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PERSPECTIVE

FDA, FTC issue joint statement on efforts to support market for biologics

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Biologics are complex drugs that include antibodies, living cells such as CAR-T cells that are used to treat cancer, and may soon include artificially produced organs for human transplant. Biologics, because of their complexity, are often more expensive and difficult to manufacture than traditional small molecule drugs. Biologics can be exquisitely sensitive to small alterations in production processes, ambient environmental conditions, or media materials. All of these contribute to biologics' increased expense relative to small molecule drugs.

How expensive are biological drugs? While biologics make up about 2% of U.S. prescription drug volume, biologics account for more than one-third of total U.S. prescription drug spend. To place this into context, over $125 billion was spent on biologics in the U.S. in 2018. And that spend will continue to rise as the number of biologics in clinical trials approaches 1,000.

One way to bring down biologics' cost is through the development and approval of biosimilars. Biosimilars are drugs which are: (1) highly similar to a biologic reference product, and (2) for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency. Biosimilars come to market through an abbreviated pathway created under the Biologics Price Competition and Innovation Act.

According to the U.S. government, a biosimilar comes with a list price that is 15% to 35% lower than the corresponding branded biologic. Thus, licensing of more biosimilars could decrease drug spend, increase market competition, and expand drug access. To date, the U.S. Food and Drug Administration has licensed 26 biosimilars. And the market potential of biosimilars has resulted in the creation of startup biosimilar companies.

Therefore, to help ensure increased biosimilar licensing and consumer and healthcare provider awareness of the benefits of biosimilars, the FDA and the U.S. Federal Trade Commission recently issued a joint statement. The statement identified four joint goals.

The two agencies will coordinate to promote greater competition in biologic markets. Actions under this goal include: educating consumers and healthcare providers about biosimilars; cooperation in efforts to facilitate biologics competition; and collaborating in future biosimilar outreach efforts.

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Next, the agencies will work to deter "behavior that impedes access to samples needed for the development of biologics." In development of biosimilar products, typically the sponsor runs comparative clinical trials with the reference biologic drug. The purpose of the comparative clinical trials is to generate data that supports the conclusion that there are no clinically meaningful differences between the biosimilar and the reference biologic drug in terms of safety, purity, and potency.

If a biosimilar clinical trial sponsor cannot obtain the reference biological drug, the biosimilar clinical trial sponsor cannot generate the clinical data needed to support the FDA's licensing of the biosimilar. Restricted distribution programs, including risk evaluation and mitigation strategy (REMS) restricted distributions - that are often required for approval of the branded biologic drug - can prevent biosimilar clinical trial sponsors from obtaining enough of the branded biologic to run comparative clinical trials. The statement recites that the FDA and the FTC "will collaborate to identify and deter tactics used to prevent or impede access to samples of the reference product."

One way to alleviate restricted drug access would be for congress to create a stockpile of branded drugs (including biologics), to be used to facilitate comparative clinical trials. The government would pay the manufacturer for sufficient drug to allow for running of comparative clinical trials, and hold the drug in a government stockpile. The biosimilar or generic drug applicant would, in turn, pay the government to gain access to sufficient drug, taken from the stockpile, to run its comparative clinical trial.

Additionally, the statement notes the FTC and FDA "intend to take action against false or misleading communications about ... biosimilars." With precedents going back over 100 years, U.S. federal courts have determined that companies, including drug companies, have limited commercial free speech rights under the 1st Amendment. These limited rights include the ability to communicate commercial information, so long as the information is truthful and non-misleading. In practice, this limited commercial free speech right can allow drug companies to engage in limited, truthful and non-misleading, off-label drug promotion.

The agencies are concerned with false or misleading statements, which are not protected commercial free speech, and which could improperly deceive consumers or deter competition. For example, the agencies would be concerned if a branded drug company were to make false or misleading statements about the safety or efficacy of a biosimilar. The agencies "intend to take appropriate action to address such [false or misleading] communications."

This area of law, especially regarding whether a commercial communication is or is not misleading, can be nuanced. Because of the nuance, and the stakes involved should any commercial communication be found to be false or misleading, FDA regulatory, FTC, and antitrust counsel should be regularly consulted in promotional matters. The statement notes the FDA is "publishing a draft guidance outlining considerations for FDA-related advertisements and promotional labeling that contains information about biologic products."

Finally, the agencies note the FTC "will review patent settlement agreements involving ... biosimilars ... for antitrust violations." The FTC obtains and reviews patent settlement agreements between reference product and biosimilar manufacturers. The analysis of whether a patent settlement implicates an antitrust violation is also nuanced and high stakes, and must generally be evaluated on a fact-by-fact, and case-by-case basis. For any such settlement, or evaluation of any such settlement, robust consultation with antitrust counsel is strongly recommended.

Biosimilar manufacturers, and branded drug companies, should carefully consider the statement to gain insight into how the FDA and the FTC intend to work together to promote a more competitive biologics and biosimilar marketplace. ■

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