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ANTITRUST TRADE AND PRACTICE

Health Care Remains a Key FTC Focus

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Reform of traditional antitrust enforcement and competition law globally has been an ongoing discussion amongst enforcers, politicians, advisors, economic experts, and academics. While conversations pertaining to antitrust reforms have been widely centered around resolving the issues presented by Big Tech, the pharmaceutical industry remains a key focus of competition agencies globally. This article will discuss two recent steps enforcement agencies have taken to address competition in the pharmaceutical industry—the recently announced multi-jurisdictional Working Group and the 6(b) Order issued to six health insurance companies by the Federal Trade Commission (FTC). Both working groups and 6(b) Orders are well established tools in the FTC's tool kit and their use has been increasingly common in an era of heightened antitrust enforcement.

What Is the Multi-Jurisdictional Working Group?

The FTC is authorized "to gather and compile information concerning, and to investigate from time to time the organization, business, conduct, practices, and management of any person, partnership, or corporation engaged in or whose business affects commerce …" 15 U.S.C. §46(a). It has used working groups at various times to study and report on particular questions of interest. A working group will typically provide recommendations based on its findings.

Pursuant to this authority, on March 16, 2021, Acting FTC Chair Rebecca Slaughter announced the launch of a multi-jurisdictional Working Group to update the current approach to analyzing the effects of pharmaceutical mergers and to ensure the most effective enforcement. See Press Release, Fed. Trade Comm'n, FTC Announces Multilateral Working Group To Build a New Approach to Pharmaceutical Mergers (March 16, 2021) (hereinafter March FTC Release). This Working Group will include the Federal Trade Commission, the U.S. Department of Justice Antitrust Division, Offices of State Attorneys General, the Canadian Competition Bureau, the European Commission Directorate General for Competition, and the U.K.'s Competition and Markets Authority. See id. The Working Group will consider:

(1) How can current theories of harm be expanded and refreshed?

(2) What is the full range of a pharmaceutical merger's effects on innovation?

(3) In merger review, how should pharmaceutical conduct

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such as price fixing, reverse payments, and other regulatory abuses, be considered?
(4) What evidence would be needed to challenge a transaction based on any new or expanded theories of harm?
(5) What types of remedies would work in the cases to which those theories are applied?
(6) What have we learned about the scope of assets and characteristics of firms that make successful divestiture buyers?

EU Commissioner Margrethe Vestager emphasized the importance of an "innovative and well-functioning pharmaceutical sector," welcoming the Working Group. See Press Release, Eur. Comm'n, Competition: The European Commission Forms a Multilateral Working Group with Leading Competition Authorities to Exchange Best Practices on Pharmaceutical Mergers (March 16, 2021).

Acting Chair Slaughter has expressed concern with the high volume of pharmaceutical mergers in the past few years, and the consequential skyrocketing of drug prices, as well as other anticompetitive conduct such as pay-to-delay arrangements. See *March FTC Release, supra.* For example, there were 1,276 pharmaceutical transactions with an aggregate value of $411 billion in 2019, up from 1,230 transactions valued at $298 billion in 2018. Jaimy Lee, *Drug Manufacturers Have Spent a Record $342 Billion on M&A in 2019*, Market Watch (Dec. 10, 2019, 7:14 a.m.). In addition, the cost of brand-name oral prescription drugs rose more than 9% a year from 2008 to 2016, with critics suggesting this increase in price cannot always be attributed to innovation. See Alison Kodjak, *Prescription Drug Costs Driven by Manufacturer Price Hikes, Not Innovation*, NPR (Jan. 7, 2019, 5:04 p.m.).

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The announcement of the multijurisdictional Working Group may foreshadow the approach a Democrat-led FTC likely will take towards pharmaceutical mergers in the near future. Pharmaceutical companies should anticipate even more vigorous antitrust enforcement from the FTC, potentially focused on novel theories as well as continuing interest on the debate around remedies (divestitures) and whether they have adequately addressed competition concerns. Acting Chair Slaughter suggested that the Working Group will also evaluate already approved and consummated mergers not only to inform future approaches to pharmaceutical mergers, but also to take corrective action on consummated mergers if necessary.

Current Approach to Mergers

The FTC's current approach to pharmaceutical mergers often results in a merger being approved on the condition that the parties agree to divest overlapping products in concentrated product areas or where the overlapping products are uniquely close substitutes. Acting Chair Slaughter has argued that this approach does not thoroughly account for the future effects on innovation. For example, in *AbbVie*, the Commission found that the acquisition of Allergan by AbbVie would result in harm to consumers in the market for treatment of exocrine pancreatic insufficiency (EPI), and moderate-to-severe Crohn's disease. See *AbbVie, Docket No. C-4713*, (F.T.C. Sept. 3, 2020). The proposed consent agreement required AbbVie and Allergan to divest Allergan's assets related to the EPI drugs and the assets related to Crohn's disease drug Brazikumab. See id. at 15-16. The

Commission approved this consent agreement 3-2. See id. at 33. Acting Chair Slaughter stated that the Commission did not thoroughly investigate the effects of the merger on innovation, and proposed that it should gather evidence relevant to analyzing innovation competition at the earliest stage possible in an investigation. See Dissenting Statement of Commissioner Slaughter at 2, AbbVie, Docket No. C-4713 (F.T.C. May 5, 2020). Notably, the concerns raised in her dissent appear to be reflected in the topics the multi-jurisdictional Working Group will be considering.

