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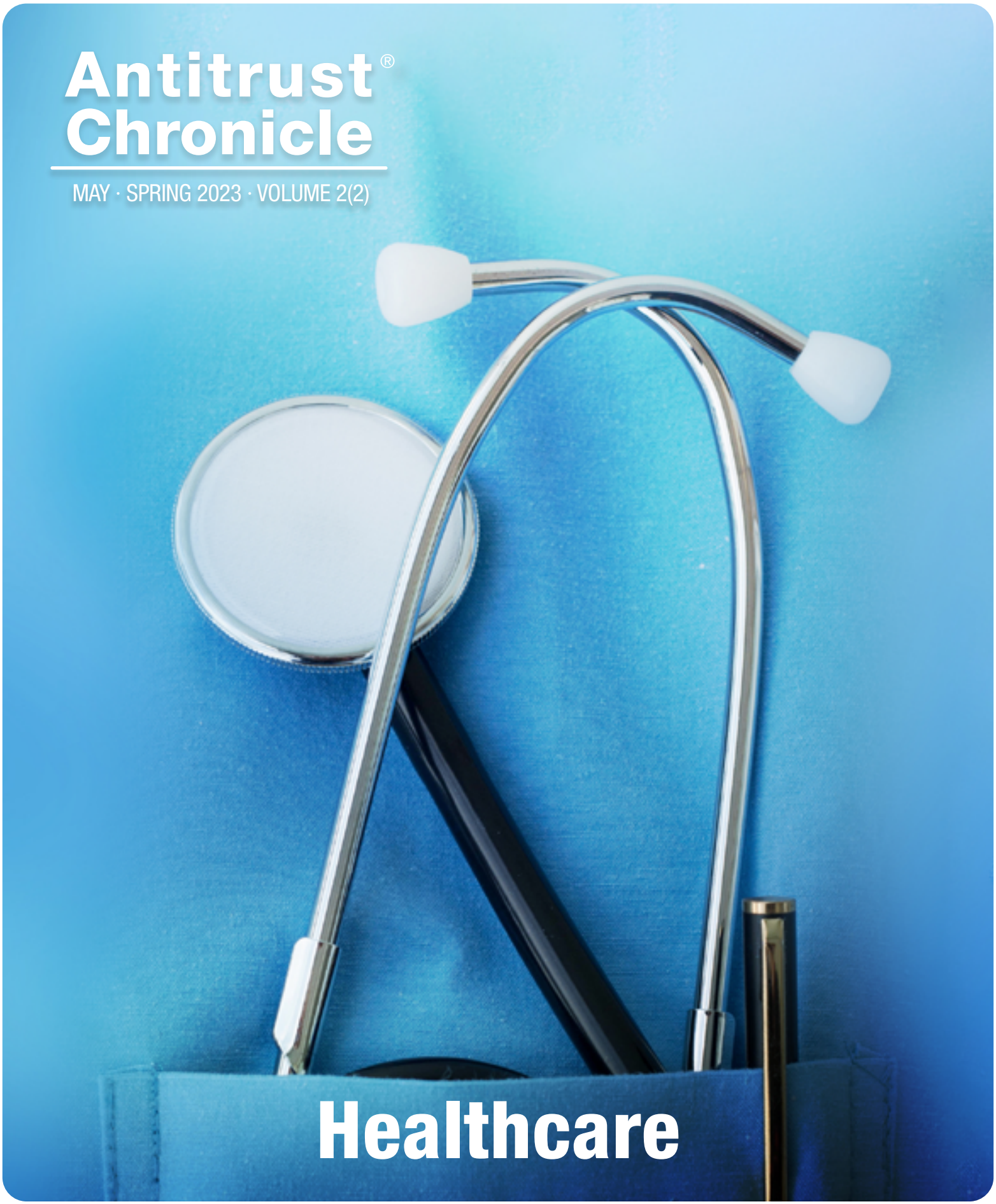

Healthcare

CPI COMPETITION POLICY® INTERNATIONAL

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LETTER FROM THE EDITOR

Dear Readers,

Of all areas of public policy, few raise passions as intensely as healthcare. After all, healthcare touches the entire human experience, in the famous words of Churchill, "from the Cradle to the Grave." Indeed, regulating healthcare involves making decisions that affect birth, death, disease suffering, and, from an antitrust perspective, the economic welfare of individuals and the State.

