April 9, 2020

Submitted electronically via http://www.regulations.gov

Dr. Stephen Hahn
Commissioner
Food and Drug Administration
Attention: FDA-N-6050
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: FDA/FTC Workshop on a Competitive Marketplace for Biosimilars; Public Workshop; Request for Comments (FDA-N-6050)

Dear Commissioner Hahn:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to offer comments in response to the *FDA/FTC Workshop on a Competitive Marketplace for Biosimilars*, a public workshop held March 9, 2020, and the associated Request for Comments published in the Federal Register (85 FR 6203) on February 4, 2020.[1]

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 270 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program (FEHBP), and the health insurance exchanges established by the Affordable Care Act (ACA).

PCMA supports the acceleration of entry and greater availability of lower cost generic drugs and biosimilar products. Increasing competition through the approval of biosimilars is key to lowering prescription drug costs for patients, health plan sponsors, and public programs.

We commend the Food and Drug Administration (FDA) and Federal Trade Commission (FTC) for their collaboration to promote competitive markets for biological products. We agree on the need to encourage a competitive marketplace for biosimilars, including by curtailing anticompetitive practices that discourage their use. PCMA also appreciates and strongly supports the many important steps the FDA has taken to facilitate greater availability of biosimilars, including the Agency's final guidance on interchangeable biosimilars[2], Biosimilars

[1] 85 Fed. Reg. 6203, February 4, 2020.
[2] FDA. "Considerations in Demonstrating Interchangeability with a Reference Product: Guidance for Industry." May 2019. https://www.fda.gov/media/124907/download

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Action Plan[3], and comprehensive campaign to educate clinicians about the benefits and health care cost savings possible through these innovative therapies. In concert with 20 other health care stakeholders, we also support FDA guidance allowing biosimilar and interchangeable insulin products and encourage the Agency to finalize this guidance as quickly as possible.[4,5]

On March 9, 2020, PCMA presented at the *FDA/FTC Workshop on a Competitive Marketplace for Biosimilars*.[6] These comments supplement that public presentation and discuss promotional labeling and advertising for interchangeable products, therapeutic substitution and interchangeability, anticompetitive practices, and further enhancements to the Purple Book, and clarify our recommendations in response to a FDA Staff question on guidance considerations for naming conventions and promotional labeling.

Promotional Labeling and Advertising for Interchangeable Products

Regulation and perception of the category of interchangeability has allowed for confusion, complexity, and uncertainty around switching and substitution of biosimilars for their biological reference products. Patients and clinicians need express clarity that these therapeutic substitutions are indeed interchangeable. For many patients and clinicians alike, these therapies are new and there may be a degree of uncertainty. As the FDA's voice represents the gold standard for safety and efficacy, then, when the FDA has approved a product for interchangeability, it should be labeled and marketed as such without conflict or confusion. Anything short of that clarity would reinforce caution from patients and clinicians and thus impede the ability to achieve a truly competitive biosimilar market.

Avoiding inaccurate perceptions about the safety and effectiveness of biological products based on their licensure pathway is supportive of a competitive biological products marketplace. We have been encouraged by the FDA's recent efforts to reduce barriers to achieving interchangeability, including final guidance limiting the cases in which switching studies were required.[7] The Agency also has designed an approval pathway allowing manufacturers to use comparator products not approved in the U.S. for biosimilar development.

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[3] FDA. "Biosimilars Action Plan: Balancing Innovation and Competition." July 2018. https://www.fda.gov/media/114574/download

[4] FDA. "Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products: Draft Guidance for Industry." November 2019. https://www.fda.gov/media/133014/download

[5] Biosimilars Council. "Letter to the FDA Re: Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products; Draft Guidance for Industry; Availability." January 28, 2020. https://biosimilarscouncil.org/wp-content/uploads/2020/01/Group-Letter_Biosimilar-Interchangeable-Insulin-Guidance_1.28.20.pdf

[6] FDA. "Public Workshop: FDA/FTC Workshop on a Competitive Marketplace for Biosimilars." Meeting Transcript. March 9, 2020. Pages 278-282. https://www.fda.gov/media/136791/download

