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# Urgent Care: Current Antitrust Enforcement Trends in the Healthcare Industry

#### March 25, 2024

The healthcare industry remains a focal point of President Biden's antitrust agenda. The president's July 2021 *Executive Order on Promoting Competition in the American Economy*<sup>1</sup> called on federal agencies to focus antitrust enforcement efforts on health care, among other industries, and to coordinate on oversight, investigations and remedies where agency jurisdiction overlaps. The Federal Trade Commission (FTC), the Department of Justice Antitrust Division (DOJ) and the Department of Health and Human Services (HHS) later announced plans to address antitrust concerns in the healthcare industry. FTC Chair Lina M. Khan highlighted ongoing healthcare-related enforcement initiatives in a February 2024 speech before the American Medical Association.<sup>2</sup> The FTC, DOJ and HHS launched an interagency inquiry into private equity and corporate ownership in health care shortly thereafter.<sup>3</sup>

We summarize below the latest federal antitrust activities in the healthcare industry. Based on these activities, companies and other stakeholders in the healthcare industry should expect:

 <u>A continued "whole of the government" approach</u>: Participants in the healthcare industry should expect robust scrutiny by federal authorities and increased interagency coordination regarding antitrust policies and enforcement actions, at least while the current federal antitrust leadership remains in place.

<sup>&</sup>lt;sup>1</sup> Presidential Action, Executive Order on Promoting Competition in the American Economy (July 9, 2021), https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/.

<sup>&</sup>lt;sup>2</sup> Remarks by Chair Lina M. Khan at American Medical Association National Advocacy Conference, Fed. Trade Comm'n (Feb. 14, 2024), https://www.ftc.gov/news-events/news/speeches/remarks-chair-lina-m-khanamerican-medical-association-national-advocacy-conference.

<sup>&</sup>lt;sup>3</sup> Press Release, Fed. Trade Comm'n, Federal Trade Commission, the Department of Justice and the Department of Health and Human Services Launch Cross-Government Inquiry on Impact of Corporate Greed in Health Care (Mar. 5, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/03/federal-trade-commission-department-justice-department-health-human-services-launch-cross-government.

- <u>Increased attention to private equity and corporate ownership in health care</u>: Private
  equity firms that invest in companies in the healthcare industry and their partners should
  anticipate close scrutiny of acquisitions and their broader role in the industry.
- <u>Continued aggressive enforcement in the pharmaceutical industry</u>: Pharmaceutical companies should prepare for ongoing heightened merger scrutiny. The agencies are also increasingly focusing on the practices of companies in the pharmaceutical distribution chain, including pharmacy benefit managers, group purchasing organizations and drug wholesalers.
- <u>Ongoing scrutiny in labor markets</u>: Despite setbacks in court, DOJ remains ready to criminally prosecute no-poach and wage-fixing agreements. Healthcare companies should expect the FTC to continue to bring enforcement actions against employment noncompete agreements the agency believes are overbroad. The FTC may also engage in rulemaking to ban a wide range of employment non-competes.
- <u>Continued merger enforcement</u>: Enforcers will persist in closely monitoring mergers in the healthcare sector, including by investigating and potentially bringing challenges based on novel theories of harm or that will particularly affect underserved consumer groups or workers.
- <u>Increased attention to health data</u>: Industry participants, including data brokers, should anticipate increased scrutiny of practices concerning health data and patient privacy.

#### The FTC's Five Enforcement Pillars

Khan's February 14 speech outlined *five enforcement pillars* for FTC action in the healthcare industry.<sup>4</sup> These pillars include enforcement initiatives that have largely gone untested in US courts, underscoring the agency's aggressive positions regarding the healthcare industry.