The provision of healthcare services varies widely across jurisdictions, perhaps best exemplified by the contrasting approaches in the U.S., where reliance on private healthcare providers and insurers is the norm, and the approaches in European jurisdictions, where the State plays a more prominent role, though private healthcare markets exist in parallel. On both sides of the Atlantic, changes are afoot, as discussed in the timely contributions to this edition of the Chronicle.

Starting with the U.S., **Holden Brooks** examines how major changes are underway with respect to how healthcare deals get done in the U.S., with new merger guidelines and HSR reporting requirements waiting in the wings, new analytical frameworks being explored, and new pre-close notice and clearance laws proliferating at a rapid pace at the state level. More small-scale healthcare deals will be subject to some type of antitrust scrutiny than ever before, with many clients confronting antitrust principles and processes for the first time. As a result, for practitioners, providing effective advice to healthcare clients will become increasingly complex.

Reflecting further on the sudden nature of these changes, **Dionne Lomax & Lisl Dunlop** focus on how, in a largely unheralded announcement, the U.S. Department of Justice Antitrust Division ("DOJ") withdrew three major antitrust policy statements applying to the health care industry (the Health Care Guidelines). The announcement has been met with widespread concern about the impact of the withdrawal on the industry, which over the last 30 years has arranged its affairs in the context of this guidance. This is in a context where Government health care policies have encouraged a broad range of collaborations, and the Guidelines have provided an important foundation upon which many of those collaborations are built. Before dismantling that scaffold, the authors argue that the agencies should engage in research, consultation, and provide clear and transparent guidance for the industry going forward.

Similarly, **Patrick D. Souter** delves into the implications of these U.S. policy shifts. The U.S. healthcare sector is composed of numerous types of actors that would, in the normal course of events, be considered to be competitors from an antitrust standpoint. However, their collaboration has been accepted in certain circumstances, due to perceived benefits to patients deriving from such arrangements. Historically, such actors could rely on the policy statements and guidance issued by the U.S. Department of Justice and Federal Trade Commission to assist in developing business arrangements and exchanging information. The author explores the implications of recent moves to withdraw such guidance and to revise the method by which healthcare business arrangements are reviewed, particularly in the light of the federal government's heightened level of scrutiny in its analysis of healthcare-related transactions.

Turning to a specific (but important) issue in U.S. merger control, **Cory Capps, Leyla Karakas & Tetyana Shvydko** focus on evidence of systematic price increases following certain types of "cross-market" hospital mergers and acquisitions, i.e. combinations of hospitals that are too far apart to be close substitutes or in the same relevant antitrust market. The literature on such mergers continues to grow, and antitrust agencies have in recent years investigated transactions on the basis of cross-market concerns. As yet, however, no agency has fully litigated a cross-market challenge. The authors review the mechanisms that could drive cross-market price with a particular focus on the common customer mechanism, which posits that hospitals can be substitutes from the perspective of employers and the health insurers that market products to them, even if they are not substitutes for individual patients. Importantly, the piece emphasizes that, while complementarity between sellers is ruled out by definition for in-market mergers, parties to a cross-market merger can be complements or substitutes.

An important component of the healthcare debate in the U.S. is the role of administrative costs within the system. **Barak D. Richman & Dr. Kevin A. Schulman** underline that even though the U.S. healthcare system exhibits higher administrative costs than any other OECD nation, they have not received substantial attention from policymakers despite their cost and impact on the market. The authors argue that competition policy could meaningfully reduce these costs. Electronic health records have arguably departed from pro-competition principles by failing to understand how healthcare firms can direct business processes exploit their incumbent positions in the market. The authors' overarching argument is that high administrative costs in the health sector is not an inevitable consequence of a private payer system, but rather due to poorly conceived policies and a lack of competition and innovation.

On the European side, while healthcare systems in EU countries is typically characterized as being "socialized" in nature, **Dr. Theodosia Stavroulaki** underlines that new healthcare markets are forming in Europe. Indeed, some European countries, such as the Netherlands, have adopted a choice and competition model for healthcare delivery. The goal of competition among providers, however, may in certain cases conflict with essential goals of EU health systems including access and health equity. Competition authorities will be unable to address the main competition concerns that may emerge in light of these conflicts if they do not first address the core question of how to define and assess healthcare quality. There are three different models under which competition authorities around the globe may define and assess quality. Taking as an example the Google/Fitbit deal, this piece takes the stance that if the Commission had examined the transaction deal under what the author terms a "Regulatory" and/or a "Holistic" Approach, it might have been better able to detect the less visible harms such data-driven deals may cause to vulnerable populations and high-risk consumers.

