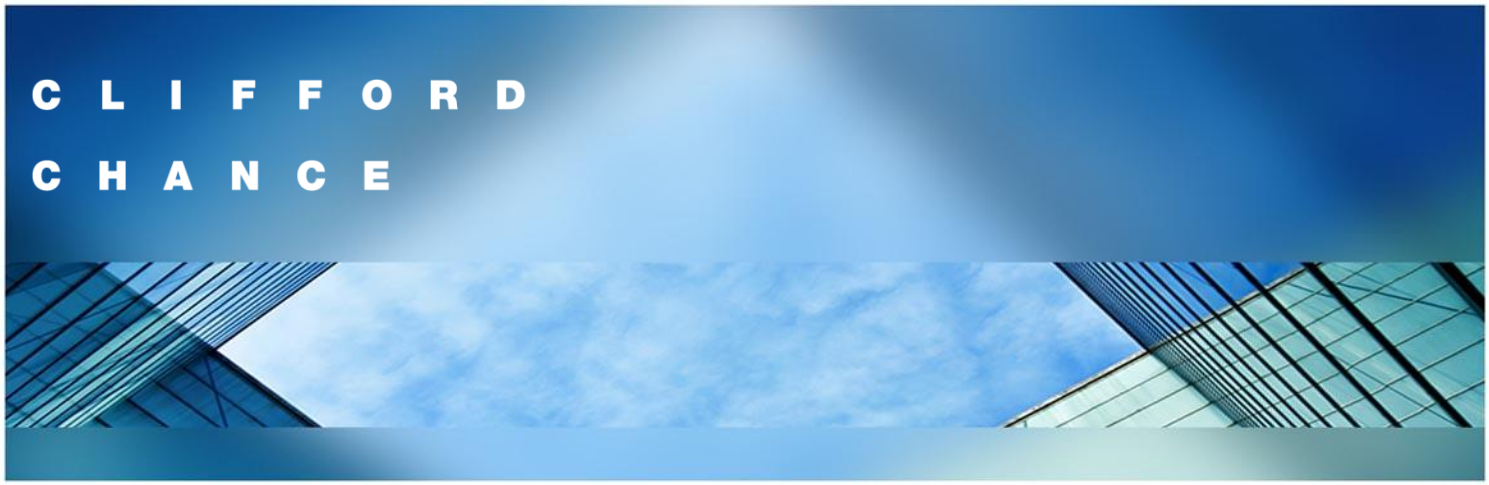

THE FUTURE OF PHARMACEUTICALS: AGENCY FOCUS ON PBMS AND PHARMACEUTICAL MERGERS

Hot off the heels of Alvaro M. Bedoya's confirmation as the fifth FTC Commissioner, the antitrust agencies have doubled down on enforcement in the pharmaceutical sector with three recent actions. First, the FTC voted 5-0 to initiate a Section 6(b) study of pharmaceutical benefit managers (PBMs). As part of the PBM study, the FTC issued six broad subpoenas to the top PBMs in the country: CVS Caremark, Express Scripts, Inc., OptumRx, Inc., Humana, Inc., Prime Therapeutics LLC, and MedImpact Healthcare Systems, Inc. The FTC says that the inquiry will examine the impact of vertically integrated PBMs on the access to and affordability of prescription drugs.

Key takeaways

- The FTC believes that Section 2(c) of the Robinson-Patman Act can be used to challenge anticompetitive rebates and fees in the pharmaceutical space.
- The antitrust agencies will increase scrutiny on serial pharmaceutical acquisitions and cross-market effects (e.g., portfolio leveraging).
- The FTC believes that pharmaceutical divestitures may no longer be enough to prevent mergers from being anticompetitive.
- The FTC will also target perceived killer acquisitions in the pharmaceutical space, which it sees as suppressing a once-competitor's promising pipeline.

Second, the FTC recently identified behavior that it believes deserves more scrutiny in the pharmaceutical sector. On June 16, 2022, the FTC issued a Policy Statement on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products, using insulin as a case study. According to the Policy Statement, common industry rebates and fees "may shift costs and misalign incentives" that exclude or deprioritize generics or lower-priced drugs in formulary management. The Policy Statement also raised Section 2(c) of the Robinson-Patman Act as a revived tool that the agency may use to target commercial bribery. Commissioner Rebecca K. Slaughter, in supporting the Policy Statement, separately emphasized the renewed use of Section 5's unfair methods of competition clause to go after egregious pricing behavior (which the agency recently used in its victory against pharma bro Martin Shkreli). She also noted that the FTC and FDA are committed to working together to address "false or misleading statements" by biological product manufacturers.

Third, and most notably, the FTC and DOJ recently completed a summit entitled, "The Future of Pharmaceuticals: Examining the Analysis of Pharmaceutical Mergers." The two-day workshop was a part of the Pharmaceutical Merger Task Force multijurisdictional effort that explored "new approaches to enforcing the antitrust laws in the pharmaceutical industry." Panels were comprised primarily of academics and enforcers; topics included the pharmaceutical industry's market

structure and how regulators should assess remedies, innovation arguments, and prior bad acts by merging parties as part of their merger review. A summary of each Pharmaceutical Workshop session is below.

KEYNOTE SPEECH FROM COMMISSIONER REBECCA KELLY SLAUGHTER

Commissioner Slaughter began the summit by highlighting the work of the Pharmaceutical Merger Task Force, a cross-jurisdictional team consisting of the FTC, DOJ, US states, and foreign authorities. Commissioner Slaughter's remarks included the following:

- Although pharmaceutical mergers "are traditionally thought of as the FTC's domain," the FTC is now "substantively, directionally, and cooperatively aligned" with DOJ.
- The FTC's merger review focuses not only on "existing products and pipeline products" but also competition in innovation and research and development ("R&D"), where companies compete in bringing new drugs to market and in developing methods of conducting clinical trials or delivering drugs.
- The Commission, when evaluating both initial acquisitions and divestiture buyers, is especially likely to consider parties' prior bad acts in the pharmaceutical context, given the industry's "particularly checkered legacy of anticompetitive conduct."