*First pillar*. Khan stated that the FTC will scrutinize the actions of intermediaries across healthcare supply chains. She announced the launch of a request for information (RFI) seeking public feedback on how group purchasing organizations and drug wholesalers may contribute to generic drug shortages. The FTC will conduct the inquiry along with HHS.<sup>5</sup>

This sort of collaboration among the federal agencies is consistent with their prior actions. The FTC, DOJ and HHS have all announced plans to enhance interagency coordination in response to

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<sup>&</sup>lt;sup>4</sup> Remarks by Chair Lina M. Khan at American Medical Association National Advocacy Conference, Fed. Trade Comm'n (Feb. 14, 2024), https://www.ftc.gov/news-events/news/speeches/remarks-chair-lina-m-khan-american-medical-association-national-advocacy-conference.

<sup>&</sup>lt;sup>5</sup> *Id.;* Press Release, Fed. Trade Comm'n, FTC, HHS Seek Public Comment on Generic Drug Shortages and Competition Amongst Powerful Middlemen (Feb. 14, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/02/ftc-hhs-seek-public-comment-generic-drug-shortages-competition-amongst-powerful-middlemen.

President Biden's July 2021 Executive Order. The FTC and DOJ announced in December 2023 that each agency will appoint Counsel for Health Care, who will spearhead interagency and policy initiatives regarding healthcare competition.<sup>6</sup> Similarly, HHS recently appointed Stacy Sanders to the agency's new role of Chief Competition Officer. Sanders will work with both the FTC and DOJ to "promote competition in health care markets."<sup>7</sup>

<u>Second pillar</u>: Khan reemphasized the FTC's focus on allegedly unlawful consolidation and "rollups" in the healthcare industry, where a series of acquisitions over time results in market concentration—according to Khan, "even if each individual transaction seems benign."<sup>8</sup>

On March 5, the FTC, DOJ and HHS announced an RFI to obtain feedback on the impact of private equity ownership in the healthcare industry.<sup>9</sup> That same day, the agencies held a workshop on the topic, where officials expressed concern that private equity ownership has led to increased healthcare costs and diminished quality and access.<sup>10</sup>

The FTC's recent unprecedented lawsuit against a private equity investor and the RFI regarding private equity ownership in the healthcare industry make clear that federal enforcers will maintain their focus on private equity for the foreseeable future. One unsettled issue is how a series of transactions could violate the antitrust laws if no single transaction, by itself, is illegal. To be sure, serial acquisitions can culminate in an illegal acquisition (the one that broke the camel's back), but that is different than the proposition that a series of transactions can be illegal when each individual transaction is benign.

Khan also mentioned the FTC's history of challenging allegedly unlawful healthcare provider mergers. The agency is currently litigating its challenge to Novant's proposed acquisition of

<sup>&</sup>lt;sup>6</sup> Press Release, Fed. Trade Comm'n, FTC, DOJ and HHS Work to Lower Health Care and Drug Costs, Promote Competition to Benefit Patients, Health Care Workers (Dec. 7, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/12/ftc-doj-hhs-work-lower-health-care-drug-costs-promote-competition-benefit-patients-health-care.

<sup>&</sup>lt;sup>7</sup> Press Release, U.S. Dep't of Health and Human Servs., Secretary Becerra Names Chief Competition Officer to Help Identify Areas to Promote Competition in Health Care (Jan. 8, 2024), https://www.hhs.gov/about/news/2024/01/08/secretary-becerra-names-chief-competition-officer-to-help-identify-areas-to-promote-competition-in-health-care.html.

<sup>&</sup>lt;sup>8</sup> Remarks by Chair Lina M. Khan at American Medical Association National Advocacy Conference, Fed. Trade Comm'n (Feb. 14, 2024), https://www.ftc.gov/news-events/news/speeches/remarks-chair-lina-m-khanamerican-medical-association-national-advocacy-conference.

<sup>&</sup>lt;sup>9</sup> Press Release, Fed. Trade Comm'n, Federal Trade Commission, the Department of Justice and the Department of Health and Human Services Launch Cross-Government Inquiry on Impact of Corporate Greed in Health Care (Mar. 5, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/03/federal-trade-commission-department-justice-department-health-human-services-launch-cross-government.