As always, many thanks to our great panel of authors.

Sincerely,

CPI Team

SUMMARIES

SUMMARIES

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HEALTHCARE ADMINISTRATIVE COSTS AND COMPETITION POLICY

By Barak D. Richman & Dr. Kevin A. Schulman

Even though the U.S. healthcare system exhibits higher administrative costs than any other OECD nation, they have not received substantial attention from policymakers despite their enormous cost and impact on the market. We argue that competition policy could meaningfully reduce these administrative costs. We first describe how efforts to deploy electronic health records departed from pro-competition principles by failing to understand how healthcare firms would direct business processes exploit their incumbent positions in the market. We then argue that there is an urgent need to reduce costs and increase competition by standardizing and digitizing business processes across the health sector. High administrative costs in the health sector is not an inevitable consequence of a private payer system. To the contrary, it is a product of poorly conceived policies and a lack of competition and innovation.

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THE EVOLUTION OF ANTITRUST ANALYSIS FOR THE HEALTHCARE INDUSTRY: IS IT FOR THE BETTER OR WILL IT RESULT IN UNNECESSARY HURDLES

By Patrick D. Souter

The healthcare industry is comprised of numerous types of providers and suppliers who are generally considered competitors from an antitrust standpoint, but their collaboration has been accepted in certain circumstances by governmental regulators due to the benefits derived by the patients from such arrangements without being detrimental to competition. For decades these healthcare market participants were able to utilize multiple policy statements and guidance issued by the United States Department of Justice and Federal Trade Commission to assist in properly developing various business arrangements and exchanging information among competitors. Additionally, these authorities provided a guidebook whereby the parties were able to determine whether federal antitrust laws were negatively implicated in the process. However, the United States government has recently taken action to withdraw this guidance and revise the method by which healthcare business arrangements are reviewed. The end result is that valuable resources long relied upon by healthcare market participants are no longer available for legal authority in conjunction with the federal government's heightened level of scrutiny in the analysis of such proposed transactions.

WHAT'S NEXT?

For June 2023, we will feature an Antitrust Chronicle focused on issues related to (1) **Online Advertising**; and (2) **Algorithmic Bias**.

ANNOUNCEMENTS

CPI wants to hear from our subscribers. In 2023, we will be reaching out to members of our community for your feedback and ideas. Let us know what you want (or don't want) to see, at: antitrustchronicle@competitionpolicyinternational.com.

CPI ANTITRUST CHRONICLES July 2023

For July 2023, we will feature an Antitrust Chronicle focused on issues related to (1) **Coordinated Effects**; and (2) **Judicial Review of Economic Evidence**.

Contributions to the Antitrust Chronicle are about 2,500 – 4,000 words long. They should be lightly cited and not be written as long law-review articles with many in-depth footnotes. As with all CPI publications, articles for the CPI Antitrust Chronicle should be written clearly and with the reader always in mind.

Interested authors should send their contributions to Sam Sadden (ssadden@competitionpolicyinternational.com) with the subject line "Antitrust Chronicle," a short bio and picture(s) of the author(s).

The CPI Editorial Team will evaluate all submissions and will publish the best papers. Authors can submit papers on any topic related to competition and regulation, however, priority will be given to articles addressing the abovementioned topics. Co-authors are always welcome.

U.S. HEALTHCARE ANTITRUST IN THE TRANSACTIONAL SPACE: SCANNING THE HORIZON FOR CHANGE

BY HOLDEN BROOKS[1]

1 McGuireWoods LLP.

In the remainder of 2023, providing effective representation of U.S. healthcare clients in the transactional space will increasingly depend on scanning the horizon to identify and understand new laws and enforcement priorities at the state and the federal level. This article attempts to describe in brief some of the rapid and unprecedented developments in enforcement in this area and the ways that these developments will fundamentally change the timelines and processes for getting deals through; and make practical suggestions for how to prepare.

