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# DOJ and FTC Virtual Workshop: Agencies Discuss Novel Approaches to Address Competition Issues in Pharmaceutical Mergers

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On June 14 and 15, 2022, the Department of Justice Antitrust Division ("DOJ") and the Federal Trade Commission ("FTC") hosted a virtual workshop to discuss antitrust analysis of pharmaceutical mergers and anticipated focal points for the agencies moving forward. Workshop participants discussed the effects of concentration, prior remedies in pharmaceutical mergers and anticipated changes going forward, harm to innovation, and stricter scrutiny for pharmaceutical mergers involving prior bad conduct. The workshop reinforces that this is a priority area for the agencies; parties in the pharmaceutical sector looking at prospective mergers should keep a close eye on future merger challenges and anticipate stricter scrutiny by the agencies going forward.

In their opening remarks, DOJ Assistant Attorney General Jonathan Kanter and FTC Chair Lina Khan emphasized that the workshop comes at a critical time as prices for pharmaceutical products are increasing across the market. Chair Khan noted that the median price for new drugs has increased by 20% per year along, and highlighted the frequency of acquisitions of would-be or nascent competitors. AAG Kanter spoke on the directive of the DOJ to ensure that medicines are available to Americans at affordable prices, and that access to care should include both quality and innovative care.

**FTC Commissioner Rebecca Slaughter gave the keynote address, in which she emphasized that the antitrust agencies should go beyond the traditional pharmaceutical merger analysis of "existing products and pipeline products" to look further at harm to innovation and loss of research and development.** Commissioner Slaughter noted that the pharmaceutical industry has a "checkered legacy" or anticompetitive conduct, and that the FTC and DOJ would be working collaboratively together going forward to address competition issues in the pharmaceutical industry.

Concentration Levels in the Pharmaceutical Industry: Panelists discussed the potential anticompetitive effects of the concentration in the pharmaceutical space that sees the same companies operating as market leaders over the last decade. Some panelists opined that firm size presents significant advantages in negotiating with health insurance payers and pharmacy benefit managers ("PBMs") for drug prices, while pointing to the limited evidence that firm size increases

research and development productivity. Panelists discussed the harms of vertical concentration within the industry, noting the increased prevalence of vertical integration between PBMs and health insurance payers and the corresponding effect on the overall supply chain. The FTC is already taking a closer look at the role of PBMs on drug pricing following the commission of a study under Section 6(b) of the FTC Act.

Remedies in Pharmaceutical Mergers: Panelists discussed the efficacy of remedies for previous pharmaceutical mergers, and proposed alternatives going forward. Panelists noted that remedies involving the divestiture of certain drugs, particularly "pipeline" drugs, had mixed returns due to the fact that divestiture buyers face difficulty to bring a pipeline drug to market relative to an already developed drug; looking at 56 pipeline drug divestitures, only 36% of those products have an active marketing license today, suggesting that divestiture may not be as effective for protecting innovation as previously thought. Panelists also discussed the difficulties for agencies to review the overall competitive effect of a larger firm acquiring several smaller firms through separate transactions. Youenn Beaudouin, Case Handler at the European Commission ("EC"), provided his perspective, noting that the EC only accepts remedies that are grounded in market reality, with a strong preference for structural remedies such as divestitures. Synda Mark, Acting Deputy Assistant Director of the FTC's Office of Policy & Coordination, previewed the FTC's plans for a "holistic rethink" of many policies that could include a formal update on their remedy policies, particularly given the number of settlements since the agency's previous review in 2015.

Assessment of Innovation: While innovation competition was discussed throughout the workshop, including, as noted above, by Commissioner Slaughter, the third panel focused exclusively on innovation competition and pharmaceutical mergers. Caroline Holland, attorney advisor to Commissioner Slaughter, stated that she was concerned about killer acquisitions—especially those deals that are not public and fall outside of the agencies' radar—and their effect on innovation competition. She suggested that the Commission pursue remedies such as prior approval and notice in consent decrees to capture more of these potential acquisitions. Some panelists also argued that uncertainty around pipeline products and overlaps should not necessarily mean that anticompetitive mergers involving pipeline overlaps should be cleared. According to the panelists, the agencies should look closely at business plans and evidence surrounding entry and expansion to gain a better understanding of the pipeline overlaps.

Prior Bad Acts: During the last panel of the workshop, the panelists debated how to account for prior bad conduct during merger reviews. Professor Scott Hemphill of NYU Law reasoned that prior bad conduct by a firm could be informative of the firm's intent for the merger under review. Gwendolyn Cooley, Assistant Attorney General for Antitrust, Wisconsin Attorney General's Office, agreed, stating that prior bad conduct could be considered a plus factor—the merger creates competitive harm, but the evidence of prior bad acts puts it over line. For example, if a firm has a history of engaging in sham litigation or price fixing, the FTC/DOJ should account for that history and be more skeptical of the merger. Finally, the panelists discussed how their advice could apply to the merger guidelines revisions. Several of the panelists agreed that the revised guidelines need to include: (1) expended attention to nascent competition; (2) attention to buy side harms and sell side harms; and (3) attention to bargaining leverage.

The discussions throughout the two-day workshop emphasized that the DOJ and FTC will be prioritizing competitive harms in pharmaceutical industry within the context of merger review. Going forward, we can expect increased focus by the agencies on effects of concentration and harm to innovation, as well as potential new policies regarding remedies and mergers by parties that have previously been engaged in anticompetitive conduct.

Indeed, one day after the workshop, on June 16, the FTC announced it would increase its enforcement of PBMs and their rebate structures. Specifically, the Commission announced in an enforcement policy statement that it would increase enforcement against fees and rebate schemes paid by drug manufacturers to PBMs that may incentivize PBMs and other intermediaries to favor high-cost drugs. Rebate structures were discussed during the second panel of the workshop, with some panelists noting that large drug makers can leverage the rebate system to disadvantage smaller competitors.



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