change statutory text to remove the interchangeability status, a change which Vizient would support, we applaud the FDA for its efforts to rely on more recent data and experience in evaluating products to streamline approvals of interchangeable biosimilars. 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 FDA for providing us the opportunity to comment on the Draft Guidance. Please feel free to contact me or Jenna Stern at jenna.stern@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these issues.

Respectfully submitted,

Shoshana Krilow
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Vizient, Inc.