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FTC/DOJ Pharmaceutical Merger Workshop Signals Significant Changes Likely in Future Reviews

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On June 14 and 15, 2022, the Federal Trade Commission ("FTC") and the Antitrust Division of the Department of Justice ("DOJ") held a virtual workshop (the "Workshop") focused on re-examining antitrust enforcement in the pharmaceutical industry. The Workshop was the culmination of the work of the Multilateral Pharmaceutical Merger Task Force ("Task Force"), formed by the FTC in March 2021. Speakers from both U.S. federal enforcement agencies and others from state and international antitrust authorities discussed a wide array of issues including possible new approaches to analyzing, challenging and remedying pharmaceutical mergers.

Based on statements made at the Workshop, it is clear that current FTC leaders have serious concerns about industry consolidation and believe competition and innovation in the pharmaceutical sector have decreased significantly over the years. As a result, they appear to be considering changes to merger reviews that could have significant consequences for dealmakers. Three key takeaways from the Workshop are that:

- FTC leaders appear to be considering new approaches to evaluating harm to innovation that may be caused by pharmaceutical mergers;
- Several speakers focused on how mergers may result in harm from cross-portfolio contracting, while academic members of the Task Force advocated for creating presumptions based on firm size; and
- A number of Workshop participants, including FTC officials, expressed interest in a retrospective review of past pharmaceutical merger remedies.

FTC CONSIDERING NEW APPROACHES TO EVALUATING HARM TO INNOVATION IN PHARMACEUTICAL MERGERS

FTC Commissioner Rebecca K. Slaughter's keynote speech emphasized her view of the importance of understanding fully the ways that pharmaceutical mergers may harm competition, including the potential impact of having fewer firms engage in R&D races in specific therapeutic categories or for particular technologies. She indicated that pharmaceutical merger reviews should incorporate new approaches to evaluating potential harms to innovation, including:

- Assessing whether mergers between large firms may negatively affect innovation incentives of *non*-merging firms (for example, by reducing the number of large firms likely to buy pharmaceutical startups, which may in turn reduce capital available to such startups as they seek to grow); and
- Analyzing whether a merged firm's perceived ability to foreclose innovators in a particular space might deter investment in that area.

Signaling a desire for more aggressive enforcement, Caroline Holland, Commissioner Slaughter's attorney advisor, explained that she is more concerned with under-enforcement of the antitrust laws in the pharmaceutical sector than over-enforcement, especially in the context of large firms acquiring nascent threats to their business.

Based on the statements of these FTC officials, and others, pharmaceutical companies should expect intense scrutiny when they propose transactions involving firms that are currently or may in the future invest in or develop products in the same areas. During investigations, such pharmaceutical companies should expect the agency to issue broad Second Requests seeking information related to a wide range of innovation theories, including some that may not have been pursued by the FTC in the past.

CROSS-PORTFOLIO CONTRACTING CONCERNS AND ADVOCACY FOR PRESUMPTIONS BASED ON FIRM SIZE

During the Workshop, several participants indicated that they believe a shortcoming of the FTC's approach to analyzing past pharmaceutical mergers is that it did not address harms that might result from merged firms expanding their drug portfolios. A number of speakers expressed concern that mergers can add blockbuster products to large pharmaceutical companies' portfolios, allowing them to engage, post-merger, in cross-portfolio contracting to secure preferred access to pharmacy benefit managers' formularies for their entire portfolio. Panelists argued that such practices may lead to the exclusion or reduced competitiveness of products sold by rivals of the merged firm that do not possess similarly large portfolios.

In addition, two academics, Patricia Danzon of the Wharton School, University of Pennsylvania, and Michael Carrier of Rutgers Law School, argued that mergers involving two large pharmaceutical companies—roughly defined as in the top 10 firms by U.S. sales—should face a presumption of competitive harm that would shift the burden of proof to the merging parties to show that sufficient merger-specific efficiencies exist to outweigh the presumed harm.

Given that the FTC created the Task Force and sponsored the Workshop at which new approaches to evaluating innovation competition, cross-portfolio bargaining and firm-size-based presumptions were discussed—at the same time it is working with the DOJ to revise the agencies' merger guidelines[1]—it will be important to monitor whether any of the recommendations or suggestions raised during the two-day event are incorporated into new guidance, as many possible changes could have an enormous impact on future reviews.

FTC LIKELY TO INITIATE A RETROSPECTIVE REVIEW OF THE EFFECTIVENESS OF PAST REMEDIES

Participants in the Workshop also discussed whether enforcers should pursue different remedies than they have in the past, highlighting their dissatisfaction with prior FTC divestitures used to resolve horizontal competitive concerns. One proposal raised during the Workshop was that regulators should consider imposing remedies subjecting the combined entity to ongoing monitoring of R&D levels and patent output, to ensure that adequate resources are being devoted to innovation post-merger.

Synda Mark, an official in the FTC's Office of Policy and Coordination, also said the agency may conduct a study of the effectiveness of its past merger remedies, noting that the last time the FTC undertook such a review was in 2015. She also hinted that revised merger guidelines may include new guidance on remedies.[2]

The deep skepticism of past pharmaceutical merger remedies expressed by panelists at the Workshop is consistent with previous statements made by FTC Chair, Lina Khan, and DOJ Assistant Attorney General, Jonathan Kanter, who have both stated publicly that they believe many past remedies accepted by their agencies have failed, and more mergers should be challenged in court rather than settled.[3] Based on such statements, pharmaceutical companies proposing mergers that raise significant antitrust issues should expect it to be significantly more difficult to reach a settlement with the FTC than it may have been previously, and they should be prepared for the increased possibility that they will need to defend their merger in court to consummate it.

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Pharmaceutical companies need to pay close attention to the many changes taking place in U.S. antitrust enforcement to properly assess the antitrust risk posed by mergers they are considering. In response to these changes, they should evaluate whether antitrust efforts commitments and other terms in merger agreements should be adjusted to reflect the FTC's increased likelihood of litigating and reduced interest in settling cases. As regulators continue to alter their approach, companies should engage antitrust counsel as early as possible in the merger evaluation process to ensure they account for all recent important developments in the evolving antitrust landscape.

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[1] See FTC, *Federal Trade Commission and Justice Department Seek to Strengthen Enforcement Against Illegal Mergers* (January 18, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/01/federal-trade-commission-justice-department-seek-strengthen-enforcement-against-illegal-mergers.

[2] Synda Mark also explained that the FTC would "focus on considering labor markets more systematically in all of our reviews, including review of mergers in the pharmaceutical industry."

[3] Assistant Attorney General Jonathan S. Kanter, *Address Before the New York State Bar Association* (January 24, 2022), https://www.justice.gov/opa/speech/assistant-attorney-general-jonathan-kanter-antitrust-division-delivers-remarks-new-york ("Therefore, in my view, when the division concludes that a merger is likely to lessen competition, in most situations we should seek a simple injunction to block the transaction. It is the surest way to preserve competition."). FTC Chair Lina M. Khan, *FTC Chair Khan Shares Warren's Concerns About Giant Defense Industry Mergers* (August 12, 2021), https://www.warren.senate.gov/oversight/letters/new-ftc-chair-khan-shares-warrens-concerns-about-giant-defense-industry-mergers (explaining in a public letter to Senator Elizabeth Warren that "[w]hile structural remedies generally have a stronger track record than behavioral remedies, studies show that divestitures, too, may prove inadequate in the face of an unlawful merger. In light of this, I believe the antitrust agencies should more frequently consider opposing problematic deals outright.").