<sup>&</sup>lt;sup>10</sup> Fed. Trade Comm'n, Private Capital, Public Impact: An FTC Workshop on Private Equity in Health Care (Mar. 5, 2024), https://www.ftc.gov/news-events/events/2024/03/private-capital-public-impact-ftc-workshop-private-equity-health-care.

Community Health Systems in North Carolina. The FTC alleges that the proposed acquisition would substantially reduce competition in a market for inpatient general acute care services.<sup>11</sup> The FTC's challenge comes on the heels of the agency's suit to block John Muir Health's proposed purchase of Tenent's San Ramon Regional Medical Center in Northern California, which ended when the parties abandoned the deal shortly after the complaint was filed.<sup>12</sup>

*Third pillar*: Khan outlined the FTC's strategy to address potential antitrust harms in labor markets, including as a result of mergers.<sup>13</sup> On February 26, the FTC challenged Kroger's proposed acquisition of Albertsons, alleging in part that the deal would result in harm to union grocery workers.<sup>14</sup> In the healthcare space, Khan and FTC Commissioner Rebecca Kelly Slaughter previously wrote a concurring statement to the FTC's complaint to block *Lifespan-Care New England*, positing that the transaction could significantly reduce competition in a relevant upstream labor market, in addition to the relevant downstream markets alleged in the complaint.<sup>15</sup> Stakeholders should expect the federal antitrust agencies to seek to pursue similar theories in other healthcare cases.

Khan also addressed the agency's proposed rule to ban non-compete clauses in employment contracts, which could issue as early as April 2024.<sup>16</sup> Companies should work closely with antitrust counsel to develop effective business strategies in anticipation of the forthcoming rule, given that healthcare industry participants often use non-competes. *See* FTC Announces Proposed Rule Banning Employers From Entering Non-compete Clause With Employees.

<sup>13</sup> Remarks by Chair Lina M. Khan at American Medical Association National Advocacy Conference, Fed. Trade Comm'n (Feb. 14, 2024), https://www.ftc.gov/news-events/news/speeches/remarks-chair-lina-m-khan-american-medical-association-national-advocacy-conference.

<sup>14</sup> Compl., In the Matter of The Kroger Co., Dkt. No. D-9426 (FTC Feb. 26, 2024), https://www.ftc.gov/system/files/ftc\_gov/pdf/d9428\_2310004krogeralbertsonsp3complaintpublic.pdf

<sup>15</sup> Concurring Statement of Commissioner Rebecca Kelly Slaughter and Chair Lina M. Khan, Regarding FTC and State of Rhode Island v. Lifespan Corporation and Care New England Health System, Fed. Trade Comm'n, File No. 2110031 (Feb. 17, 2022), https://www.ftc.gov/system/files/ftc\_gov/pdf/public\_statement\_of\_commr\_slaughter\_chair\_khan\_re\_lifespan -cne\_redacted.pdf.

<sup>16</sup> Press Release, Fed. Trade Comm'n, FTC Proposes Rule to Ban Noncompete Clauses, Which Hurt Workers and Harm Competition (Jan. 5, 2023), https://www.ftc.gov/news-events/news/pressreleases/2023/01/ftc-proposes-rule-ban-noncompete-clauses-which-hurt-workers-harm-competition; Dan Papscun, "FTC Expected to Vote in 2024 on Rule to Ban Noncompete Clauses," BLOOMBERG LAW (May 10, 2023), https://news.bloomberglaw.com/antitrust/ftc-expected-to-vote-in-2024-on-rule-to-bannoncompete-clauses.

<sup>&</sup>lt;sup>11</sup> Compl., In the Matter of Novant Health, Inc., Dkt. No. 9425 (FTC Jan. 25, 2024), https://www.ftc.gov/system/files/ftc\_gov/pdf/novant-chs\_part\_3\_complaint\_public\_redacted.pdf.

