FTC Unfair Methods of Competition

PE Physician Practice Deals, Biopharma/PBM Rebates Likely Challenged

Last week, on November 10, the FTC released a policy statement regarding the "Scope of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act" here. The vote to approve the brief was 3-1, with Commissioner Christine S. Wilson (Republican) voting no. It defines principles of "unfair methods of competition," which widens the FTC's scope of enforcement. The FTC will continue to follow the Biden administration's healthcare deal scrutiny and ramp up oversight.

- **The FTC defines "unfair methods of competition" guidelines are not healthcare specific.** They must be (1) methods of competition. The FTC provides examples of misusing patents, licensing, etc. to create or remove impediments to competition as a method of competition. (2) They must be unfair, in that conduct goes beyond competition on merit. Action can be taken if the conduct has the "tendency to generate negative consequences" such as raised prices, reduced output, lowered quality, limited choice, reduced innovation, etc.

- **Fourteen (14) examples of unfair competition methods are listed.** FTC's list is based on Section 5 powers. The policy statement does not have any immediate legal impact and is not considered law. However, it does broaden FTC powers.

  - Invitations to collude
  - M&A or joint ventures that may violate antitrust laws down the line
  - Loyalty rebates, tying, bundling, exclusive dealing arrangements
  - Practices that may facilitate inexplicit coordination
  - Parallel exclusionary conduct which may cause aggregate harm
  - Practices that may undermine the market's competitive conditions
  - Fraudulent actions that could interfere with patent applications
  - Price discrimination
  - M&A that may lessen current or future competition
  - Using market power to gain competitive advantage
  - Interlocking directors and officers of competing firms
  - Commercial bribery and corporate espionage that creates/maintains market power
  - False or deceptive advertising/marketing to create/maintain market power
  - Discriminatory refusals to create/maintain market power

- **NEAR TERM: FTC's intent to ramp up enforcement impacts PBM rebates and pharmaceutical practices when a Biosimilar is available (think Humira) as well as smaller biopharma tuck-ins.**
  - The Section 5 FTC 'crack down' will likely impact PBM and pharmaceutical companies, addressing rebating practices for originator drugs, even when biosimilars have emerged.
  - For pharmaceutical companies, the agency is turning its eye towards acquisitions and smaller tuck-ins that are increasingly popular. Commissioners imply that it is Congressional intent for the FTC to "protect the smaller, weaker business organizations from the oppressive and unfair competition of their more powerful rivals" through their enforcement. This means that the agency will consider more than the consumer welfare standards, the likely effect on consumers, and may look at impacts on new and smaller competitors or even ripple effects in adjacent industries.

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- **<u>NEAR TERM</u>: The FTC and DOJ will scrutinize private equity investment in the healthcare physician practice space (anesthesiology, gastro).** FTC Chair Lina Khan's comments to Financial Times (see here) and DOJ Deputy Assistant Attorney General Andrew Forman's comments at the American Bar Association's Antitrust in Healthcare Conference (see here) warned of pending oversight. State attorneys general and enforcers will follow suit. In some specialties, such as anesthesiology and gastroenterology, PE firms controlled over 2/3 of the market in 2021. The PE approach (of consolidation and hitting a level of market share that drives out competition) will be scrutinized by the FTC. Oncology and other subspecialties are impacted as well.

- **Private equity firms are buying up companies, investing almost $1 T through 8,000 deals in healthcare from cradle to grave in the past decade.** Since companies are not publicly traded, these deals fly under the FTC and DOJ's purview. More than 90% of the PE takeovers are below the $101 M threshold that requires an antitrust threshold review by the FTC/DOJ (See <u>BACKGROUND</u> for more details on *HSR Act*). Consolidation of physician groups and hospitals under PE firms affords more market power, especially when negotiating contracts with payers. But PE acquisitions are contributing to horizontal market integration, which results in increased healthcare prices for patients, payers, Medicaid, and Medicare. These are the types of deals that the FTC will likely investigate.

- **On the value-based care (VBC) front, plans partnering with PE firms do not appear to be caught in the government's crosshairs**. Welsh, Carson, Anderson & Stowe JV with Humana's CenterWell for instance providing value-based primary care clinics for Medicare patients are payer-agnostic but still a marker of vertical integration. This type of joint venture is not something that the FTC appears to be going after, despite its mention of PE in the latest statement.

- **There is an antitrust distinction made between payers and hospitals buying up provider groups.** We note that the FTC views insurer acquisitions of providers differently from hospital acquisitions of providers, the latter will likely be scrutinized. Payers typically cannot control referrals, in the way that hospital systems do. The FTC will scrutinize the potential for hospitals to conduct self-referrals into physician practices that they may acquire.

- **The FTC hints it will begin bringing cases regarding vertical consolidation, which is driving the market.** Vertical consolidation brings payers many benefits, helping to automate processes and streamline administrative workloads. Payers are not only expanding into brick-and-mortar care delivery but also home care and telemedicine. CVS Health for example, with its retail pharmacy chain, PBM (Caremark), health insurer (Aetna), home health ($8 B pending merger with Signify Health), and primary care (MinuteClinic) businesses. UnitedHealth Group and Optum operate both PBM and provider business lines. In 2018, Cigna acquired Express Scripts (PBM) for $67 B. While these deals are not ones that we think the FTC will try to unscramble, we think that the FTC is wary of market integration with concerns of <u>payers</u> gaining too much leverage.