[7] FDA. "Considerations in Demonstrating Interchangeability with a Reference Product." May 2019. https://www.fda.gov/media/124907/download

A further encouraging step in this regard is the Agency's February 2020 draft guidance, which provides that reference product promotional materials should avoid representing or suggesting a biosimilar product as less safe or effective than its biological reference product.[8]

The Draft Guidance for Industry, entitled "Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products Questions and Answers Guidance,"[9] does not address interchangeable products. To sustain and strengthen forward progress, guard against misrepresentations of safety and efficacy, and deliver regulatory alignment between interchangeable and reference products, we ask the Agency to finalize this Draft Guidance as soon as possible and update its existing biosimilar guidance to address promotional labeling and advertising of interchangeable products.

***PCMA Recommendation*: PCMA recommends the FDA finalize this guidance as soon as possible. We also recommend the Agency update its existing biosimilar guidance to address promotional labeling and advertising of interchangeable products.**

Therapeutic Substitution and Interchangeability of Biosimilar Products

As with generic medicines, the authority for pharmacists to substitute interchangeable products enhances the ease in which patients will access safe, more affordable medicines. The interchangeable designation increases the confidence of prescribers and patients in biosimilars. Further, the interchangeable designation helps reduce the administrative costs and burdens on prescribers who must now review and approve each request for substituting a biosimilar product for a reference product. While in no way detracting from the safety and benefits of biosimilar products, the interchangeable designation furthers the vision of the Biologics Price Competition and Innovation Act of 2009.

For these reasons, PCMA applauded the FDA for promulgating final guidance quickly[10] and for undertaking a comprehensive program to educate clinicians on the benefits and savings of biosimilar and interchangeable products for patients. Any measures FDA can take to seek to increase awareness about these new treatments will be beneficial.

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[8] FDA." Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products Questions and Answers Guidance. Draft Guidance for Industry." Docket No. FDA-2019-D-5473. February 2020. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/promotional-labeling-and-advertising-considerations-prescription-biological-reference-and-biosimilar

[9] FDA. "Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products Questions and Answers Guidance. Draft Guidance for Industry." Docket No. FDA-2019-D-5473. February 2020. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/promotional-labeling-and-advertising-considerations-prescription-biological-reference-and-biosimilar

[10] FDA. "Considerations in Demonstrating Interchangeability with a Reference Product." May 2019. https://www.fda.gov/media/124907/download

An important and necessary next step to further facilitate a competitive biosimilar marketplace is for the FDA to promote the therapeutic substitution of lower cost interchangeable biosimilars for their reference products. Importantly, even once the FDA determines interchangeability, that evaluation does not determine whether the biosimilar can be substituted for the reference product at the pharmacy. Substitution of a biosimilar for a reference product is a matter of state pharmacy law and is a decision that is outside of FDA's regulatory role.

Some state laws discourage substitution of interchangeable biosimilars: Between 2013 and 2019, state legislation regulating the substitution of interchangeable biosimilars has been adopted in 45 states and Puerto Rico. The provisions of state legislation vary[11], but there are several features and requirements that may discourage substitution:

- Prescriber Decides: The prescriber would be able to prevent substitution by stating "dispense as written" or "brand medically necessary."
- "Notification" vs. "Communication": In bills enacted in 2013 and 2014, the language usually required that the prescriber "must be notified" of any allowable substitution made at a pharmacy. In 2015 bills, the language commonly was adjusted to say, "communicate with," allowing a notation in an electronic medical record, PBM records, or "pharmacy record that can be electronically accessible by the prescriber."
- Patient Notification: The individual patient must be notified that a substitute or switch has been made.

Prescribing physicians can always switch a patient to a lower net cost biosimilar from a reference product if they believe that to be the more appropriate therapeutic option for their patient, even without an interchangeability designation. However, the "notification" provision requiring that the prescriber "must be notified" can serve as a barrier to the uptake of interchangeable biosimilars. For the Agency to foster a competitive biosimilar marketplace, we urge the FDA to be explicit and to clarify to states that the therapeutic substitution of lower net cost interchangeable biosimilars for their reference products is acceptable and encouraged in the retail and specialty pharmacy setting.