I. WHAT TO WATCH FOR ON THE FEDERAL HORIZON

Much was made of President Biden's Executive Order of July 2021 and its exhortation to federal antitrust enforcers to focus on "excessive concentration" in healthcare.[2] Since that time, the Federal Trade Commission ("FTC") has succeeded in its efforts to stop four separate hospital transactions;[3] the Department of Justice Antitrust Division ("DOJ") has withdrawn well-worn healthcare antitrust enforcement guidance in place since the 1990s, in part addressing transactions;[4] and together have otherwise maintained an enforcement focus on healthcare. But even more interesting than this first phase are developments that are likely to come into focus in the near future that will have a significant impact on healthcare transactions.

A. Upcoming Hart Scott Rodino Act Changes Designed to Deter Serial Acquisition Strategies

Changes to the Hart Scott Rodino Act merger notification process may have a particular impact on healthcare transactions. The FTC recently indicated that it will hold merger parties accountable for following all requirements of the HSR Act;[5] implemented a new filing fee scale with significantly increased fees for large deals;[6] and, perhaps most importantly, previewed that it intends to introduce changes to the HSR form that are expected to have a "significant deterrent effect" on transactions by requiring the disclosure of more information by the parties.[7] Specifically, a new HSR form,[8] which is expected to be introduced after a notice and comment process, will require more information regarding prior transactions to shed light on "roll up" strategies that may have been pursued through deals that fell below the relevant HSR thresholds. Because "roll ups" in healthcare that involve smaller transactions have been specifically called out as a concern by both the FTC and DOJ,[9] it is reasonable to expect that the new HSR forms will be calibrated so that they reflect information pertinent to past (or potentially future) serial acquisitions in the same geography and service line.

B. New Merger Guidelines and Focus on Private Equity in Healthcare

Another potentially significant change may be revealed in the updated FTC/DOJ Merger Guidelines, which are expected to be released in the very near term. As part of the revision process, the agencies released a "Request for Information" to solicit public feedback to certain questions that FTC and DOJ posed relating to specific topics.[10] A relatively large number of comments in response to the Request for Information published by the agencies relate to vertical and horizontal healthcare transactions and urge the FTC and DOJ to adopt healthcare-specific analytical frame-

2 Exec. Order No. 14036, 86 FR 36987 (Jul 9, 2021) (Executive Order on Promoting Competition in the American Economy), https://www.whitehouse.gov/briefing-room/presidentialactions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/.

3 *In re Care New England, Lifespan,* https://www.ftc.gov/legal-library/browse/cases-proceedings/211-0031-lifespancne-matter; *In re RWJ Barnabas Health, Saint Peter's,* https://www.ftc.gov/legal-library/browse/cases-proceedings/2010145-rwj-barnabas-healthsaint-peters-healthcare-system-matter; *In re HCA, Steward Healthcare*, https://www.ftc.gov/legal-library/browse/cases-proceedings/2210003-hca-healthcaresteward-health-care-system-matter; *In re Hackensack Meridian Health, Inc., Englewood Healthcare Fndtn.*, https://www.ftc.gov/legal-library/browse/cases-proceedings/2010044-hackensack-meridian-health-inc-englewood-healthcare-foundation-matter.

4 Press Release, DOJ, Justice Department Withdraws Outdated Healthcare Guidance (February 3, 2023), https://www.justice.gov/opa/pr/justice-department-withdraws-outdated-enforcement-policy-statements.

5 Holly Vedova, Director, FTC Bureau of Competition, Spring Meeting Update Blog Post (March 31, 2023), https://www.ftc.gov/enforcement/competition-matters/2023/03/spring-meeting-updates.

6 Press Release, FTC, FTC Announces 2023 Update of Size of Transaction Thresholds for Premerger Filings and Interlocking Directorates (Jan. 23, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/01/ftc-announces-2023-update-size-transaction-thresholds-premerger-notification-filings-interlocking.

7 Shaoul Sussman, Associate Director for Litigation, FTC Bureau of Competition, Antitrust Effects: US Industries, Loyola University Stigler Center, Beyond the Consumer Welfare Standard Conference (April 20, 2023), 2023 Antitrust and Competition Conference - Beyond the Consumer Welfare Standard? Day One. - YouTube (at approximately 3:14 in video).

8 See Vedova blog post, *supra* note 3.

9 Andrew Forman, Deputy Assistant Attorney General, DOJ, The Importance of Vigorous Antitrust Enforcement in Healthcare, Remarks at the ABA Antitrust in Healthcare Conference (June 3, 2022), https://www.justice.gov/opa/speech/deputy-assistant-attorney-general-andrew-forman-delivers-keynote-abas-antitrust ("Forman Remarks").