Commissioner Chopra, who joined Acting Chair Slaughter in multiple merger dissents during the Trump administration, has also expressed concern with the traditional approach taken by the FTC in evaluating pharmaceutical mergers. For example, the FTC voted to settle allegations that Mylan's proposed acquisition of Pfizer's generic drug business is unlawful with a requirement that the companies divest seven individual products. See *In the Matter of Pfizer/Mylan N.V., Docket No. C-4727* (F.T.C. Oct. 30, 2020). Commissioner Chopra criticized the settlement, stating that the Commission's status quo approach and the lack of litigation "creates the strong impression that the FTC simply look[s] to strike settlement deals involving individual product divestitures." See Dissenting Statement of Commissioner Chopra at 2, In the Matter of Pfizer/Mylan N.V., Docket No. C-4727 (F.T.C. Oct. 30, 2020). Commissioner Chopra further argued that the approach misses some of the fundamental elements of how firms compete in the industry. Id. at 5.

The FTC recently published clarification stating that the temporary suspension of granting early termination does not apply in two circumstances.

It is important to acknowledge that, while the multi-jurisdictional Working Group aims to re-evaluate current theories of harm in efforts to capture more mergers, the U.S. courts and Agency guidelines have an established framework for evaluating mergers. While some critics have discussed the need to reverse court decisions and update relevant antitrust laws, the FTC is limited to enforcing the law as it currently stands.

FTC 6(b) Orders to Health Insurance Companies

In addition to authorizing working groups, Section 6 of the FTC Act empowers the Commission to require an entity to file "'annual or special … reports or answers in writing to specific questions' to provide information about the entity's 'organization, business, conduct, practices, management, and relation to other corporations, partnerships, and individuals.'" See Fed. Trade Comm'n, A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority (October 2019) (alteration in original) (citing 15 U.S.C. §46(b)). The FTC does not need to have a specific law enforcement purpose to conduct such studies. Id. These so-called 6(b) studies have become increasingly popular—for example, in recent years, the FTC employed 6(b) studies to explore the impact of non-HSR reportable transaction by large technology companies and how social media and streaming series use consumer data. See Press Release, Fed. Trade Comm'n, FTC Issues Orders to Nine Social Media and Video Streaming Services Seeking Data About How They Collect, Use, and Present Information (Dec. 14, 2020). No public action has come from these studies to date.

In January, the FTC announced that it is conducting another 6(b) study in the health care space. See Press Release, Fed. Trade Comm'n, FTC To Study the Impact of Physician Group and Healthcare Facility Mergers (Jan. 14, 2020). The Commission

voted (5-0) to issue Orders to file a Special Report to several health insurance companies in order to study the effects of physician practice mergers and hospital acquisitions of physician practices that occurred from 2015-2020. Id. The orders request "patient-level commercial claims data for inpatient, outpatient, and physician services in 15 U.S. states from 2015 through 2020." Id. According to the Physicians Advocacy Institute, between 2016 and 2018, 8,000 physician practices were acquired by hospitals, and the percentage of hospital-owned practices increased by 5%. Physicians Advoc. Inst., Updated Physician Practice Acquisition Study: National and Regional Changes in Physician Employment 2012-2018 (February 2019). Then Chairman Simons noted the goal of this initiative is "to encourage economists both inside and outside the agency to carry out more retrospective studies to test our analytical tools and strengthen our enforcement efforts." See Press Release, Fed. Trade Comm'n, FTC's Bureau of Economics to Expand Merger Retrospective Program (Sept. 17, 2020). The current Biden-led FTC is expected to continue this study and continue aggressively to scrutinize physician and hospital related transactions, as health care remains a priority industry for the FTC regardless of the political party in the White House.

Conclusion

The announcement of the multi-jurisdictional Working Group and the FTC 6(b) Order on six health insurance companies demonstrates the FTC's continued focus on the health care industry in efforts to expand or improve antitrust enforcement. These studies will likely be influenced by incoming Biden political appointees to the agencies and their perspectives on potential reforms to the antitrust laws. Because the FTC's use of its investigative power to learn more about industries has led to change in enforcement in the past, health care companies should continuously monitor developments from the multi-jurisdictional Working Group and the FTC 6(b) Order to determine whether it will result in significant changes to merger enforcement in the health care industry.

Early Termination Update

We had previously reported on the FTC's temporary suspension of granting early termination under the HSR Act. Although the suspension remains in place, the FTC recently published clarification stating that the temporary suspension of granting early termination does not apply in two circumstances. The first circumstance is when the FTC or DOJ issue a Second Request—the agencies' tool for investigation potentially problematic transactions—and determine through investigation prior to the parties' substantial compliance with the Second Request, that the transaction is unlikely to substantially lessen competition. M. Petrizzi and H. Johnson, *HSR Early Termination After a Second Request Issues*, Fed. Trade Comm'n: Competition Matters (March 12, 2021, 3:15 p.m.). The second circumstance is when parties receive a Second Request, but then work with the agency to negotiate a consent agreement to resolve any competition concerns. Id. All other scenarios are still subject to the full 30 day HSR waiting period until further notice.