

# Biosimilars

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## F O R U M

### **February 3, 2022 Testimony**

Good morning. My name is Juliana Reed, and I am the President of the Biosimilars Forum. On behalf of the Forum members, I would like to thank you for inviting me to participate in the hearing today.

The Forum is a non-profit trade association whose mission is to educate stakeholders on the value of biosimilars and to improve access to biosimilars in the United States. Our members represent the majority of companies with the most significant U.S. biosimilars development portfolios, including: Biogen, Boehringer Ingelheim, Coherus BioSciences, Organon Inc., Pfizer Inc., Samsung Bioepis, Sandoz, Teva, and Viartis. My remarks today represent the views of our members, all of whom manufacture or market biosimilar products.

Biosimilars have the potential to provide very significant health care savings in the U.S. Although biologics represent only four percent of medicines prescribed to patients in the US, the cost of these drugs represents approximately 40 percent of total prescription drug spending. Biosimilars provide necessary competition to allow Americans access to lower-cost biologic alternatives, and their timely licensure and launch is vital to ensuring timely patient access to many life-saving or life-altering medications.

The Biosimilars Forum is supportive of the negotiated BsUFA III agreement, and we believe it represents important progress in facilitating timely access to safe and effective biosimilar medicines for patients. We are pleased the commitment letter codifies review timelines for labeling supplements, provides meeting management enhancements, and promotes best practices of communication between FDA and sponsors. These commitments will go a long way toward improving the efficiency of the biosimilar review process.

The Forum is particularly pleased that the BsUFA III program will include a regulatory science program that can help bring more biosimilars to market faster. Since the BPCIA was enacted over a decade ago, there have been many advances in the science of developing biological drugs. The regulatory science program will provide FDA and industry the ability to incorporate the latest scientific innovations into biosimilar development and regulation. It is a win-win for all.

Although we are very satisfied with the progress represented in the BsUFA III commitment letter, we want to stress that the pandemic has impacted biosimilars and patient access disproportionately hard for almost two years. We would like to ask the FDA for clarity to sponsors and the public as to the estimated timelines the FDA believes it will take to address the backlog in inspections and reviews.

Additional COVID-19 variants have stalled on-site inspections, making the situation even more uncertain. Per the Agency's May 2021 Resiliency Roadmap for FDA Inspection Oversight, biosimilar inspections are not, on their own, considered to be "mission critical" and thus are not prioritized. This has the ultimate outcome of preventing patients from quickly accessing lower cost biosimilars.

The COVID-19 related inspectional backlog has had a significant impact on biosimilars. The percentage of on-time actions for original biosimilar product applications, including resubmissions, has been unstable since the summer of 2020. On the other hand, over the past two years, on-time actions for the GDUFA and PDUFA programs have averaged over 90%; the BsUFA program, however, plunged to 75% during Quarter 4 of FY 2020, and further dropped to 67% during Quarter 1 of FY 2021. The program briefly recovered in Quarter 3, but the latest data shows another drop to 67% in Quarter 4, demonstrating unrelenting challenges for on-time action on biosimilars. This trend for biosimilar applications is markedly worse than for other user fee programs and suggests that biosimilars have been more adversely affected by pandemic-related inspectional issues. For the BsUFA III Commitment Letter to be a success and for FDA to meet its goals of first-cycle licensure of biosimilar and interchangeable products, the inspection backlog for biosimilars must be addressed.

The Forum is encouraged by FDA's commitment to hire and retain sufficient numbers and types of technical and scientific experts to efficiently conduct reviews and applauds the agency's efforts to improve its use of data and technology. In this vein it would be very helpful for the Agency to report separately on metrics related to 351(a) "original" biologics and 351(k) "biosimilars." These metrics are currently combined, making it difficult to truly assess the FDA's performance as it relates to biosimilars.

As we head into BsUFA III we look forward to working with the Agency to implement the commitment letter to the mutual benefit of biosimilar sponsors and FDA. We are excited by the fact there is now a robust biosimilar industry, with significant development experience, to help BsUFA further develop over the next five years. We are at a critical inflection point for the biosimilars industry and we believe that enhancing the process for biosimilar review will be critically important to sustaining and cementing the biosimilar pathway for years to come, which will help us all achieve our goal of improving patient access to biosimilars.

To conclude, thank you for the opportunity to speak today. The Forum strongly supports efforts to advance a robust biosimilars program. Policies that support timely approval of biosimilars will ensure that patients have more access to high quality, safe, effective, and affordable biological therapies.

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