PCMA Recommendation: PCMA suggests the FDA provide clear direction to states in favor of therapeutic substitution of interchangeable biosimilars for their reference products without burden or barriers, such as "notification" provisions, in such cases where the substitutable drug is a lower net cost.

[11] See National Conference of State Legislatures (NCSL) website for list of all state biosimilar laws. "State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars." http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx

Anticompetitive Practices

We appreciate the collaboration between the FDA and the FTC, which has argued that tactics aimed at "gaming" FDA rules may be anticompetitive and unlawful. PCMA remains concerned tactics used by prescription drug manufacturers to block generic and biosimilar entry, including "pay-for-delay" patent settlement agreements, the creation of patent thickets, product adjustments ("evergreening"), abuse of the regulatory process, including the FDA citizen petition process, and other anticompetitive practices. We urge consideration of further action when manufacturers employ such tactics to delay market availability of lower cost biosimilars.

PCMA Recommendation: PCMA urges consideration of further action by the FDA and FTC to curb anticompetitive tactics used by manufacturers to delay market availability of lower cost biosimilars.

Naming Convention for Biosimilars Products

The FDA has moved forward with an approach for biosimilars that have been approved to date that requires the use of a "non-meaningful" four-letter suffix as part of their non-proprietary name.[12] In making this decision, however, the Agency did not retroactively name any already-approved biologic, which has resulted in these reference drugs not having a suffix.

PCMA continues to recommend the FDA revise its current approach to biosimilar naming and promotional labeling, which is different than that for small-molecule drugs where no suffix is used. We believe this convention confuses patients and clinicians and can promote the mistaken belief that interchangeable products are not truly interchangeable. Interchangeable biosimilars should bear identical names and labels to their biological reference products. While we believe the FDA should revise its approach for biosimilars to be consistent with that for small-molecule generic drugs, should the FDA continue to believe that suffixes are necessary, PCMA asks the Agency to align naming guidance for biologic reference, biosimilar, and interchangeable products by requiring suffixes for the non-proprietary names of reference products.

PCMA Recommendation: PCMA recommends the FDA revise its current approach to biosimilar naming and promotional labeling to be consistent with that for small-molecule generic drugs. Should the Agency continue to believe suffixes are necessary, we ask the FDA to align naming guidance for biologic reference, biosimilar, and interchangeable products by requiring suffixes for the non-proprietary names of reference products.

[12] FDA. "Nonproprietary Naming of Biological Products: Update. Draft Guidance for Industry." March 2019. https://www.fda.gov/media/121316/download

Further Enhancements to the Purple Book

We support FDA's recent announcement of enhancements to the Purple Book, otherwise known as the "Database of FDA-Licensed Biological Products," including expansion and digitation, to improve the accessibility of information about biosimilars.[13,14] Further enhancements may include a searchable and interactive format, more complete information (e.g., patents for the biologic reference product), and additional information, including summary information for patent settlement agreements. Regarding summary information for settlement agreements, we note that publishing such information need not disclose sensitive intellectual property information around the discovery and manufacture of such products and will better inform all stakeholders in the health community.

***PCMA Recommendation*: PCMA recommends further enhancements to the Purple Book, including a searchable and interactive format and additional and more complete information, including summary information of any "pay-for-delay" patent settlement agreements to which an approved biologic product is subject.**

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We appreciate the opportunity to provide remarks at the March 9, 2020 Public Workshop and to follow-up in writing herein. PCMA looks forward to working with you and the FTC to enhance competition in the biological products marketplace. If you have any questions about these comments, please contact me at (202) 756-5732 or by email to cwiniarek@pcmanet.org.

Sincerely,

Claire Wulf Winiarek
Vice President, Policy

cc: Kristin Bass
Wendy Krasner

[13] FDA. "FDA In Brief: FDA Enhances Purple Book to Support Transparency in Biosimilars." February 24, 2020. https://www.fda.gov/news-events/fda-brief/fda-brief-fda-enhances-purple-book-support-transparency-biosimilars
[14] 85 Fed. Reg. 12927, March 5, 2020.