Comment from Alliance for Safe Biologic Medicines

This is a Comment on the **Food and Drug Administration** (FDA) Other: **Citizen Petition from AbbVie, Inc**

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Comment

I am chairman of the Alliance for Safe Biologic Medicines (ASBM), a group of physicians, patients, pharmacists, researchers, manufacturers of both biologics and biosimilars, and others who share the goal of promoting the introduction and ensuring the safe use of these important medicines. Formed in 2010, ASBM has worked with regulators worldwide to help craft biosimilar policy that increases access without compromising patient safety. Prior to being named chairman, I served for three years on ASBMs advisory board, offering my clinical perspective to their efforts.

As a practicing pediatric rheumatologist, I marvel every day at the dramatic transformation these innovative therapies have made in the lives of my patients and their families. I have watched us go from the days of walkers and wheelchairs to running and the possibility of a cure for chronic rheumatic diseases. I welcome and am excited over the many new therapeutic options on the horizon that will accompany the arrival of biosimilars. However, the complexity of biologic medicines, their high sensitivity to manufacturing differences, to light, to heat, to denaturing, and their potential to stimulate unwanted immune reactions in patients makes clear, transparent labeling absolutely essential.

In February 2015, a month prior to the FDAs approval of its first biosimilar, Zarxio (filgrastim-sndz), ASBM conducted a study of 400 U.S. physicians to learn what information they considered important to include on the label of a biosimilar. These physicians are certified in specialties in which biologics are regularly and routinely used (Dermatology, Endocrinology, Oncology, Nephrology, Neurology, or Rheumatology) and all currently prescribe biologics.

Physicians were asked to rate information on a scale from 1 to 5, (with 1 being not important and 5 being very important for inclusion on a biosimilars label). Presented below are the

items which prescribers of biologics consistently rated either a 4 or 5 (indicating high or very high importance) for inclusion:

90% - That product is a biosimilar
79% - A definition of biosimilarity
82% - Analytical data used by biosimilar sponsor to demonstrate its similarity to its reference product
83% - Clinical data used to demonstrate biosimilar is highly similar to reference product
79% - Post-market surveillance data on the biosimilar
77% - Name of the biosimilar's reference product
79% - Indications for which the originator is approved, but the biosimilar is not
79% - Clearly distinguish reference product data from biosimilar data
79% - Clinical similarity data including immunogenicity effects
80% - Which approved indications were actually studied, vs. which were extrapolated from data in other indications?
79% - Whether or not the biosimilar is "interchangeable" with its reference product

The full survey is available on the ASBMs website at www.safebiologics.org.

Unfortunately, none of this information is currently incorporated on Zarxios label.

This lack of adequate transparency regarding the data used to show biosimilarity on the Zarxio label was particularly troubling. The label lacks the clinical &/or analytical data used to demonstrate Zarxio's similarity to its reference product. It does not state for which of the five approved indications there is data, or which (if any) of these approved indications were based on extrapolation rather than trials. The label simply presents the data of the originator medicine without indicating the source of that data, potentially implying more information on Zarxio than what truly exists. Were Zarxio to produce different effects than its originator product, that information would not be easily available to physicians or patients.

Given the serious and timely nature of these concerns I shared the results of our physicians survey on labeling in a letter to the FDA Acting Commissioner Stephen Ostroff, MD. This letter is attached to these comments for your reference.

At a recent Continuing Education course for pharmacists ASBM conducted at Long Island University, many of the 125 pharmacists in attendance shared our concerns. Subsequently, three prominent pharmacists (including two former presidents of national pharmacy associations) wrote the FDA on the importance to the pharmacist community of clear, transparent labeling of biologic medications. I have also attached this letter for your reference.

It is our hope that our study results and their implications will serve to assist the FDA in its difficult task of approving future biosimilar medications as well as in developing your policy on product labeling, which I understand is scheduled to be issued later this year.

Thank you for the opportunity to weigh in on this important issue.

Sincerely,

Harry L. Gewanter, MD, FAAP, FACR
Chairman, Alliance for Safe Biologic Medicines

Attachments (2)

Comment from Alliance for Safe Biologic Medicines

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