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THE LATEST: Divestitures of Complex Pipeline Pharmaceutical Products off the Table at the FTC

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WHAT HAPPENED:

- Bruce Hoffman, acting director of the Bureau of Competition at the Federal Trade Commission (FTC), announced that the FTC will no longer accept divestitures of inhalant and injectable pipeline drugs in pharmaceutical mergers.
- Hoffman, speaking at the Global Competition Review Seventh Annual Antitrust Law Leaders Forum on February 2, 2018, explained that divestitures of pipeline products were not working well for complex pharmaceuticals, such as inhalants and injectables.
- Instead, in situations in which the parties to the transaction own both a successfully manufactured inhalant or injectable and an overlapping pipeline inhalant or injectable in a concentrated market, the FTC will seek a divestiture of the manufactured product.
- An internal study at the FTC revealed that the rate of failure was “startlingly high” for divestitures of certain complex pipeline pharmaceutical products. Hoffman blamed the high failure rate on the difficulty in actually getting the complex pipeline pharmaceutical to market by a divestiture buyer. He explained that a divestiture buyer, for example, could struggle to reliably manufacture an inhalant or injectable product, frustrating its ability to ultimately bring the product to market.

WHAT THIS MEANS:

- In pharmaceutical mergers in which one party owns a complex manufactured product and the other party owns a complex pipeline product in a relevant market that the FTC considers concentrated, the merging parties should expect the FTC to push for an order to divest the manufactured product.
- The new policy on pipeline pharmaceutical products aligns with a broader FTC initiative to improve the success rate of its remedies. After releasing its Merger Remedies Study (the Study) in February 2017, which self-evaluated the effectiveness of FTC remedies from 2006 – 2012, the FTC has taken several measures to improve its remedy efficacy.
- The goal of this FTC policy change is to minimize the potential that a remedy fails. Given the high failure rate cited by the FTC for complex pipeline pharmaceutical products, the FTC is shifting the risk of failure from the public to the merging parties. While Hoffman focused on this policy’s application in complex pharmaceutical mergers, and inhalants and injectables in

particular, it’s possible that these principles could also be applied in other similar settings (*e.g.*, biotech devices) in which the parties are being forced to divest pipeline research and development assets that overlap with an already manufactured product.

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