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EXAMINING FDA'S GENERIC DRUG AND BIOSIMILAR USER FEE PROGRAMS
HOUSE ENERGY AND COMMERCE COMMITTEE
SUBCOMMITTEE ON HEALTH

Good morning Chairman Burgess, Ranking Member Green, and Members of the Subcommittee on Health. Thank you for the opportunity to participate in this timely and important hearing.

I am Bruce Leicher, Senior Vice President and General Counsel at Momenta Pharmaceuticals, and Chair of the Biosimilars Council Board of Directors.

The Biosimilars Council, a Division of the Association for Accessible Medicines (AAM), formerly known as GPhA, works to ensure a positive regulatory and policy environment for biosimilar products, and educates the public and patients about the safety and effectiveness of biosimilars. We are deeply committed to accessible, affordable and high quality medicines.¹

We strongly support the BsUFA II package.

¹ The Council's members aim to provide patients with access to safe, effective alternatives to expensive biologic therapies. Biologic medicines now account for nearly 40% of annual drug approvals by the FDA. Bernard Munos, 2015 New Drug Approvals Hit 66-Year High!, Forbes.com (Jan. 4, 2016), <http://www.forbes.com/sites/bernardmunos/2016/01/04/2015-new-drug-approvals-hit-66-year-high/#4ecaa3c11044>. With annual U.S. spending on biologic drug therapies exceeding \$100 billion, and biosimilars only recently becoming available on the U.S. market, biosimilars offer the potential for tens of billions of dollars in health care savings. And savings are not limited to patients and private insurers; the federal government spends more than \$5 billion each year on biologic medicine through Medicaid and Medicare. See The Biosimilars Council, *The Next Frontier for Improved Access to Medicines: Biosimilars and Interchangeable Biologic Products* 14 (2015), available at <http://www.biosimilarscouncil.org/pdf/GPhA-biosimilars-handbook.pdf> See also, Pew Charitable Trusts, *Can Biosimilar Drugs Lower Medicare Part B Drug Spending?* (Jan. 3, 2017), <http://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2017/01/can-biosimilar-drugs-lower-medicare-part-b-drug-spending>.

Introduction

I would like to start with a personal story, as someone who has worked in the biotechnology industry for over 25 years, and in the biosimilars industry since its inception.

About eight years ago, I appeared before the House Judiciary Subcommittee on Courts and Competition Policy to support the Biologics Price Competition and Innovation Act (BPCIA).

Many of the witnesses testified about their fears of biosimilars, how biosimilars were more complicated than generics, and how we should be very careful about proceeding with the biosimilars legislation. I testified about how significant scientific innovation would address these concerns and make biosimilar competition possible. I emphasized that American ingenuity would make us global leaders by enacting legislation that did not put a ceiling on biosimilar innovation.²

² A key innovation in the BPCIA was the inclusion of the scientific discretion delegated to the FDA to determinate the nature and extent of clinical trials and other development requirements based on its scientific expertise. In implementing the biosimilar regulatory pathway, the FDA adopted a highly innovative approach providing that, to the extent applicants can more fully characterize and understand the structure and function of the reference biologic and the biosimilar, and reduce any differences, clinical trials could be targeted to demonstrating that the differences did not have clinically meaningful differences. This innovation offered biosimilar companies the opportunity to innovate analytical science to reduce development costs and accelerate biosimilar development. The result has been improved understanding of all biologics, and the United States assuming a leadership role in setting standards for biosimilar development. In addition, the inclusion of the interchangeable biologic provisions in the law, made the United States the leader in the development of interchangeable biologics that could, when approved, be substituted at the pharmacy like generics. This created the investment opportunity in the United States to innovate even more and to lead in the development of accessible, affordable biologics. *See* Scientific Considerations in Demonstrating Biosimilarity to a Reference Product (April 2015) <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291128.pdf> (“Scientific Guidance”).

Congress listened and acted with courage. It passed the BPCIA³. American ingenuity and innovation were unleashed. Many prior opponents of biosimilar competition entered the business. Today we have a growing and thriving biosimilars industry -- creating good jobs and leading the world with our innovative science -- particularly in the science of more fully understanding our biologic products.