<sup>&</sup>lt;sup>12</sup> Press Release, Fed. Trade Comm'n, Statement Regarding the Termination of John Muir's Takeover of San Ramon Regional Medical Center from Tenet Healthcare (Dec. 18, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/12/statement-regarding-termination-john-muirs-takeover-san-ramon-regional-medical-center-tenet.

*Fourth pillar*: Khan described the agency's plan to combat allegedly unlawful practices in the pharmaceutical industry, including through aggressive merger enforcement.<sup>17</sup> In its recent challenge to *Amgen-Horizon*, the FTC demonstrated a willingness to challenge pharmaceutical industry transactions on unconventional grounds. That case marked the first federal antitrust challenge of a transaction in over 40 years based on a "conglomerate" theory of harm. The FTC approved its final order to settle the lawsuit in December 2023, requiring Amgen to, among other things, refrain from bundling its drugs with two of Horizon's drugs, both of which the FTC claimed were monopoly products in their respective markets.<sup>18</sup> See Blast From the Past: FTC Revives Conglomerate Concerns as Basis for Merger Challenges. Khan stated that the agency's challenge to *Amgen-Horizon*, along with its challenge to *Sanofi-Maze Therapeutics*, "laid out how these pharma deals risked depriving Americans of access to affordable, innovative drugs—worsening the affordability crisis that too many patients already face."<sup>19</sup>

Khan also referenced the FTC's recent letters to pharmaceutical companies that challenged the lawfulness of patents allegedly improperly listed in the FDA's Orange Book.<sup>20</sup> The FTC is relying on the United States Court of Appeals for the First Circuit's decision in *In re Lantus Direct Purchaser Antitrust Litigation*, which held that a patent for Sanofi's Lantus SoloSTAR injector pen solely covering a drive mechanism was improperly listed in the Orange Book because it did not "claim the drug, [Lantus SoloSTAR/ insulin glargine]" or "a method of using the drug[,]" as required by the Hatch-Waxman Act.<sup>21</sup> The court reasoned that since the defendant "improperly submitted a patent for listing in the Orange Book, … [it] is potentially liable under the antitrust laws to drug purchasers who were allegedly harmed by the effective extension of Sanofi's monopoly[,]" as the listing

<sup>20</sup> Id.

<sup>&</sup>lt;sup>17</sup> The FTC is also conducting a study of practices in the pharmacy benefit manager industry, and has since cautioned that industry participants should not rely on FTC advocacy statements and reports from 2004 to 2014, which found that "certain state and federal proposals to increase PBM transparency could undermine competitive processes." Press Release, Fed. Trade Comm'n, FTC Votes to Issue Statement Withdrawing Prior Pharmacy Benefit Manager Advocacy (July 20, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/07/ftc-votes-issue-statement-withdrawing-prior-pharmacy-benefit-manager-advocacy; Press Release, Fed. Trade Comm'n, FTC Launches Inquiry Into Prescription Drug Middlemen Industry (June 7, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry.

<sup>&</sup>lt;sup>18</sup> Press Release, Fed. Trade Comm'n, FTC Approves Final Order Settling Horizon Therapeutics Acquisition Challenge (Dec. 14, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/12/ftc-approves-final-order-settling-horizon-therapeutics-acquisition-challenge.

<sup>&</sup>lt;sup>19</sup> Remarks by Chair Lina M. Khan at American Medical Association National Advocacy Conference, Fed. Trade Comm'n (Feb. 14, 2024), https://www.ftc.gov/news-events/news/speeches/remarks-chair-lina-m-khan-american-medical-association-national-advocacy-conference.

