

December 18, 2020

The Honorable Stephen M. Hahn, MD
Commissioner Food and Drug Administration
Dockets Management Staff (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: FDA-2015-N-3326; Reauthorization of the Biosimilar User Fee Act; Public Meeting;
Request for Comments

Dear Commissioner Hahn:

On behalf of the 54 million American adults and children with doctor-diagnosed arthritis, the Arthritis Foundation is pleased to offer comments on the Reauthorization of the Biosimilar User Fee Act (BsUFA). We thank the FDA for the invitation to provide testimony at the November 19, 2020 public meeting. This topic is of great importance to the arthritis community, as 12 biosimilars have been approved for arthritis and 3 have entered the market. Our comments below expand upon our testimony.

To a patient, the promise of biosimilars is more affordable and therefore increases access to medications. Understanding the factors contributing to biosimilar uptake is essential towards realizing that promise. While certain factors are market-related and outside the scope of the FDA, many relate to patient and provider knowledge, trust, and confidence in biosimilars, which is a major area of focus for the Arthritis Foundation.

The current biosimilars landscape is quite different than five years ago when the FDA last reauthorized BsUFA. There were no biosimilars on the market for arthritis at that time, and the Arthritis Foundation had begun to publish basic webinars and educational resources on the topic. Since then, we not only have biosimilars on the market, but we have also published multiple educational resources and conducted robust surveys and focus groups, gaining critical insights about those questions of trust, knowledge, and confidence. Specific highlights from our 2017 findings include the following:

- Less than half of respondents were **familiar** with biosimilars, and 27% had never heard the term
- There was **confusion** about the difference between a biologic and a biosimilar
- A little over half of respondents said they would be **confident** using a biosimilar knowing they have been approved by the FDA
- They care deeply about the **provider-patient relationship** and want decisions about switching to be made at the provider-level

In focus groups since then, we have learned that patients may not take a biosimilar if:

- They don't know about them
- Their doctor has not talked about biosimilars as a treatment option
- They fear they will not work as well and have concerns about interchangeability
- They may not have easy access through their formulary or the out-of-pocket cost is not significantly lower

Top sources of information about biosimilars include: their health care provider, which is both the most popular and the preferred source for information; the FDA, which is a highly trusted source; and many arthritis patients learn about biosimilars from the internet (46% in our 2017 survey).

From that data we concluded that barriers to uptake fall into four main categories:

- A lack of incentives to the patient
- Communication bias or misinformation
- Inherent fear of “the new”
- Formulary access challenges

The Arthritis Foundation has undertaken a number of activities to address these barriers, including enhancing our patient education to “normalize” the term biosimilars in our materials and outreach; coordinating closely with provider groups; working with the FDA on their patient education materials; and working with a broad group of stakeholders to address barriers to biosimilars uptake.

We recognize that developing best practices and coordinating education and outreach activities with the broader patient and provider community is essential, and as such we brought together patient and provider groups across therapeutic areas in the summer of 2019 to identify areas of collective activity. The biosimilars landscape had changed significantly in the previous couple of years, and we wanted the opportunity to learn what barriers groups had experienced, and any lessons learned and best practices from education and outreach efforts. Several clear themes emerged that we turned into a set of principles signed by 21 patient and provider groups, available on our [website](#). The two most relevant principles for the FDA are:

1. Patient trust in the safety and efficacy of biosimilars, and physician confidence in prescribing them, are crucial factors for driving broader uptake.
 - a. FDA is a vital resource that patients, physicians, and others turn to for trusted information. The agency will continue to be an essential source for providing education and communication about biosimilar products to patients, physicians, and other health care stakeholders.
 - b. We are committed to fostering peer-to-peer opportunities for patients to learn from one another about all biological products and sharing their experiences with policymakers.

- c. Patient and provider organization websites are a vital resource for patients and providers to get trusted information about biological products, including biosimilars
2. The language health care stakeholders use to talk about biosimilars matters.
 - a. Many stakeholders use different terms to describe biosimilars, which can lead to confusion and bias
 - b. Using language from the FDA can help avoid unintentional bias and accurately convey concepts that are often nuanced and complex
 - c. When discussing potential adverse impacts, distinctions should be made regarding transitions between reference biologics versus transitions between a reference biologic and a biosimilar. Stakeholders should come together on a common set of terms to describe these differences

In our discussions we collectively agreed on the importance of the FDA as the top resource for education and information about biosimilars. From there we identified two core needs: collecting more data on patient and provider perceptions of biosimilars, and in particular the differences in perception among patients who are biologic naïve versus those who have been stable on their biologic; and developing best practices around communicating unbiased information to our patients and providers. On the latter, we have learned a lot about the nuanced nature of communicating about biosimilars, and how simple word choices can influence how patients feel about them. Using seemingly innocuous phrases like “they are cheaper” can lead patients to believe they are also lesser. Further, there is data to suggest this can have an impact on patient perception of the efficacy of the drug, potentially leading to the nocebo effect.

With that in mind, we have a sense of urgency in addressing these issues, and our goal is to turn those principles into practice. We hope the FDA shares that sense of urgency, as we know that over the course of BsUFA III more biosimilars will be approved and come to market, including self-injectables, which will make these themes even more important.

The FDA has been a tremendous partner in working with the patient community and being readily available to partner on patient and provider education.

Our recommendations for BsUFA III correlate directly with our priorities for moving those patient-provider principles forward:

- First, we call on the FDA to continue to work with the patient and provider communities on biosimilars education, and in particular to work hand in hand with us to maximize our reach:
 - On data collection, for example, there are additional layers of information about patient preferences and concerns that need to be collected, and there are ways we can collect data that the FDA cannot, and vice versa.
 - On addressing bias, it would be a tremendous asset to have a set of best practices organizations can use to ensure the materials they are developing

on biosimilars do not include unintentional bias; one such best practice might be making it a standard practice for organizations to vet their language with the FDA before publishing their materials

- Second, there are specific needs around education; and in particular there remains a great deal of confusion about interchangeability. Clearing up lingering points of confusion can help increase confidence in biosimilars, and in particular biosimilars that are not deemed interchangeable.
- Finally, patient engagement should remain a priority, and to the extent applicable, we would encourage the FDA to carry over lessons from PDUFA patient engagement activities into BsUFA. This could include versions of patient-focused drug development meetings, guidance on collecting and implementing real world evidence, and engaging patients throughout the approval and post-approval processes. To reiterate previous points, understanding what leads to patient trust and confidence requires talking to patients and learning from them.

Thank you for the opportunity to comment on the BsUFA reauthorization. We look forward to collaborating with the FDA through development and implementation of BsUFA III. Please contact me at ahyde@arthritis.org should you have any questions or would like further information about our comments.

Anna Hyde



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