PANEL: CONCENTRATION LEVELS IN THE PHARMACEUTICAL SECTOR:

Panelists argued that past merger review practices in the pharmaceutical sector had been myopic and had contributed to significant concentration and high prices. Their arguments included the following:

Future merger review should be more wide-ranging and should not merely examine transactions on a product-by-product basis.

Enforcers should look at the various roles of physicians, insurers, and PBMs, and should look more broadly at cross-market and portfolio-wide effects in the broader supply chain.

Size advantages are substantial in contracting, marketing, and financing; large pharmaceutical firms with large or significant portfolios obtain "cross-market leverage," which they can use to engage in exclusionary practices (including bundling, tying, and rebates) with physicians and PBMs.

PANEL: BROKEN FIXES? REMEDIES IN PHARMACEUTICAL MERGERS

Panelists considered what remedies they believed could contribute to competition enforcement in the pharmaceutical merger context. Panelists disagreed about the successes of past divestitures. Some argued that divesting pipeline products is often unhelpful; the divestiture buyer might not have the same willingness or ability to get the divested product to market, and business leaders restructuring the entities may not be aligned with scientists working on the drug. Others advocated

for structural remedies, noting that there are a variety of possible divestitures (facilities, products, brands, and even research teams) and that conditions can be placed on divestitures to reduce the likelihood of failure.

All panelists agreed that the complex structure of the pharmaceutical industry made designing remedies more complicated. Panelists' arguments included the following:

- Regulators should consider the market power firms may gain across different markets by, for example, engaging in a number of small mergers, and should consider pharmaceutical firms' interactions with PBMs in designing any remedy.
- Behavioral remedies can be difficult, especially where a monitor is required, given the possibility of the parties switching to a new formulation (e.g., product-hopping) that may also be anticompetitive.
- A monitor's goal should not be to "enforce the rule of reason" but instead to ensure compliance with a clear mandate, such as patent output or new-chemical-entity output.

Synda Mark, Acting Deputy Assistant Director for the Office of Policy & Coordination at the FTC, stated that the agency plans to "take a more holistic rethink of all [FTC] process and practices" in the pharmaceutical industry, including remedies. She added that, as with any other industry, the FTC was looking at labor markets as part of its review of pharmaceutical mergers.

PANEL: ASSESSMENT OF INNOVATION ASPECTS IN PHARMACEUTICAL MERGERS

Panelists discussed their views on how pharmaceutical mergers can affect competition in innovation. All panelists agreed that while most pharmaceutical mergers and acquisitions have legitimate synergies and have no significant anticompetitive effects, a small but significant number may be characterized as "killer acquisitions." In the pharmaceutical industry, these transactions generally involve a large firm acquiring a small firm possibly to prevent or delay the distribution of a competing drug. Panelists' remarks included the following:

- In assessing benefits and harms to innovation from mergers, agencies should look at competition at all levels of innovation, including future competition as well as immediate or "dynamic" competition, bearing in mind the amount of time and investment required for entry.
- The framework used by the European Commission ("EC") provides a helpful model. The EC examines parties' existing products and pipelines and predicts how a merger might affect the parties' incentives to invest in R&D programs (with special consideration for the potential for the delay, discontinuation, or reorientation of pipeline drugs).
- Agency reviews of early pipeline overlap, and of small biotech companies with little to no revenue, are unlikely to have a "chilling effect" on investment in innovation. These reviews are generally not intrusive and rarely lead to intervention.

PANEL: PRIOR BAD ACTS AS FACTORS IN PHARMACEUTICAL MERGER REVIEWS

Panelists discussed the extent to which merger review should consider past anticompetitive conduct in which the parties may have engaged. All panelists agreed that past "bad acts" should play an important role in agencies' analysis. Panelists' remarks included the following:

- Parties who have previously engaged in anticompetitive acts are more likely to be entering into their present transaction with anticompetitive intent. Moreover, if the previous conduct has continuing or residual anticompetitive effects, a merger or acquisition might amplify or reinforce those harms.
- Evidence of merging parties' past anticompetitive conduct can bolster the agencies' challenge to a merger in several ways: it can imply market power, demonstrate the likelihood of coordinated effects in the industry, and provide context for key documents.
- Prior bad acts, in illustrating parties' intent, can be especially relevant where the parties do not obviously compete head-to-head. Past conduct can indicate whether there may be nascent competition, a potential "patent thicket," or other competition concerns.

CONCLUSION

In the span of only nine days, the FTC launched a 6(b) study into pharmacy benefit managers, issued a policy statement on drug rebate practices, and held a two-day joint summit with DOJ on antitrust enforcement in the pharmaceutical industry. These actions demonstrate the FTC's focus on competition in the pharmaceutical industry. The FTC is considering competition in the industry more holistically and increasingly examining vertical and cross-market relationships. The agency also pledged to look at harms to competition in terms of reduced innovation and development, in addition to price effects.

The FTC has also emphasized that it strongly favors litigating challenges rather than settling for remedies. In the past week alone, parties to two proposed hospital mergers abandoned their deals in the wake of FTC complaints (*In re HCA Healthcare/Steward Health Care System* and *In re RWJ Barnabas Health/Saint Peter's Healthcare System*). When exploring pharmaceutical transactions, companies should account for the FTC's new, more aggressive approach.

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