<sup>&</sup>lt;sup>21</sup> 950 F.3d 1, 4, 7 (1st Cir. 2020); 21 U.S.C. §§ 355(b)(1)(A)(viii), 355(c)(2); Federal Trade Comm'n, Statement Concerning Brand Drug Manufacturers Improper Listing of Patents in the Orange Book (Sept. 14, 2023), https://www.ftc.gov/system/files/ftc\_gov/pdf/p239900orangebookpolicystatement092023.pdf (referencing *Lantus*, 950 F.3d at 7).

triggered the automatic 30-month stay barring generic approval under the Hatch-Waxman framework.<sup>22</sup>

*Fifth pillar*: Khan described the agency's commitment to vigilant oversight of privacy in the healthcare industry. She noted that "the FTC is making clear that [companies including data brokers] must secure the sensitive health data they collect." Consistent with this objective, the FTC and HHS recently collaborated on updating guidance on collecting and disseminating consumer health data. This initiative aims to provide businesses with guidance on complying with relevant federal statutes and regulations.<sup>23</sup>

### Ongoing DOJ Enforcement Initiatives

DOJ has also been closely monitoring companies in the healthcare space. The agency issued second requests in August 2023 to review United's proposed acquisition of home health provider Amedisys.<sup>24</sup> The transaction received substantial public attention.<sup>25</sup>

DOJ continues to bring criminal enforcement actions in the healthcare industry.<sup>26</sup> A federal grand jury recently indicted a healthcare executive who held positions at three home health agencies in Las Vegas for allegedly conspiring to fix the wages of nurses employed by those agencies. The trial is set for October 2024.<sup>27</sup> In August 2023, DOJ obtained a guilty plea from an oncologist involved in a roughly 17-year conspiracy to allocate chemotherapy and radiation treatment markets for cancer

<sup>&</sup>lt;sup>22</sup> *Id.* at 3—4.

<sup>&</sup>lt;sup>23</sup> Lesley Fair, Business Blog, Updated FTC-HHS publication outlines privacy and security laws and rules that impact consumer health data, Fed. Trade Comm'n (Sept. 15, 2023), https://www.ftc.gov/business-guidance/blog/2023/09/updated-ftc-hhs-publication-outlines-privacy-security-laws-rules-impact-consumer-health-data; Fed. Trade Comm'n, Collecting, Using, or Sharing Consumer Health Information? Look to HIPAA, the FTC Act, and the Health Breach Notification Rule, https://www.ftc.gov/business-guidance/resources/collecting-using-or-sharing-consumer-health-information-look-hipaa-ftc-act-health-breach.

<sup>&</sup>lt;sup>24</sup> Sec. Exch. Comm'n, Amedisys, Inc., Proxy Statement, Schedule 14A (Aug. 10, 2023), https://www.sec.gov/Archives/edgar/data/896262/000110465923089839/tm2321414-3\_defm14a.htm.

<sup>&</sup>lt;sup>25</sup> Letter from Senator Elizabeth Warren and Representative Pramila Jayapal to Assistant Attorney General Kanter and Chair Khan (Oct. 3, 2023),

https://www.warren.senate.gov/imo/media/doc/2023.10.03%20Letter%20to%20DOJ%20and%20FTC%20re%20United%20Health%20Amedisys%20Acquistion.pdf.

<sup>&</sup>lt;sup>26</sup> See Dep't of Justice, Generic Drugs Investigation Targets Anticompetitive Schemes (updated June 15, 2023), https://www.justice.gov/atr/division-operations/division-update-spring-2021/generic-drugs-investigation-targets-anticompetitive-schemes.

<sup>&</sup>lt;sup>27</sup> United States v. Lopez, Case No. 23-cr-00055, ECF No. 97 (D. Nev. 2023); Press Release, U.S. Dep't of Justice, Health Care Staffing Executive Indicted for Fixing Wages of Nurses (Mar. 16, 2023), https://www.justice.gov/opa/pr/health-care-staffing-executive-indicted-fixing-wages-nurses; Press Release, U.S. Dep't of Justice, Fraud Charges Added Against Health Care Staffing Executive in Las Vegas (Sept. 7, 2023), https://www.justice.gov/opa/pr/fraud-charges-added-against-health-care-staffing-executive-las-vegas.