10 FTC and DOJ Request for Information on Merger Enforcement (January 18, 2022) https://www.regulations.gov/document/FTC-2022-0003-0001.

works or protocols (e.g. lowering reporting thresholds for healthcare transactions; using healthcare-specific concentration indices) to address concentration in payor and provider spaces.[11] Whether or not there will be guidelines specific to particular markets remains to be seen (and the wisdom of a market-specific approach is itself a point of debate in the comments), but if there are market-specific guidelines in the draft that is eventually released, it would not be unexpected to see some that are focused on healthcare transactions.

As part of the merger guidelines revision process, the FTC and DOJ conducted "listening sessions" in 2022, including one on healthcare. [12] Deputy Assistant Attorney General Andrew Forman of DOJ recounted the feedback in stark terms, with a particular spotlight on private equity, which was a specific topic on which the FTC and DOJ sought feedback in the Request for Information:

> [W]e heard from folks throughout the health care industry who described their firsthand experiences about the effect of consolidation and acquisitions by private equity groups. They described fewer caregivers, degradation of care, commoditization of health care services, and increased prices. This group of speakers from across the industry raised important topics that we are considering today. We are also aware of, and are analyzing, recent competition studies that have suggested the negative impact of certain private equity acquisitions and conduct in important health care products and services, including home health care, inpatient services, outpatient services, and pharmaceuticals.

Forman's remarks are consistent with other comments made by FTC and DOJ and enforcement actions taken, including addressing perceived health care roll ups with prior approval orders[13] and taking on other issues that the agencies consider to be closely associated with private equity investment, such as incentives to "focus solely on short-term financial gains;" the perceived tendency of private equity investment in competitive entities to result in interlocking directorates that may violate Section 8 of the Clayton Act;[14] and what is seen as a pattern of less-than-perfect compliance with HSR filing requirements.[15] Once the draft guidelines are released, there is likely to be a public comment period and debate about whether the agencies' negative-leaning approach is justified, in the healthcare context and in other industries, and about potential procompetitive upsides to private equity investment.[16]

C. Cross Market Transactions Among Providers

Another potential development to watch for is an enforcement action targeting a cross market healthcare provider transaction in which the parties do not operate in the same geography and, arguably, are not competing for inclusion in payor networks or for patients as traditional competitors would be. Several theories of competitive harm have been developed in the economic literature that could potentially support an enforcement action under Section 7 of the Clayton Act, including, for example, that a merged health system may raise prices where insurers need providers and facilities across more than one geography.[17] Although the FTC has reviewed multiple cross market transactions involving health care providers, and have in some cases undertaken prolonged investigations, they have yet to challenge one. In light of the fact that some state enforcers now have multiple cross market transaction enforcement actions in the books (including for what might appear to be fairly modest acquisitions

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11 See e.g. Purchaser Business Group on Health, Comment of William Kramer, Executive Director on Health Policy (April 21, 2022), https://www.regulations.gov/comment/FTC-2022-0003-0747 (expressing concern regarding concentration resulting from provider transactions); American Medical Association, Comment of Dr. James Madara, (April 21, 2022) https://www.regulations.gov/comment/FTC-2022-0003-1494 (expressing concern regarding concentration resulting from payor transactions); American Hospital Association, Comment of Melinda Hatton, General Counsel (March 31, 2023) https://www.regulations.gov/comment/FTC-2022-0003-0279 (advocating for guidelines that recognize the procompetitive benefits of hospital mergers).

12 FTC/DOJ Healthcare Listening Session Transcript (April 14, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/FTC-DOJ-Listening-Forum-%20Health-Care-Transcript.pdf.

13 Press Release, FTC, FTC Imposes Strict Limits on Davita, Inc.'s Future Mergers Following Proposed Acquisition of Utah Dialysis Clinics (Oct. 25, 2021), https://www.ftc.gov/news-events/news/press-releases/2021/10/ftc-imposes-strict-limits-davita-incs-future-mergers-following-proposed-acquisition-utah-dialysis; see also FTC Policy Statement Regarding Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act (Nov. 11, 2022), https://www.ftc.gov/legal-library/browse/policy-statement-regarding-scope-unfair-methods-competition-under-section-5-federal-trade-commission.

