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New Laws Expand Requirements for Pharmaceutical Companies to File Agreements With FTC and DOJ

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Food, Drug, and Device and Antitrust/Competition

What occurred and why does it matter?

President Trump on October 24 signed the SUPPORT for Patients and Communities Act (H.R. 6),[1] which together with the Patient Right to Know Drug Prices Act (S. 2554),[2] signed October 10, expands the scope of pharmaceutical product-related agreements subject to filing requirements under subtitle B of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Of particular note, parties to certain agreements regarding biosimilar applications now must file the agreements with the Department of Justice (DOJ) and the Federal Trade Commission (FTC). H.R. 6 also broadens the scope of required filings for agreements related to generic drugs.

Prior Requirements

Prior to the enactment of H.R. 6 and S. 2554, the MMA required the filing of agreements with DOJ and the FTC related to abbreviated new drug applications (ANDAs) that contained paragraph IV certifications, *i.e.*, challenges to a brand company patent. Filing was required for agreements between an applicant for such an ANDA and the holder of the new drug application (NDA) for the brand name drug or patent owner regarding (1) manufacture, marketing, or sale of the brand name drug; (2) manufacture, marketing, or sale of the generic drug; or (3) 180-day "first applicant" exclusivity as it applied to the ANDA or any other ANDA referencing the brand name drug. ANDA applicants who provided paragraph IV certifications to the same brand name drug also had to file agreements between them regarding 180-day exclusivity. Additionally, the filing requirement extended to any other agreements that were contingent upon, provided a contingent condition for, or were otherwise related to an agreement that was required to be filed.

Changes to the Law

The amendments require companies entering into agreements related to biosimilar applications to file with DOJ and the FTC agreements that meet the following criteria:

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[1] Pub. L. No. 115-271, § 4004 (2018).

[2] Pub. L. No. 115-263, § 3 (2018).

1. The agreement is between the applicant who has submitted a biosimilar application and a brand name drug company (*i.e.*, the holder of the biologics license application for the reference product or the owner or exclusive licensee of a patent included in a list provided under section 351(l)(3) of the Public Health Service Act (PHSA)), where such agreement relates to:
   - the manufacture, marketing, or sale of the reference product for the biosimilar application;
   - the manufacture, marketing, or sale of the biosimilar product that is the subject of the application; or
   - exclusivity for the first interchangeable product under PHSA 351(k)(6) as it applies to the biosimilar application or any other biosimilar application based on the same reference product; or
2. The agreement is between two or more biosimilar applicants that have submitted biosimilar applications citing the same reference product, where the agreement relates to either exclusivity for the first interchangeable product or the manufacturing, marketing, or sale of a biosimilar product.

If a biosimilar-related agreement meets the filing criteria, the existing MMA requirement to file any other agreements that are contingent upon, provide a contingent condition for, or are otherwise related to an agreement also applies.

H.R. 6 also expands the scope of "other agreements" that parties must file with an agreement that meets the required filing criteria: The filing of any agreement that was entered into within 30 days of an agreement that is subject to the filing requirement—regardless of whether the agreement relates to an ANDA or biosimilar application—now must be filed.

Next Steps

Clients should consider and plan for these new filing requirements as they negotiate and execute covered agreements.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Drug, and Device and Antitrust/Competition practices:

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