FTC Recommends Ways to Increase Competition and Stimulate Growth in Biosimilars and Interchangeable Market

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The Federal Trade Commission (FTC) recently provided comments on the Department of Health and Human Services’ (HHS) Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. The Blueprint seeks, among other things, to “increase competition and end the gaming of regulatory processes that may keep drug prices artificially inflated or hinder generic, branded, or biosimilar competition.” Healthy competition in biologics markets is likely to benefit consumers by lowering prices, increasing access to higher quality biologics and encouraging innovation. Increase in marketplace competition will also significantly reduce healthcare costs in the United States.

Congress passed the Biologics Price Competition and Innovation Act (BPCIA) of 2009 with the expectation that it would support competition in biologics markets and lower the costs of biologics drugs. But the biosimilar marketplace in the United States has advanced slower than expected. Since 2009, only 12 biosimilars have been approved, yet only three of those biologics have launched commercially. The Congressional Budget Office previously estimated the BPCIA could reduce total U.S. expenditure on biologics by $25 billion over a 10-year period. But recent analysis estimates the actual savings from biosimilar competition to be only $240 million.

Given the slower than expected growth in the biosimilars marketplace, FTC recommends that FDA:

A. Continue to create a pathway for expedited approval of interchangeable biologics;
B. Reconsider the current naming guidance for biologics in light of the Blueprint; and
C. Improve the Purple Book.

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A. Expedited Approval of Interchangeable Biologics

FDA issued draft guidance for approval of interchangeable biosimilars in January 2017 and announced that the final guidance would be released by May 2019. The absence of guidance may be contributing to delays in the investment, application, approval and entry of interchangeable biologics that otherwise would likely provide the most significant price competition in biologics markets.

To date, no biosimilar molecule has gained interchangeable designation, and without an interchangeable designation, a biosimilar product cannot be automatically substituted at the pharmacy. Automatic substitution is expected to result in increased market penetration of biosimilars, achieving substantial consumer savings. Accordingly, FTC has encouraged FDA to issue the final guidance for approval of interchangeable biosimilars as soon as possible to reduce the uncertainty in the regulatory process for approval of interchangeable biosimilars. Also, FTC has suggested including ways to overcome barriers to entry and, thereby, expedite approval of biosimilars and interchangeables in the final guidance.

B. Reconsider Final Naming Guidance for Biologics

FTC has recommended FDA reconsider its guidance on naming convention for biosimilars to achieve FDA's objectives without hindering competition. The naming guidance issued by FDA requires assigning a unique suffix to the drug substance name of each individual biosimilar. Such naming differences could cause patients and physicians to mistakenly believe that a biosimilar product differs from reference product in clinically meaningful ways and dissuade the physician from prescribing the biosimilar. By definition, an approved biosimilar has been shown to be highly similar to the reference product and to have no clinically meaningful differences from the reference product in terms of safety, purity and potency. FTC thus reiterates its concern that FDA's current naming guidance for biosimilars is hindering biosimilars from effectively competing with the reference biologic product.

C. Suggested Changes to Purple Book

According to FTC, the Purple Book should be changed so its features are, at least, similar to the Orange Book used for small-molecule pharmaceuticals. FTC recommends changing the Purple Book from its current static PDF form to a searchable form so users can search the book by active ingredient name, proprietary name, dosage form, route of administration and other features. According to FTC, reorganizing information in the Purple Book so that it is easier for a physician to find when a biosimilar shares an active ingredient name with the reference product would be beneficial in increasing competition and market acceptance of biosimilars. Also, adding fields that inform the public about applicant name, date application was filed, active ingredient name (not the product's proper name), patents (if any), applicant holder and/or application number would be helpful.

For More Information

If you have any questions about this Alert, please contact Patrick C. Gallagher, Ph.D., Neelaabh Shankar, Ph.D., any of the attorneys in our Intellectual Property: Generic Pharmaceuticals and Biosimilars Practice Group or the attorney in the firm with whom you are regularly in contact.

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