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Brand, Generic Groups Differ on Biosimilar Labeling

From Pharmaceutical Law & Industry Report

By Bronwyn Mixter

June 6 — While the generic pharmaceutical industry wants less information in biosimilar labeling, the branded biopharma industry says more information is needed.

In comments on a draft guidance released by the Food and Drug Administration in March (14 PLIR 511, 4/8/16), the generic industry said providing too much information in biosimilar labels could confuse health-care providers and patients and lead to less use of biosimilars. However, the branded biopharma industry said more information is needed in the labels so patients and providers can make informed decisions.

Specifically, the Generic Pharmaceutical Association (GPhA) and 11 pharmaceutical supply chain groups and companies said in separate comments that the agency shouldn't require biosimilar labels to state that the product is a biosimilar and shouldn't include studies and analyses supporting biosimilarity.

Meanwhile, the Biotechnology Innovation Organization (BIO) and a coalition of patient advocacy organizations said in separate comments that the labels should say that the product is a biosimilar, should state whether the product meets a higher standard of interchangeability with

the original or reference product and should include the biosimilarity studies.

Comments on the draft guidance were due June 3, but the FDA extended the comment period until Aug. 2 (Docket No. FDA-2016-D-0643) (*see related story*). A biosimilar is a biological product that is approved by the FDA based on a showing that it is highly similar to an already approved biological product, known as a reference product (RP) or brand biologic. The biosimilar also must show it has no clinically meaningful differences in terms of safety and effectiveness. The Affordable Care Act created an abbreviated pathway for the FDA to approve follow-on biologic drugs, or biosimilars.

So far, the FDA has approved two biosimilars. Zarxio (filgrastim-sndz), Sandoz's biosimilar of Amgen's cancer treatment Neupogen and Inflectra (infliximab-dyyb), Pfizer's and Celltrion's biosimilar of Johnson & Johnson's arthritis treatment Remicade.

Generic, Supply Chain Groups

The Generic Pharmaceutical Association (GPhA) said in comments that the proposed biosimilarity statement in the draft guidance "not only is unnecessary but also may be confusing to patients and healthcare providers."

The GPhA said the FDA has never required generic products to be labeled as generics and "such information simply is immaterial to prescribing decisions."

"More significantly, the biosimilarity statement may suggest to patients and healthcare professionals that biosimilars have clinically meaningful differences from their RPs in terms of safety, purity, or potency when, in fact, they do not," the GPhA said. "This, in turn, could impede the update and use of biosimilar products and impair effective competition."

The GPhA said it supports the FDA's recommendation that biosimilar labeling "should focus on information on the clinical studies for the RP rather than the studies and analyses supporting biosimilarity." The group also said it supports the FDA's recommendation that biosimilar labeling should generally be modeled on the labeling of the reference product, like the labeling for small molecule generic drugs.

In separate comments, a group of 11 pharmaceutical supply chain associations also said a biosimilarity statement on labels is unnecessary and "will be confusing to patients and providers who are unfamiliar with this type of unprecedented statement. This confusion could put biosimilar utilization, and savings, at risk." The groups said

they support labeling that will lead to the increased access and cost-saving promise of biosimilars.

The supply chain associations include the Academy of Managed Care Pharmacy (AMCP), America's Health Insurance Plans (AHIP), the American Pharmacists Association (APhA), the Blue Cross Blue Shield Association (BCBSA), CVS Health, Express Scripts, the Healthcare Supply Chain Association (HSCA), the Pharmaceutical Care Management Association (PCMA), Premier Healthcare Alliance, Prime Therapeutics and UAW Retiree Medical Benefits.

BIO Weighs In

In its comments, BIO said that while it is "pleased to see the agency's recognition that a clear statement of biosimilarity provides essential information to inform the safe prescribing and use of biosimilar biological products," it is concerned that the proposed biosimilarity statement doesn't include information on interchangeability with a reference product.

"The failure to include such information risks creating confusion among prescribers, payers and other stakeholders regarding whether the biosimilar product has been determined to be interchangeable with the reference product," the industry group said.

BIO said that the draft guidance emphasizes that biosimilar labeling shouldn't include specific information about the biosimilar, but should instead rely on the reference product's data and information. "As BIO has long advocated, the labeling for a biosimilar should flow from the fundamental premise that due to the scientific complexities of biologics, biosimilars are neither expected nor required to be structurally identical to the reference product," the group said. "In this regard, more information is preferable to less."

BIO said that providing limited information in the labeling "leaves questions unanswered for healthcare providers in need of information to prescribe safely and effectively for an individual patient, as well as for formulary and other decision makers who rely on the label to determine how the biosimilar will be used."

"The prescribing physician needs to have access to all relevant information, including the relevant nonclinical and clinical data supporting the finding of biosimilarity, and the resulting labeling should be transparent to allow the prescriber to identify whether the described studies were conducted with the biosimilar or reference product," BIO said.

Patient Views

Meanwhile, the Patients for Biologics Safety and Access (PBSA), a coalition of more than 20 patient advocacy organizations, said in its comments that "patients and prescribers should have all pertinent information to make a knowledgeable decision whether to use an innovative biologic or biosimilar."

"In addition, adequate material on biosimilars must be available to patients and prescribers in a format that allows them to make such an informed choice that includes clear and transparent product labeling information as a critical component," the PBSA said. "We are pleased that the guidance requires products to be clearly labeled as biosimilars and contain standard information about immunogenicity concerns."

The PBSA said the final guidance should require pertinent clinical data and adverse events specific to the biosimilar to be included on the label, as well as a statement declaring whether or not the product has been approved as interchangeable.

"This information will help patients and prescribers have the necessary facts to make a fully informed choice whether to use the original biologic medicine or biosimilar," the PBSA said.

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For More Information

The draft guidance is at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInfor

The supply chain stakeholders comments are at http://www.gphaonline.org/media/cms/Biosimilars_Labeling_Group_Letter_

BIO's comments are at http://src.bna.com/fCU

PBSA's comments are at http://src.bna.com/fCb.