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The Top Four Antitrust Enforcement Issues in Healthcare Today

Recent enforcement efforts by the DOJ and FTC show that the healthcare sector is under heightened scrutiny from US competition authorities. In 2021, the Biden administration issued an Executive Order on Promoting Competition in the American Economy, which directed federal agencies to take a number of steps to address perceived competitive harm occurring in the sector. Against this backdrop, here are the top four antitrust issues impacting the healthcare industry today.

#1: Heightened Scrutiny of Healthcare M&A

The Biden administration's prioritization of competition enforcement in the healthcare sector can be seen in its approach to merger enforcement and policy. On merger challenges, the DOJ (unsuccessfully) attempted to block UnitedHealth's acquisition of Change Healthcare, while the FTC's efforts to unwind Illumina's acquisition of Grail remain ongoing. Notably, both cases involved vertical mergers where the parties had proposed settlements to address the competitive concerns, which are exceedingly difficult challenges for the agencies to win in court. The fact that the agencies continue to bring such difficult cases is indicative of their aggressive posture and greater willingness to litigate in the healthcare space. Most recently, the FTC sued to block Amgen's proposed acquisition of Horizon based on an aggressive "cross-market bundling" theory of harm, notwithstanding there being no competitive overlap between the companies' product portfolios. In contrast to the agencies' approach in the UnitedHealth and Illumina transactions, rather than litigate its case to decision, the FTC entered into a settlement agreement with Amgen on September 1 that will allow the acquisition to proceed subject to certain behavioral conditions.

With respect to policy statements, on June 1, 2023, the DOJ and FTC released a summary of their 2022 pharmaceutical merger summit, which sought to explore a new approach to M&A in the industry. The key priorities of the agencies included a need to address concerns about market concentration by applying heightened scrutiny for medium to larger transactions, looking at acquisitions by dominant players, and abandoning the current approach to settlements, which the agencies stated may negatively impact innovation. The summary also highlighted several themes found in the draft Merger Guidelines issued on July 19: applying a lower standard for what constitutes a concentrated market; creating a lower threshold for firms with a "dominant position" at a 30% share; and stressing the relevance of prior anticompetitive conduct (e.g., history of tacit or express collusion or exclusionary conduct) when considering the risk of competitive harm posed by the parties.

Companies considering the antitrust risks of their M&A transactions will need to take into account how prior competitive conduct may be viewed by the agencies, and should

Key Contacts



Richard Powers
Partner, New York
Litigation
richard.powers@friedfrank.com
T: +1 212 859 8906



Bernard (Barry) A. Nigro Jr.
Partner, Washington, DC & New York
Antitrust and Competition
barry.nigro@friedfrank.com
T: +1 202 639 7373



Nathaniel L. Asker
Partner, New York
Antitrust and Competition
nathaniel.asker@friedfrank.com
T: +1 212 859 8566



Aleksandr Livshits
Partner, New York
Antitrust and Competition
aleksandr.livshits@friedfrank.com
T: +1 212 859 8524

expect less willingness by the antitrust agencies to agree to settlements requiring divestiture of overlapping products or business units.

#2 Reassessing Prior Positions on Prescription Drug Price Transparency and Vertical Integration

In late July, the FTC withdrew nine prior PBM advocacy statements and reports issued between 2004 and 2014, and cautioned against relying on those documents pending the completion of an industry study that began in June 2022. In announcing the withdrawal, the FTC discussed the need for increased transparency around rebates, prices and fees due to changes in PBM market dynamics, including an increase in concentration.

At the same time, recent public reporting suggests that DOJ is looking at the managed care industry for possible monopolization issues tied to earlier vertical integration initiatives by some of the larger companies. This reporting comes on the heels of the DOJ's unsuccessful challenge to the UnitedHealth Group/Change Healthcare merger, and any investigation could involve a review of the competitive effects of transactions cleared in prior administrations.

#3: Labor Market Competition Enforcement: Non-Competes and No-Poach Agreements

In January 2023, the FTC issued a proposed rule that would ban virtually all employer/employee non-compete agreements. According to the accompanying commentary, an underlying concern for the FTC was the impact of these agreements on the cost, quality and access to healthcare by consumers, as they argued that the ban would result in a $148 billion annual decrease in health spending. The public comment period for the proposed rule closed in late April, and the final rule may not be published until 2024. The ultimate legality of any final rule will be determined by the courts, as numerous business groups have indicated an intent to challenge the rule once it becomes final. In the interim, a number of states have passed legislation banning non-competes, including some that are already in effect. Relatedly, the DOJ continues to prosecute criminally employer no-poach agreements entered into separate from any joint venture or other legitimate collaboration. Despite a series of trial losses, the DOJ has made clear through public statements that it will continue making these cases a priority, emphasizing that trial courts have viewed these types of agreements as per se, criminal antitrust violations. In addition to criminal prosecution, these agreements also create liability for companies in related, private civil litigation, where the potential for treble damages is present.

#4: Heightened Scrutiny of Information Sharing Between Competitors

Earlier this year, the DOJ and FTC withdrew the healthcare safe harbors that allowed for the sharing of competitively sensitive information under certain circumstances (e.g., historic, non-disaggregated and managed by an independent third party). The withdrawal of these guidelines coincides with a renewed push to prosecute anticompetitive information sharing agreements among competitors and a heightened concern about the ability of algorithm-based pricing tools to do the same.