The Future of Insulin Biosimilars: Increasing Access and Facilitating the Efficient Development of Insulin Biosimilar and Interchangeable Products

Testimony from the Endocrine Society

Docket No. FDA-2019-N1132

The cost of insulin has nearly tripled in the past fifteen years, making it difficult for many of the over 7 million people who use insulin to afford this medication and effectively manage their diabetes. This has put patient safety in jeopardy as patient self-rationing of their insulin may lead to unnecessary hospitalizations, complications or death and should not be a cost-savings approach that people with diabetes are forced to choose. The issue of insulin affordability is a top priority for the Endocrine Society and one we hear frequently about from our members, many of whom have conversations daily with their patients about their ability to afford their insulin. The Society represents over 18,000 basic and clinical researchers and physicians-in-practice worldwide. We commend the FDA for holding this public hearing to ensure that the approval of insulin biosimilars considers the safety of the product as the highest priority but still allows for approval of these products in an expediated manner.

Competition from multiple medications in a class typically drives down price, but this has not been the case with insulin. The price of modern insulins has continued to increase despite the availability of multiple competing brands on the market. Currently, no interchangeable biosimilar version of insulin is available due to the complexity of biologically replicating a human hormone and the strict FDA review process for the approval of biosimilars. Congress recognized the need for a less arduous approval process for biosimilars with the passage of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). The abbreviated licensure pathway set to go into effect on March 23,

2055 L Street NW
Suite 600
Washington, DC
20036

T. 202.971.3636
F. 202.736.9705

endocrine.org

2020 will allow for the development of interchangeable medications at a lower cost and will likely encourage new manufacturers to enter the insulin market.

The expectation is that availability of new biosimilar insulin products will result in cost-savings for Medicare, Medicaid, commercial insurers, and most importantly, patients. Analysis shows that new biosimilars are being introduced at an average price that is 47 percent lower than the reference biologic's list price.[1] Furthermore, cost savings may be realized from the regulation of insulin as a biologic as it will establish interchangeability with the reference product and allow for pharmacy-level substitutions. Although biosimilar drugs do not apply as great a downward pressure on drug costs as a true generic, the introduction of lower-cost insulin products is an important and meaningful step in improving the affordability of insulin. We support FDA's efforts to address the challenges of developing and approving biosimilar insulins.

In addition, it is critical that the FDA work with patients, caregivers, clinicians, pharmacists to educate and increase their awareness of biosimilars. Educating these stakeholders about the efficacy and safety of biosimilar insulins will be key to realizing the full benefit that additional insulin products can have on competition and price. A survey conducted in 2014 in the United States and European Union to understand the awareness and knowledge of biosimilars among patients, caregivers, and the general population found that general awareness was higher among patients with a diagnosed disease than the general population, and the greatest awareness was among those who were active in disease-specific advocacy groups. The study also found that those who had some familiarity with biosimilars had a more positive view of the safety and efficacy of these medications. These findings illustrate

[1] Analysis of IQVIA wholesale acquisition cost data for January 2019. The Center for Biosimilars. https://www.centerforbiosimilars.com/contributor/christine-simmon/2019/04/left-handright-hand-does-the-administration-know-that-fda-is-undermining-its-efforts-to-lower-patient-drug-costs-via-biosimilar-competition

the importance of a comprehensive education campaign around the value of biosimilars in general and with the introduction of each new biosimilar. Partnering with disease advocacy groups may be the most effective way to create positive impressions among patients and partnering with provider advocacy groups will be important to educate the clinicians prescribing the medications. If the biosimilar product will be interchangeable with the reference product at the pharmacy, the stakeholders must understand the differences and similarities between the products and that the biosimilar product will be equally as effective at treating their disease.

The Endocrine Society is encouraged by the potentially positive effect that the introduction of biosimilar insulins will have on competition and ultimately on the ability of patients to afford their insulin. If patients no longer need to choose between taking their full dose of insulin or paying their rent, they will be able to more effectively manage their disease and avoid costly, and possibly life-threatening, complications. However, the FDA must ensure that the approval process for biosimilars establishes equal safety and efficacy as the existing reference product in order to protect patients and build stakeholder confidence in biosimilar medications.