New York State Bar Association
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COMMENTS SUBMITTED ON BEHALF OF THE BIOLOGICS COMMITTEE FOR THE FOOD, DRUG AND COSMETIC LAW SECTION TO THE U.S FOOD AND DRUG ADMINISTRATION REGARDING THE AGENCY'S FACILITATING COMPETITION AND INNOVATION IN THE BIOLOGICAL PRODUCTS MARKETPLACE

Docket No. FDA-2018-N-2689

Food, Drug and Cosmetic Law #2 September 21, 2018

On behalf of the New York State Bar Association's Biologics Committee for the Food, Drug and Cosmetic Law Section we are pleased to offer these comments regarding the U.S. Food and Drug Administration's (FDA) *Facilitating Competition and Innovation in the Biological Products Marketplace (FDA-2018-N-2689).*

Committee Purpose

The purpose of the Biologics Law Committee is, in part, to keep the biologics and biosimilars industry and legal practitioners up to date and provide practical advice concerning issues that are of interest to the industry. Such issues involve the U.S. Food and Drug Administration's regulation of biological products, including its implementation of the Biologics Price Competition and Innovation Act (BPCIA) and related reimbursement and substitution rules, interactions with the Food and Drug Administration, Federal Trade Commission, and state agencies, and legislative developments. The Committee also follows the recent trends in litigation involving consumer class actions, labeling claims, biosimilars "patent dance", among others.

The Committee also seeks to engage members in programming and activities to contribute to the development of sound laws, policies, and regulations concerning the biologics industry, including biosimilars.

We have witnessed how the FDA has recently become more involved in the debate of encouraging greater biosimilar utilization. This has been seen from Commissioner Gottlieb's Congressional testimony to the release of the FDA's Biosimilar Action Plan addressing the following four areas:

- Improving the efficiency of the biosimilar and interchangeable product development and approval process;
- Maximizing scientific and regulatory clarity for the biosimilar product development community;
- Developing effective communications to improve understanding of biosimilars among patients, providers, and payers; and
- Supporting market competition by reducing attempts to unfairly delay market competition to follow-on products.

Committee Position(s)

While the Committee takes no official position on whether physicians should prescribe biosimilars or their referenced biologic products for their patients, we wanted to point out some policy issues that should continue to be addressed for the marketplace to fully realize the benefits of including biosimilar versions of their referenced biologics products in the same marketplace.

A. Payer Reform

We believe that insurers especially pharmacy benefit managers (PBMs) need to be proactive to encourage biosimilar market access. We understand that the model behind PBM/insurers are to lower costs through formulary management and other cost containment protocols. The FDA, in conjunction with the Federal Trade Commission, needs to be more proactive to ensure that the biosimilars that FDA approves can be marketed, so that competitive pricing can be encouraged to improve the access to biologic therapies generally.

B. Price Transparency

The issue of pharmaceutical pricing and rebates have caught the attention of Congress as well as federal and state regulators. Once PBMs are more proactive with respect to approved biosimilars, we believe that more transparency regarding how rebates are calculated and used should be provided along with simplified pricing models, so consumers can better understand how the rebates are being used to determine actual pricing for patients and their medical plan payers. In particular, consumers as well as PBM/insurer contracting partners should know how biosimilars will be covered and how negotiated rebates will be passed onto either the consumer or respective government program such as Medicare and Medicaid. Then, we believe that the FDA should work with both state and federal policymakers to ensure that there is PBM/insurer transparency, when it comes to how PBMs will utilize biosimilars in their respective formularies. The goal of such transparency would be to encourage biosimilar applicants to lower their prices to help encourage more pricing competition.

C. BPCIA Patent Litigation Reform

The BPCIA provided for a voluntary patent exchange mechanism that is dysfunctional at best and unworkable in many instances. FDA should work with Congress to consider patent litigation reform to provide a more efficient and predictable process for resolution of patent litigation disputes regarding biosimilar products.

D. BPCIA Interchangeability Reform

While on the one hand the BPCIA is the only system in the world with an interchangeable biosimilar process, the system does not appear attainable by most biosimilar applicants, creating an unworkable concept. FDA should consider alternative mechanisms for demonstrating interchangeability.

Conclusion:

Thank you for the opportunity to allow us to submit comments on this important issue. We welcome the opportunity to serve as a resource to you if you have further questions as you proceed further in your deliberating process.

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Committee on Biologics Law Chair — Ron Lanton III, Esq.