CLIENT ALERT

FTC and DOJ Re-Examine their Analysis of Pharmaceutical Mergers

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On June 1, 2023, the Federal Trade Commission ("FTC") and the U.S. Department of Justice ("DOJ") released a summary of their 2022 joint pharmaceutical merger analysis workshop.[1] In June 2022, the FTC and DOJ hosted a two-day workshop to evaluate new approaches to enforcing antitrust laws in the pharmaceutical industry, welcoming remarks from other enforcement agencies, international enforcement partners, and academia, among others.[2] This workshop was the result of the Multilateral Pharmaceutical Merger Task Force, which had been formed in March 2021 to consider how to address the diverse concerns around competition raised by pharmaceutical mergers and acquisitions,[3] and responsive to President Biden's call for agencies "to combat the excessive concentration of industry, the abuses of market power, and the harmful effects of monopoly and monopsony—especially as these issues arise in . . . prescription drug markets. . . ."[4]

Both FTC Chair Lina M. Khan and DOJ Assistant Attorney General for the Antitrust Division Jonathan Kanter identified specific issues that have been troubling the agencies, including increasing drug prices, "'killer' acquisitions [that have] shut down potential competitors," allegations of "illegal bundling and tying practices,"[5] and the dampening of innovation.[6] In

1 FTC, *FTC, DOJ Issue Summary on Joint Pharmaceutical Merger Analysis Workshop* (Jun. 1, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/06/ftc-doj-issue-summary-joint-pharmaceutical-merger-analysis-workshop?utm_source=govdelivery.

2 FTC, *The Future of Pharmaceuticals: Examining the Analysis of Pharmaceutical Mergers* (Jun. 14–15, 2022), https://www.ftc.gov/news-events/events/2022/06/future-pharmaceuticals-examining-analysis-pharmaceutical-mergers.

3 *Id*.

4 THE WHITE HOUSE, *Executive Order on Promoting Competition in the American Economy* (Jul. 9, 2021), https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy.

5 FTC, *The Future of Pharmaceuticals: Examining the Analysis of Pharmaceutical Mergers FTC-DOJ Workshop Summary* (Jun. 1, 2023) p. 1, https://www.ftc.gov/system/files/ftc_gov/pdf/Future%20of%20Pharma%20Workshop%20--%20Summary.pdf.

6 *Id*.

response to those concerns, several panelists suggested: (1) expanding the set of issues that should be assessed in pharmaceutical industry mergers, including innovation effects and prior bad acts; and (2) applying a heightened level of scrutiny and presumption of competitive harm to large-scale mergers.[7] These suggestions, if implemented, would meaningfully affect the agencies' scrutiny of pharmaceutical mergers.

Sliding-Scale Standard of Review. Traditionally, pharmaceutical merger reviews examine whether a merger increases the dominance in individual product markets.[8] But Patricia Danzon, Professor of Health Care Management at the Wharton School of the University of Pennsylvania, asserted that this approach overlooks complex customers in pharmaceutical markets, and cross-market effects due to company size.[9] She recommended that when larger-scale companies merge, the standard of review should be heightened: mergers of companies in the top decile of U.S. sales, should be presumed harmful and the companies should bear the burden of showing how the efficiency gains from the merger outweigh potential competitive harms;[10] mergers of companies in the second decile of U.S. sales, particularly those with must-have or blockbuster products, should be subject to heightened scrutiny.[11] Rena Conti, Associate Professor at Boston University Questrom School of Business, asserted that manufacturers of excipients (i.e., inactive substances in a drug) are highly concentrated, and therefore there needs to be more transparency into the U.S. prescription drug supply chain as well.[12] It is important to understand who is making the products and the market structure in order to determine whether a merger might shift that market structure.[13]

Broader Set of Remedies. Historically, agencies have required the divestiture of overlapping products in pharmaceutical mergers that present antitrust concerns.[14] Robin Feldman, Professor of Law at UC Hastings Law, posited that past remedies have not adequately addressed product hopping, the practice of shifting market share to existing drugs with minor modifications, and recommended imposing conduct remedies to prohibit such behavior.[15] She also recommended that regulators seek the divestiture of existing drug products, instead of pipeline drug products.[16] Barak Richman, Professor of Law at Duke University School of Law, commented on the competition between pharmaceutical companies to be included in the formularies of pharmaceutical benefit managers ("PBMs"), who act as intermediaries in the pharmaceutical distribution system.[17] He recommended that the agencies develop a two-part analysis to account for the

7 *Id*.
8 *Id*.
9 *Id*. at p. 2.
10 *Id*. at p. 3.
11 *Id*.
12 *Id*. at p. 4.
13 *Id*.
14 *Id*.
15 *Id*. at p. 5.
16 *Id*. at p. 5.
17 *Id*.

role of PBMs, similar to the approach taken by the FTC to evaluate hospital mergers and the intermediary role of insurance.[18]

Stricter Scrutiny of Innovation Issues. Caroline Holland, Attorney Advisor to U.S. Federal Trade Commissioner Rebecca Kelly Slaughter, emphasized that the agencies' assessment should go beyond a review of existing and pipeline products and include the potential loss of competition to innovate.[19] According to Holland, protecting innovation requires an evaluation of the incentives of the merging companies, as well as the non-merging companies, especially with respect to their research and development capabilities.[20] She also noted that enforcers should not ignore claims about the possible chilling effect on investment because of merger enforcement.[21]

Emphasis on Prior Conduct. Speakers underscored the need for the agencies to rely on prior conduct as a guide for the future effects of proposed combinations and used a broad definition of prior bad acts. For example, it would cover pay-for-delay cases, price fixing, and territorial allocation, [22] according to Gwendolyn Cooley, Assistant Attorney General for Antitrust for the state of Wisconsin, which are all behaviors that attempt to "corner" the market on a particular drug and "maximize profits."[23] Scott Hemphill, Professor at New York University School of Law, posited that past conduct is particularly relevant to the company's intent, which can be informative of a subsequent merger's effect.[24]

The past few years have proven that the antitrust agencies are committed to intensive merger review and aggressive enforcement, a trend that is carrying through to the pharmaceutical industry. For companies operating in this space, it will be particularly important to assess the risk of agency action using a broader set of metrics with special emphasis on the effects of a combination on incentives and initiative to innovate.

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18 *Id*.
19 *Id*. at p. 9.
20 *Id*. at p. 11.
21 *Id*.
22 *Id*.
23 *Id*.
24 *Id*. at p. 12.