Biosimilars
FORUM

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Good morning Mr. Chairman and members of the Committee.

Thank you for the opportunity to be here today.

I am Juliana Reed, Vice President of Government Affairs for Coherus BioSciences and the Immediate Past President of the Biosimilars Forum. I was a member of the Forum's Biosimilars User Fee Act (BSUFA) negotiating team last year.

The Biosimilars Forum appreciates the opportunity to testify today regarding its participation in the negotiations for the BsUFA program for FY2018 - FY2022 (BsUFA II) and to provide our perspective on the reauthorization of the user fee program legislation. We urge Congress to support the outcome of BsUFA II negotiations and to reauthorize the program prior to September 30, 2017.

The Biosimilars Forum is a non-profit trade association representing biosimilars manufacturers. We are dedicated to the development of a new and sustainable biosimilars market in the U.S. with the goal of expanding access to these important medicines while lowering costs for patients and the overall U.S. healthcare system. The members of the Biosimilars Forum represent the majority of U.S. biosimilar programs in development at the FDA and are subject to the user fees that we are discussing today.

The Biosimilars Forum is solely focused on biosimilars and the associated policies necessary to foster a vibrant U.S. biosimilars market that delivers high quality, safe, and effective biosimilar medicines over the long-term. This singular focus on biosimilars is important; it is a recognition that biosimilars are unique – they are not generic drugs and they are not branded biologics. Biosimilars are a new and distinctive industry sector, created by Congress via the Biologics Price Competition and Innovation Act (BPCIA), and governed by new and individualized policies and regulations solely devoted to this sector of the bio-pharmaceutical industry. In fact, FDA's regulatory treatment of biosimilars reinforces the uniqueness of each product through the Agency's approval pathway, naming policy, and pharmacovigilance efforts. This distinction is important to the members of the Forum and something on which we continuously work to educate our partners. As we together work to build this new industry, we all need to look at biosimilars with a different lens that acknowledges this distinction.

Biosimilar products are biological products that are approved by the FDA based on demonstrating high similarity to an already-approved biological product, known as a reference product. Biosimilars have no clinically meaningful differences from the reference product in terms of quality, safety and effectiveness. The potential of biosimilars has just begun to be realized, as the first four products were approved over the last two years (with two products currently launched). Biosimilars provide affordable options for patients and contribute to the goal of increasing patient treatment options while providing significant cost savings for the U.S. healthcare system.

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The Biosimilars Forum is proud to have participated in industry negotiations with the FDA regarding the reauthorization of BsUFA, and greatly appreciates the cooperation of the Agency and the other industry groups represented during the negotiations.

The Forum entered into the BsUFA II negotiation process with four primary goals:

- Ensuring solid financial support for the program;
- Improving communication between the FDA and biosimilars product sponsors during the approval process to improve efficiency;
- Increasing transparency during the approval process and regarding the spending of user fees; and
- Preventing the expenditure of BsUFA funds on extraneous policy issues or activities that are not exclusive to biosimilars.

We are pleased to say that the resulting agreement expressed in the Commitment Letter and the implementing legislation meet these objectives.

The terms of the Commitment Letter and the reauthorization legislation will provide the necessary time and resources needed by the FDA to support a successful biosimilars program, and meet the Forum's overarching goal of providing ongoing support to this important program. This ultimately will benefit patients by advancing biosimilar approvals and access in the U.S.

Within BsUFA II, there are significant enhancements to the Biosimilar User Fee program that support the review and approval of biosimilar medicines in the U.S. These agreed-to enhancements include:

- A revised review process meant to increase transparency and communication between the FDA and biosimilars sponsors that will facilitate an increase in the likelihood of first-cycle approval;
- Agency commitments to complete and publish several draft and final guidance documents that will provide industry with additional clarity and certainty regarding the biosimilars development and review process;
- Agency commitments to augment and strengthen staffing of the biosimilars program, including hiring product reviewers; and
- Enhancements to the user fee structure and management that will allow greater transparency, predictability and long-term stability of biosimilar development programs in the U.S.

The Forum applauds the efforts made by the FDA to work with industry toward a more efficient and transparent review process. The negotiations resulted in improvements in communication and accountability between sponsors and FDA, and the focusing of the industry's contributions of BsUFA funds on matters exclusively related to the FDA's biosimilars review program. The goals set out in the Commitment Letter and reflected in the reauthorization language will help ensure timely and more transparent review of biosimilar products, to the benefit of patients who need these products.

We encourage Congress to support the BsUFA reauthorization and to provide the FDA with the necessary government resources it needs to continue building its biosimilar program. The commitments made by the FDA, combined with the financial support of Congress and industry ultimately will benefit patients by getting these important products to market.

Mr. Chairman, reauthorization of the BsUFA program is key to the successful implementation of the BPCIA. But I would be remiss if I didn't also mention that it is critical for all federal agencies to be consistent in their treatment and support of biosimilars and to recognize that this new industry has additional needs in order to further ensure that biosimilars will increase access and lower costs for patients who need these medicines. As noted, FDA has responsibility for making clinical distinctions among products and the Agency's policies support the notion that each biosimilar is unique.

Unfortunately, CMS does not share this view. Congress should require CMS to review its current reimbursement policy for biosimilars and make it consistent with FDA biosimilar policies. Specifically, FDA policy on biosimilars acknowledges the unique nature of each biosimilar, and CMS should align its policy by assigning unique, individualized billing codes to each biosimilar. FDA Guidance to Industry makes clear that each biosimilar is approved in a distinct fashion, with variances in approved clinical indications and interchangeability. FDA's Guidance for Industry on Nonproprietary Naming of Biological Products further distinguishes individual biosimilars and brand biologics by setting out a naming system whereby different suffixes will be assigned to the name of the biosimilar and its reference product, in order to differentiate between them in the marketplace. CMS policy should likewise recognize this distinction for payment and reimbursement purposes.

In addition, as the Biosimilars Forum works closely with patients and with the providers who will prescribe biosimilars, it is critical that they understand the science behind biosimilars and FDA's rigorous review process so that they have confidence when using and prescribing them. We call on all stakeholders, including the Congress, to support collaboration and education efforts to advance biosimilars in the U.S.

Thank you for the opportunity to be here today to discuss how to support the development of biosimilars and BSUFA reauthorization.

I am happy to respond to any questions.