In October, the FDA reported that over 66 biosimilar programs were under review for development of 20 different biologic products.⁴ Momenta alone has seven biosimilar development programs.⁵

This was made possible by the BPCIA, and by BsUFA I user fee funding. We learned in BsUFA I, however, that the innovation involved in biosimilar development -- the science of understanding what is in a biologic for comparison purposes -- is complicated and involves many new skills that the industry and the FDA need to understand. This requires new staff and training to assure high quality and efficient review. Historic FDA staffing cannot meet these needs which depend far less on clinical data, and far more on new innovative scientific techniques that demonstrate that a biosimilar is highly similar to the reference product and has no clinically meaningful differences.⁶ In addition, even more innovation is underway to allow for approval

³ Pub. L. No. 111-148, Tit. VII, Subtit. A, 124 Stat. 119 (2010).

⁴ This data was shared in the presentation presented by FDA to Congressional Staff on BsUFA II in October 2016. More programs that will be reviewed during BsUFA II are likely in development but because they have not reached the FDA stage of review, are not included in these statistics.

⁵ For example, Momenta Pharmaceuticals nearly doubled its employment as a result of entering the biosimilars business.

⁶ See the discussion of the stepwise development process in the Scientific Guidance, referenced in note 2, *supra*.

of interchangeable biologics which can be shown to perform the same in any given patient and, when approved, substituted at the pharmacy like generic drugs. This innovation is what makes biosimilars competitive, affordable, safe and effective for patients.⁷ But, these innovations squarely depend on having the critical additional FDA resources funded by BsUFA II.

Innovation was used to craft the BsUFA II Commitment Letter. We took a hard look at the first five years. Not only are new FDA resources needed, more efficient regulatory approaches that use funding more wisely are necessary to accelerate FDA review. Together we included innovations from BsUFA I and PDUFA to enhance the review process and to ensure regulatory clarity. The BsUFA II user fees are now tied to the level of resources needed and adjust with resource demand. It is also important to emphasize that the funding provided by user fees is in addition to, not a substitute for, Congressional appropriations. Expenditure is contingent, as in the past, on a spending trigger tied to Congressional appropriations.

Specifically these include⁸:

- Enhanced communication and meeting opportunities that eliminate unnecessary delays in development and review⁹

⁷ Substitution at the pharmacy is a key factor in making biologics affordable. Like generic drugs, interchangeable biologics will not require the same level of marketing in order to promote use allowing for even greater competition.

⁸ Other key improvements in the BsUFA II Commitment letter include the additional or written guidance for BPD Type 2 meetings to avoid unnecessary meetings and reduce the time for scientific feedback, the adoption of the 4 month review of manufacturing prior approval supplements to facilitate manufacturing expansion, and the inclusion of third party evaluation of the Program to facilitate further improvement based on objective feedback.

⁹ The meeting deadlines were adjusted based on BsUFA I experience to allow for the most effective use of the meetings to accelerate program development. Initial Advisory meeting were accelerated, and Type 2 meetings were extended to allow the Agency to have the time to provide complete answers and better guidance. At the same time an option for written advice was added which could accelerate in many situations the time to receipt of Type 2 meeting advice.

- Using resource capacity planning to set budgets, staffing levels and fees¹⁰
- Adopting the highly effective Program Review Model to increase first cycle application approvals; and training of review teams for greater effectiveness¹¹
- Commitments to dedicate staffing and to issue regulatory guidance to promote best practices and predictability
- Expanding biosimilar public education activities

Each improvement accelerates high quality development and review to help assure that patients have more timely access to life-saving, affordable, safe, and effective biosimilars.

Conclusion

In conclusion, BsUFA II is the culmination of months of hard work and negotiations between FDA and industry. It represents a careful balance among the stakeholders. We respectfully urge the Committee to approve a clean draft of BsUFA II, without any changes to the underlying agreement. Timely passage is important to ensure patients have *access* to the lifesaving biosimilar medications they require. This historic agreement provides a critical step toward accomplishing this goal. Thank you, and I would be happy to address any questions.

¹⁰ The use of capacity resource measurement and planning will help ensure that the level of funding is actually tied to the resources needed and will allow for adjustment of fees up and down as the number of programs fluctuate. This should make the review more efficient, avoid the opportunity cost of delays, and allow for adjustment of fee allocation to the kinds or resources actually needed by the Agency. For example, as the number of marketed products increase, the fees will increase and fees may be reduced on the pre-application development side.

¹¹ The Program Review Model was tested in PDUFA and puts in place performance obligations, communication commitments, pre-filing meetings, mid-cycle communication and a late cycle meeting. Experience shows that the enhanced communication conserves FDA resources and applicant resources and has enabled first cycle approval more often than when it was not in place. This should accelerate approval of high quality applications.