patients in southwest Florida.<sup>28</sup> The retired doctor was sentenced to probation, a \$50,000 fine and community service.<sup>29</sup> His medical group had previously entered into a deferred prosecution agreement and paid a \$100 million fine for market allocation in the oncology industry.<sup>30</sup> DOJ also recently secured a significant settlement in a case involving price-fixing, bid-rigging and market-allocation schemes involving generic medicines. Teva Pharmaceuticals USA, Inc. (Teva) and Glenmark Pharmaceuticals Inc., USA agreed to pay \$225 million and \$30 million criminal penalties, respectively, for their involvement in the scheme. Teva's \$225 million penalty was the largest ever for a domestic antitrust cartel.<sup>31</sup>

DOJ Deputy Assistant Attorney General Andrew Forman recently emphasized how seriously DOJ takes criminal and civil antitrust enforcement in the healthcare industry. Forman stated that "people at the Antitrust Division ... eat their cereal in the morning thinking about [enforcing competition laws in the healthcare industry] and go to sleep thinking about it too."<sup>32</sup> He went on to say that DOJ "remain[s] very focused on labor-related issues in [the healthcare] space, whether around wages, non-competes, no-poach agreements, requirements to see more patients over less time or other workplace restrictions or conditions."<sup>33</sup> Forman also expressed concern about whether data accumulation negatively affects competition in the healthcare industry.<sup>34</sup>

<sup>30</sup> Press Release, U.S. Dep't of Justice, Leading Cancer Treatment Center Admits to Antitrust Crime and Agrees to Pay \$100 Million Criminal Penalty (Apr. 30, 2020), https://www.justice.gov/opa/pr/leading-cancer-treatment-center-admits-antitrust-crime-and-agrees-pay-100-million-criminal.

<sup>31</sup> Press Release, U.S. Dep't of Justice, Major Generic Drug Companies to Pay Over Quarter of a Billion Dollars to Resolve Price-Fixing Charges and Divest Key Drug at the Center of Their Conspiracy (Aug. 21, 2023), https://www.justice.gov/opa/pr/major-generic-drug-companies-pay-over-quarter-billion-dollarsresolve-price-fixing-charges.

<sup>32</sup> Deputy Assistant Attorney General Andrew J. Forman Delivers Remarks to Capitol Forum: Health Care Competition Conference, Dep't of Justice (Oct. 26, 2023), https://www.justice.gov/opa/speech/deputy-assistant-attorney-general-andrew-j-forman-delivers-remarks-capitol-forum-health.

<sup>33</sup> Id.

<sup>34</sup> *Id.* ("We also see healthcare companies becoming more focused on accumulating data and wonder whether it is good for competition when a few players control massive data reservoirs. Does this lead to benefits, or do these information asymmetries enable these companies to dictate the terms of future innovation, determine who gets care at what price, competitively surveil their rivals or otherwise game the system?").

<sup>&</sup>lt;sup>28</sup> Press Release, U.S. Dep't of Justice, Doctor Pleads Guilty to Role in Antitrust Conspiracy That Limited Cancer Patients' Options for Life Saving Care in Southwest Florida (Aug. 24, 2023), https://www.justice.gov/opa/pr/doctor-pleads-guilty-role-antitrust-conspiracy-limited-cancer-patientsoptions-life-saving.

<sup>&</sup>lt;sup>29</sup> United States v. Harwin, No. 2:20-cr-00115, ECF Nos. 368 (M.D. Fla. Nov. 21, 2023); *id.* at ECF No. 29; Beth JoJack, "Fla. Oncologist Avoids Prison In Scheme To Limit Competition," LAW360 (Nov. 27, 2023).

These statements and actions by antitrust officials make clear that the federal government is intensely focused on threats of antitrust harms in healthcare markets. Companies in the healthcare sector should work closely with antitrust counsel to ensure that their business strategies account for potential antitrust risk. WilmerHale's Antitrust Group has extensive experience in the healthcare industry, including counseling clients through agency-facing investigations and litigations, private suits, and internal investigations.

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