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Anticompetitive Conduct in Biologics – An Enforcement Priority with FTC and FDA

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Today the Federal Trade Commission (FTC) and the Food and Drug Administration (FDA) released joint guidance concerning competition for biologics, including biosimilars. The joint guidance seeks to enhance competition for biologics and reduce manufacturers' use of false or misleading statements or promotional communications concerning the efficacy or safety of biosimilars and other biologics. This guidance appears to be part of the Trump administration's effort to reduce the cost of medications for consumers, as it is aimed at increasing the level of competition biosimilars can offer and raising awareness of the safety and efficacy of biosimilars.

The fast-growing biologics market has become an important sector of the healthcare and pharmaceutical industry. According to the joint guidance, private insurers spent over $125 billion on biologics in 2018 alone. Biologics treat many serious conditions that often lack alternative treatment options. Although Congress enacted an abbreviated FDA-approval process for biosimilars nearly a decade ago, adoption of biosimilars has been relatively slow. The FTC and the FDA will focus on competition for biologics in hopes of improving patient access to important treatment options and curbing costs. The joint guidance highlights the agencies' efforts to transfer recent investigatory and enforcement efforts to biologics markets.

The joint guidance sets forth goals for which the FTC and the FDA will agree to collaborate in their efforts to support adoption of biosimilars and enhance competition in biologics markets. These goals build on recent efforts by both agencies to deter anticompetitive conduct in the pharmaceutical industry more broadly. The joint goals include:

- **Coordinate to promote greater competition in biologic markets.** The FTC and the FDA will cooperate to facilitate greater competition for biologics to reduce costs and improve patient access to important treatment options. The FDA will develop educational materials for healthcare professionals and patients to improve the public's understanding regarding the trusted safety and efficacy of FDA-approved biosimilars. The FTC and the FDA will also collaborate on future public outreach efforts, including hosting a public meeting regarding competition in biologic markets in March.

- **Deter anticompetitive conduct that restricts access to samples vital for the development of biosimilars.** The FTC and the FDA will work jointly to identify and deter behavior by biologic manufacturers to "game" the system or unfairly delay generic competition from biosimilars. Notably, the agencies will work together to identify biologics manufacturers' attempts to prevent a prospective biosimilar applicant from accessing samples of a reference-listed biologic necessary to allow for clinical trials of the biosimilar. The agencies will consider whether additional information sharing is necessary to combat conduct aimed at inhibiting biosimilars development. The use of restrictive distribution systems to limit generic competitors' access to samples came under FTC scrutiny recently, as evidenced by the FTC's January 27, 2020, complaint against Vyera Pharmaceuticals and Martin Shkreli.

- **Monitor the use of citizen positions to deter or delay entry.** Both the FDA and the FTC have also focused on the use of abusive or repetitive citizen petitions aimed at delaying generic or other abbreviated drug applications. In July 2018, the FDA issued guidance concerning abusive citizen petitions and agreed to refer to the FTC any petitions it identifies as having the primary purpose of delaying approval of generic or biosimilar competition. In September 2018, the FTC filed a complaint against Shire ViroPharma Inc. alleging it violated the antitrust laws through the filing of serial sham government petitions aimed at delaying generic competition for its branded drug.

- **Take action against false or misleading statements about biologics, including biosimilars.** In particular, the FTC and the FDA are focused on deterring communications that make false or misleading statements about the safety or efficacy of biosimilars in an attempt to deceive consumers and deter competition. The agencies will take action within their respective authorities. The FDA will address false or misleading communications that may affect public health, and is publishing draft guidance outlining FDA-regulated advertisements or promotional labeling concerning biologics. The FTC will investigate unfair acts or practices concerning communications not subject to FDA-jurisdiction. The FTC indicates that such statements could constitute "unfair or deceptive acts or practices," which seems to indicate the FTC's willingness to challenge perceived abusive conduct not only under the Sherman Antitrust Act, but also under Section 5 of the FTC Act, which prohibits unfair methods of competition. The scope of, and limits on, Section 5 are less defined than the case law under the Sherman Antitrust Act, so the use of Section 5 to challenge commercial speech comparing products could show an expansive enforcement approach by the FTC. The Democratic Commissioners have been vocal about encouraging the FTC to increase competition and consumer protection enforcement efforts under Section 5, particularly with regard to the pharmaceutical industry.

- **Review patent settlement agreements involving biologics and biosimilars.** The FTC and FDA will evaluate patent settlements involving biosimilars, which must be filed with the FTC. The review will include identifying anticompetitive reverse payment provisions that delay or defeat the introduction of biosimilars. The FTC stated it would review such settlements under the same enforcement lens as it uses to evaluate settlements between branded and generic pharmaceuticals. The FTC will also collaborate with the FDA to ensure biosimilar development and adoption is not inhibited by other anticompetitive conduct.

The joint guidance emphasizes the serious concerns both the FTC and the FDA have concerning competition in biologics markets, including the adoption of biosimilars. Biologics manufacturers should evaluate their business practices regarding biosimilar competition, including the use of regulatory processes and citizen petitions, communications regarding biosimilars, and patent settlements. The FTC and FDA are likely to have a heightened interest in any perceived unfair or deceptive practices that undermine the public's confidence in biosimilars or reduce competition for biologics.

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