September 20, 2018

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Director
Center for Drug Evaluation and Research
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Re: Comment Submission: Facilitating Competition and Innovation in the Biological Products Marketplace; Public Hearing; Request for Comments; Docket No. FDA-2018-N-2689

The Biologics Prescribers Collaborative (BPC), a project of the Alliance for Patient Access (AfPA), is pleased to submit comments on behalf of its members in response to the FDA's public hearing, *Facilitating Competition and Innovation in the Biological Products Marketplace,* held on September 4, 2018, to gather feedback on the agency's Biosimilars Action Plan. BPC leadership, including Lead Co-convener Dennis Cryer, M.D. and AfPA Chairman David Charles, M.D., welcomed the opportunity to present at the public hearing.

BPC is comprised of member organizations representing specialist and general physicians who prescribe biologics with regularity. Member physicians are committed to providing the best patient care and welcome the therapeutics options presented by biologics and biosimilars to care for patients with debilitating and life-threatening conditions.

BPC appreciates the release of FDA's Biosimilars Action Plan as an important step towards implementing policies that support the expansion of patient access to biological therapies.

In regard to questions 1[1] and 3[2] provided by FDA, BPC encourages FDA to finalize its draft interchangeability guidance issued in 2017. Supportive data must be rigorous and risk-based, and BPC strongly recommend that manufacturers be required to perform clinical studies that include multiple switches between the reference product and proposed interchangeable, to increase physician and patient confidence. If FDA were to amend its guidance to require only one switch, in an effort to improve the efficiency of the approval process, patients would be exposed to greater risk and prescriber confidence would be weakened. Any modified rules that may lower the standards for interchangeability and thus increase the number of biosimilars that can be automatically substituted without robust clinical evidence to support this practice could alter the risk and benefit for patients after switches, as it is not known which structural differences in the products might lead to an increased risk of immunogenicity. BPC fully supports FDA's plans to develop application review templates that will not only streamline the process but enhance public information about FDA's evaluation of biosimilar and interchangeable products. BPC supports this initiative as it means more information for prescribers and patients to demystify and expand understanding of the rigorous process of evaluation for biosimilars.

To better understand prescriber sentiment when it comes to interchangeability standards, BPC recently conducted a survey through SERMO[3] of 300 U.S. physicians specializing in dermatology, gastroenterology, oncology and rheumatology. Results found that **nearly 70 percent** are either

"confident" or "extremely confident" that current draft FDA guidelines establish appropriate standards to demonstrate a biosimilar's interchangeability. When asked about confidence level if FDA were to "relax" standards to demonstrate interchangeability, the percent of physicians who would feel "confident" or "extremely confident" **falls to 46 percent**.

With regard to other elements of FDA's Biosimilars Action Plan, BPC continues to be an advocate for:

- Distinguishable non-proprietary names for all biological products, including previously approved originator drugs;
    - BPC supports FDA's goal to facilitate pharmacovigilance and prevent inadvertent substitution through use of distinguishable suffixes, however BPC encourages FDA to consider that the suffix should be memorable, which is not routinely achieved with a random suffix.
- Careful considerations and communications concerning non-medical switching, which undermines the patient-physician relationship and could allow treatment decisions to be made that are not based on medical need;
- Clear and thorough labeling for biosimilar products such that they contain all needed data for physicians to make appropriate prescribing decisions for their patients;
    - BPC applauds FDA for including in its guidance the requirement that labels accurately reflect scientific evidence; that any statements in the scope indication comparing the safety or effectiveness of drug or biological products with other agents for the same indications must be similarly supported (i.e., by substantial evidence of effectiveness); and that the indication include the product's proprietary name (or trade name) or nonproprietary name if the product does not have a proprietary name.
- Case-by-case determination of extrapolation based on extensive analytic and clinical data;
- Unique J-codes for each biosimilar product (unless deemed by FDA to be "interchangeable" with the reference biologic).

Among all elements incorporated into the Biosimilars Action Plan, education and communication are critical. While improving efficiency of the biosimilar and interchangeable pathways is an essential goal of the Biosimilars Action Plan, it is important to provide more information rather than less to prescribers and patients to support clearer understanding of these rigorous processes. BPC applauds FDA's continued efforts to produce educational materials for patients and physicians about biosimilars and safety.

BPC thanks FDA for its careful consideration throughout this process. With a dozen biosimilars now approved in the U.S., and as FDA works to finalize several important guidances to make the regulatory pathway as clear and efficient as possible for manufacturers, BPC urges the FDA to maintain appropriate, science-based regulatory standards, while implementing policies that ensure greater access to medicine for patients.

Sincerely,

Biologics Prescribers Collaborative

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[1]*Question 1: FDA is aware that many of the biosimilar products that have been licensed by FDA are not yet marketed and available to patients. What can FDA do to help biosimilars and interchangeable products reach patients more quickly after these products are licensed?*

[2]*Question 3: FDA expects that the number of licensed biosimilar and interchangeable products will continue to increase in the coming years. In many, if not most, cases, FDA anticipates that multiple products will be licensed as biosimilar to, or interchangeable with, a given reference product. What additional steps can FDA take to facilitate the evolution of the biosimilar and interchangeable product marketplace? What can FDA do to ensure that confidence in these products among patients, healthcare providers, pharmacists, and other stakeholders will continue to grow?*

[3]*SERMO is the leading global social network exclusively for doctors*