THE ERISA INDUSTRY COMMITTEE
Shaping benefit policies before they shape you.

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U.S. Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

Submitted Electronically via: www.regulations.gov

RE: Labeling for Biosimilar and Interchangeable Biosimilar Products; Guidance for Industry DRAFT GUIDANCE (FDA-2016-D-0643)

To Whom it May Concern:

The ERISA Industry Committee (ERIC) respectfully submits comments in response to the draft guidance for industry entitled "*Labeling for Biosimilar and Interchangeable Biosimilar Products*." ERIC is a national advocacy organization exclusively representing the largest employers in the United States in their capacity as sponsors of employee benefit plans for their nationwide workforces. With member companies that are leaders in every economic sector, ERIC is the voice of large employer plan sponsors on federal, state, and local public policies impacting their ability to sponsor benefit plans. ERIC member companies offer benefits to tens of millions of employees and their families, located in every state, city, and Congressional district.

ERIC supports efforts to drive better formulary access to biosimilar therapies, as doing so leads to greater competition in the market, resulting in more choices as well as lower costs for workers and their beneficiaries. Biosimilars are safe, effective, high-quality, and affordable alternatives to their reference biologics. The U.S. Food and Drug Administration (FDA) has a critical role in ensuring access to these therapies – without FDA approval, lack of access is all but assured.

We appreciate FDA's withdrawal of guidance specifying that an interchangeability statement be included in the labeling of products licensed as interchangeable. In the final guidance, we urge the agency to clearly communicate its rationale to withdraw previous guidance recommending that manufacturers include an interchangeability statement in the labeling of products licensed as interchangeable. This is a positive step towards ensuring competition and access to biosimilars.

ERIC has maintained that no difference should be drawn between biosimilar products and interchangeable biosimilar products, as both can be substituted for a reference product safely and effectively. Biosimilarity and interchangeability statements do not improve patient or health care provider understanding, and could instead be read to wrongly suggest that biosimilar and interchangeable biosimilar products are therapeutically different from their reference products, potentially leading to confusion and contributing to reluctance to place biosimilar and interchangeable biosimilar products in a preferred formulary position.

With more than 40 different biosimilars now available, including multiple interchangeable biosimilar products, patients, providers, and health care professionals are more aware of biosimilars and the educational resources available to them than they were during previous iterations of the guidance in 2016 and 2018.

Furthermore, creating an unnecessary distinction between biosimilars and interchangeable biosimilars would likely reduce access to proven and effective biosimilars and could force patients to use more expensive biologic products for no clinical reason. As the FDA has made explicitly clear:

"*[T]here may be inaccurate perceptions that interchangeable biosimilars are safer or more effective than biosimilars that are not approved as interchangeable. The interchangeability designation does not indicate a higher level of biosimilarity. Health care professionals can prescribe both biosimilar and interchangeable biosimilar products in place of the reference product with equal confidence that they are as safe and effective as their reference products*."[1]

ERIC recommends that, in addition to removing the interchangeability statement requirement from labeling, the FDA should remove the biosimilarity statements from the labeling of biosimilar products. This change would more closely align the labeling with that of small-molecule generic drugs, as labeling for those products does not include comparable statements or therapeutic equivalence ratings.

Thank you in advance for considering these comments. Please do not hesitate to contact me at 703-304-9891 or mbartlett@eric.org with any questions or if we can serve as a resource on these very important issues.

Sincerely,

Melissa Bartlett

Melissa Bartlett
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[1] Updated FDA Labeling Recommendations for Biosimilar and Interchangeable Biosimilars Products, FDA