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FTC and FDA Collaborating to Promote Biologic Competition

Today, the Federal Trade Commission (FTC) and Food and Drug Administration (FDA) issued a statement describing their efforts to "work together to promote competitive markets for biological products." As the FTC explains, biological products – or biologics – are medicines "manufactured in a microorganism or in plant or animal cells," many of which "are produced using recombinant DNA technology." Today's statement sets out ways in which the agencies "are collaborating to support appropriate adoption of biosimilars, deter false or misleading statements about biosimilars, and deter anticompetitive behaviors in this industry." A biosimilar is a biologic that is "highly similar to its reference product, a biological medication already approved by [the] FDA."

According to the statement, the agencies are sponsoring "a public meeting to discuss competition for biologics" and will engage in other public outreach efforts on the topic. The meeting, the FDA/FTC Workshop on a Competitive Marketplace for Biosimilars, will take place at the FDA on March 9, 2020.

The FTC and FDA set out several goals for their collaboration, including:

- **Access to biologic samples**. In order for a biosimilar to be approved for use by the FDA and enter the market, a manufacturer must demonstrate that it is similar to or interchangeable with the FDA-approved biologic product. To do so, the manufacturer must gain access to the original biological reference product to conduct the necessary tests. Accordingly, the "FDA and FTC will collaborate to identify and deter tactics used to prevent or impede access to samples of the reference product that the prospective biosimilar applicant needs for testing to be licensed as a biosimilar or interchangeable biosimilar." The statement does not set out specific actions the agencies contemplate taking, but indicates that they "will evaluate whether additional information sharing arrangements [between them] are warranted." Recently-enacted federal legislation created a private right of action which could, in certain circumstances, be used to compel the sale of reference products on "commercially reasonable, market-based terms."

- **Enforcement against false or misleading statements**. The statement says that the FTC and FDA will act, pursuant to their respective statutory mandates, to take "appropriate action" when "a communication makes a false or misleading comparison between a reference product and a biosimilar in a manner that misrepresents the safety or efficacy of biosimilars, deceives consumers, or deters competition." The FDA published draft guidance "for FDA-regulated advertisements and promotional labeling that contains information about biologic products."

- **Evaluation of patent settlement agreements**. The 2018 Patient Right to Know Drug Prices Act requires in part that patent settlements between branded and generic manufacturers involving biosimilar biological products must be notified to the Department of Justice and FTC. Competition issues surrounding actions by patent holders to delay the entry into the market of generic pharmaceuticals have been a focus of the FTC for some time. According to today's statement, the FTC will review patent settlements involving biosimilars "in the same manner that FTC has been reviewing patent settlement agreements between brand and generic drug manufacturers." The statement also says that the agencies "will collaborate on efforts to ensure biosimilar development and uptake are not hindered by other anticompetitive practices."

In addition to taking action against certain patent settlement agreements, the FTC has also brought enforcement actions where it has alleged that branded pharmaceutical manufacturers have filed "citizen petitions" with the FDA with the intent of delaying generic entry. According to the statement issued today, the "FDA will . . . refer to [the] FTC and highlight in [the] FDA's annual report to Congress its determinations of petitions submitted with the primary purpose of delaying an approval" of generic and biosimilar medicines.

According to the statement, "[s]trengthening the partnership and interagency coordination between [the] FDA and FTC will help each agency address and deter anticompetitive behavior in the U.S. market for biological products." In recent years, the FTC has been active in bringing enforcement proceedings challenging conduct delaying the entry of generic pharmaceuticals. However, the cooperation with the FDA announced today may result in increased – or at least swifter – action.

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This memorandum is not intended to provide legal advice, and no legal or business decision should be based on its content. Questions concerning issues addressed in this memorandum should be directed to:

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