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

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Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Attention:

RE: Considerations in Demonstrating Interchangeability with a Reference Product: Update; Draft Guidance for Industry [Docket No. FDA-2017-D-0154]

To Whom It May Concern:

The ERISA Industry Committee (ERIC) is pleased to submit the following comments in response to the Draft Guidance on the U.S. Food and Drug Administration's (FDA) "*Considerations in Demonstrating Interchangeability with a Reference Product*" ("Guidance").

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.

Employer-sponsored insurance covers over 180 million Americans, the largest source of health care coverage for patients. Each year, employers face staggering rises in the costs of health care, resulting in increases in health plan premiums and high out of pocket costs. While several factors may contribute to these increases, drug spending growth is among the top. Employers may mitigate the impact of growth in drug spending by ensuring their workforce has robust access to affordable drug therapies, particularly biosimilars. According to a 2023 study, since the first biosimilar launched almost ten years ago, patients and the health care system have saved nearly $24 billion.[1] Importantly, during this period, biosimilars were used in over 694 million days of patient therapy and patients received over 344 million additional days of therapy that otherwise would not have been provided.[2]

[1] Association for Accessible Medicines (AAM). (September 2023) "The U.S. Generic & Biosimilar Medicines Savings Report." Page 27. Accessible at https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf

[2] Association for Accessible Medicines (AAM). (September 2023) "The U.S. Generic & Biosimilar Medicines Savings Report." Page 9. Accessible at https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf

There is more that can be done to facilitate a sustainable, competitive drug marketplace. FDA's proposed revisions to the Guidance will, hopefully, lead to quicker access by patients to biosimilar therapies through the commercial pharmacy benefit. We have come a long way in our understanding of biosimilars, their safety, and efficacy. When the biosimilar regulatory pathway was created through the *Biologics Price Competition and Innovation Act of 2009* (BPCI Act), there was a rebuttable presumption created by the statute that since biosimilar products are not the same as their reference drug products, they are somehow presumed to be less safe or effective.[3] This is evident by the application of the interchangeability standard and the obstacles to approval it presents.

To that end, ERIC strongly supports legislation that would remove the interchangeability designation altogether[4], and strongly opposes legislation at the state level attempting to insert substitution requirements tied to interchangeability.[5] We applaud the FDA's work to date to right this ship – this includes the agency's recent efforts to remove the interchangeability statement from labeling, and its clarifications through advertising and promotional guidance that there are no safety, effectiveness, or quality differences between interchangeable biosimilars and biosimilars. With the proposed revision to this Guidance, the agency is taking an important step to further correct the false assumption that biosimilars without an interchangeability designation are less safe and effective.

Specifically, ERIC applauds the agency for recognizing the switching study requirement for what it is – a hurdle which delays and prevents competition. Removal of the switching study requirement does not compromise safety, efficacy, or quality. This is supported by FDA's own published research, as well as other published studies analyzing the wealth of information generated from biosimilars on the market.

With over 40 biosimilars now approved, the rebuttable presumption referenced above has begun to reverse.[6] As the agency explains, it issued the Guidance many years ago, before it had received and reviewed any biologics license applications (BLAs) submitted for approval as an interchangeable biosimilar. Now, as the agency clearly states, "*experience has shown that for the products approved as biosimilars to date, the risk in terms of safety or diminished efficacy is insignificant following single or multiple switches between a reference product and a biosimilar product*."[7]

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[3] Public Health Service Act § 351(k)
[4] Biosimilar Red Tape Elimination Act (S. 2305). Accessible at https://www.congress.gov/bill/118th-congress/senate-bill/2305
[5] ERIC. (November 2023) "ERIC Written Testimony and Request for Amendment to HB 291 – Allowing Formulary Substitution of Cost-Saving Biosimilar Medical Products." Accessible at https://www.eric.org/wp-content/uploads/2023/11/ERIC-Written-Comments-Ohio-HB-291-Biosimilars-11.1.23.pdf
[6] Association for Accessible Medicines (AAM). (September 2023) "The U.S. Generic & Biosimilar Medicines Savings Report." Page 9. Accessible at https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf
[7] FDA. (June 2024) "Considerations in Demonstrating Interchangeability With a Reference Product: Update Guidance for Industry." Page 1 and 2. Accessible at https://www.fda.gov/media/179456/download

ERIC agrees with this statement and appreciates the agency's clear communication of its rationale for removing the switching study requirement and updating the Guidance. This is a positive step towards ensuring competition and access to biosimilars, helping bring more affordable drug choices to patients faster.

Thank you for the opportunity to provide comments and for your consideration. Please do not hesitate to contact me at 202-789-1400 or mbartlett@eric.org with any questions or if ERIC can serve as a resource on these very important issues.

Sincerely,

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