- **Courts will provide the final check; FTC indicates a willingness to be bolder and riskier in challenges to anticompetitive conduct.** However, the bar of evidence that they need to show to the courts remains unchanged and it is uncertain if the courts will agree with their broader definition of Section 5. We will be watching to see what types of healthcare cases the FTC brings to the court, as this will define the scope of what they plan to crack down on. According to the policy statement, the FTC could pursue a wide range of cases. Courts are typically more conservative when it comes to antitrust (as seen by the FTC setback in the Illumina/Grail case and the DOJ loss in the UnitedHealth/Change Healthcare case, with courts siding against government). However, the Biden administration continues to appoint more judges, who may side more with the FTC going forward. The GOP House may be hostile to the FTC's new policy approach and bring FTC Chair Lina Khan

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in for questioning. The House may also try to deny FTC funding and add appropriations riders, but their efforts will not make it far as they would not pass the Democrat-controlled Senate.

- **NEXT STEPS:** Despite midterm results, agencies are expected to continue oversight of anticompetitive threats. (1) We will watch pending transactions for FTC action. (2) Updated merger guidelines are expected to be released by early 2023. The combination of these factors indicates that FTC will be stepping up scrutiny in 2023 and companies in highly visible markets like healthcare may see an increased burden in proving that they are not engaging in anti-competitive practices or mergers. (3) FTC's PBM 6(b) Study results are likely to be released in the next 3 to 6 months. (4) FTC Physician Group and Healthcare Facility Mergers Report will probably be out next year as well. After the tech industry, healthcare is second on the priority list for the FTC going forward under the Biden administration. See **BACKGROUND** below for more details.

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BACKGROUND

- **Recall FTC has authority over the pharmaceutical and hospital industries.** DOJ has authority over health plans & PBMs. Both agencies operate under the same regulatory & statutory framework but have expertise in different industries.

- **Through reactivation of Section 5, FTC reformulates the law and broadens its powers.** Section 5 is an FTC enforcement tool aimed at prohibiting "unfair methods of competition" that didn't fall into the *Sherman and Clayton Acts*. Yet, traditionally, antitrust oversight has still been based on *Sherman and Clayton Acts*, with the exception being FTC oversight on the "invitation to collude." The new statement is likely more in line with Congress's intent in 1914's *FTC Act*.

- **Broad, sweeping principles raise questions.** The new policy statement fills the void left by the 2015 bipartisan antitrust enforcement guidance that the FTC rescinded in July 2021. Unlike the 2015 guidance, the recent policy offers very broad principles. It raises questions about what the FTC will consider unlawful. Justifications for conduct are undefined and the FTC does not provide concrete guidance. The FTC will oppose any conduct that is "facially unfair," but what is deemed facially unfair is unclear.

- **More details on the flags raised by private equity that have caught the FTC's attention.** KHN Database analyzes 600 deals made by 25 PE firms who frequently invest in healthcare, see here. Top investors include Shore Capital Partners (261 deals), Audax Group (245 deals), Webster Equity Partners (145 deals), and Waud Capital Partners (144 deals). A recent JAMA study found that PE takeovers are tied to an average increase of $71 per claim filed and a 9% increase in lengthier and costlier patient visits. See the study here. Since 2014, PE firms have already paid more than $500 M in fines for ~34 lawsuits under the False Claims Act (which cracks down on false billing submissions to the federal government).

- **This change in scope of review for enforcement is not unexpected.** We have previously noted that the FTC is looking to reassess what defines antitrust and looking beyond efficiency when assessing anticompetitive practices. With increasingly complex and interconnected healthcare markets, the FTC is also in the process of revising its horizontal merger guidelines.

- **Recall also that FTC is also investigating PBMs, and commissioners note important supply chain role in Rx prices.** In June 2022, the FTC announced that it will investigate the six largest PBMs (Caremark; Express Scripts, OptumRx, Humana, Prime Therapeutics, and MedImpact Healthcare Systems). See announcement here. The study aims to gather information on scrutinized practices including PBM control over formularies, pressure on independent pharmacies, and spread pricing. Consolidation in the PBM market is also expected to be addressed in this investigation. Companies have 90 days from the order to respond and we expect the investigation to take several more months. Ongoing PBM study will inform FTC Pharma merger work. The antitrust authorities recognize that pharma does not operate in a vacuum. "Root causes" may lie in the entire supply chain, according to Chair Lina Khan.

- **Three major federal antitrust laws.** Key policies follow.
    - *The Federal Trade Commission Act*: See here. Enacted in 1914. This prohibits unfair methods of competition in interstate commerce and created the Federal Trade Commission to police violations. It carries no criminal penalties.
    - *The Clayton Antitrust Act*: See here. Enacted in 1914. This is a civil statute and does not carry any criminal penalties. M&A likely to lessen competition is prohibited. M&A

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consideration of a certain scale or higher is required to be reported to the Antitrust Division and the Federal Trade Commission.
  - *The Sherman Antitrust Act*: See here. Enacted in 1890. Contracts, conspiracies, and agreements to unreasonably restrict international and interstate trade are outlawed. Agreements to fix prices, allocate customers, and rig bids are all punishable as criminal penalties. Monopolizing any part of interstate commerce is also illegal.

- ***Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976.*** See legislation here. Reminder that during the June 2022 FTC and DOJ Workshop, agencies' leaderships supported lowering the HSR threshold ($101 M) for merger scrutiny. The *HSR Act* requires most of the proposed transactions that affect commerce in the United States over a certain size to be reviewed by the FTC or the DOJ. Either agency can take legal action to block deals that it believes would "substantially lessen competition."

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