14 Press Release, DOJ, Directors Resign from the Boards of Five Companies in Response to Justice Department Concerns about Potentially Illegal Interlocking Directorates (Oct. 19, 2022), https://www.justice.gov/opa/pr/directors-resign-boards-five-companies-response-justice-department-concerns-about-potentially (describing resignation of director from healthcare analytics firm board).

15 Forman Remarks, *supra* note 7; see also Vedova blog post, supra note 3.

16 A current and comprehensive examination of these issues can be found here: Kenneth Schwartz, Michael Singer, Isabel Tecu, *Private Equity and Competition*, Antitrust Magazine Online (April 2023), https://www.americanbar.org/digital-asset-abstract.html/content/dam/aba/publications/antitrust/magazine/2023/april/full-issue.pdf. Another interesting consideration of private equity in healthcare can be found here, Laura Alexander, Ola Abdelhadi, Brent Fulton, Richard Scheffler, "Private Equity's Entry Into Healthcare Reveals Gaps In Competition Policy" (October 2022), https://www.competitionpolicyinternational.com/private-equitys-entry-into-healthcare-reveals-gaps-in-competition-policy/#_ftn25.

17 Leemore Dafny, Kate Ho, Robin Lee, *The Price Effects of Cross-Market Hospital Mergers*, 50 RAND J. ECON. 2, 286-325 (2019) https://www.nber.org/papers/w22106.

of single facilities)[18] without meaningful challenges to those efforts, a federal enforcement action based on cross market theories may not be far behind.

D. Heightened Risks from Disclosure of Information in Healthcare Merger Investigations

Another new enforcement risk related to undergoing a healthcare transaction review is the risk that disclosure of information to the FTC or DOJ in the course of a merger review will lead to criminal or other exposure outside the review itself, which can result in steep fines, imprisonment for individuals, and — of particular concern for healthcare providers — debarment from public payor programs such as Medicaid and Medicare. In December 2022, the DOJ and the United States Department of Health and Human Services ("HHS") signed a Memorandum of Understanding ("MOU") that lays out a protocol for HHS sharing information with DOJ that may relate to potential antitrust violations and or DOJ to share with HHS evidence of violations of laws within its enforcement purview, including HIPAA and the Social Security Act:

> Through coordination in information sharing, enforcement activity, and training, the two agencies will strengthen the enforcement of federal laws, including the full force of [Office of Inspector General's] exclusion authorities and the antitrust laws enforced by the Justice Department's Antitrust Division, while ensuring the continuity of health care products and services. In particular, this MOU will allow the two agencies to make referrals of potentially illegal activity to each other, as appropriate, and to coordinate on policy, strategy, and training.[19]

In addition, in March 2023 the FTC Bureau of Competition formally announced the creation of a Criminal Liaison Unit ("CLU"), which is tasked with referring to DOJ or other criminal prosecutors "conduct uncovered during the course of FTC investigations and litigations."[20] Since its creation in 2022, the Unit has referred potential criminal matters involving potential Sherman Act violations, spoliation, influencing witness testimony, fraud, and obstruction — including in the healthcare context. The CLU will make referrals of substantive antitrust violations detected during merger and other civil investigations but also non-antitrust violations, including of healthcare laws or related to conduct that takes place during those investigations. Counseling healthcare clients about these new risks and budgeting time and resources to conduct appropriate interviews and reviews of materials prior to production in merger investigations will be important steps to add to the deal process.

II. WHAT TO WATCH FOR ON THE STATE HORIZON

A. Proliferating State Pre-Close Approval Requirements for Healthcare Transactions

Within the past decade, several state legislatures have passed statutes that require parties to qualifying healthcare transactions to provide notice to state healthcare agencies or offices of the attorney general and to delay closing until after an initial waiting period has elapsed (mostly 30 to 90 days) or the relevant regulator has issued an approval or concluded an investigation (which may take much longer and require payment of a significant fee). In many instances, these laws supplement statutes already on the books that cover transactions involving non-profit hospitals and cover transactions between for-profit and smaller healthcare entities including physician groups, medical and dental services organizations, durable medical equipment providers, payors, and other "healthcare adjacent" companies. They usually include a requirement that parties provide extensive information about themselves and the transaction with the filing (which may be public and posted on the agency's website), but also respond to what can be extensive requests for additional information. They may be triggered by certain annual revenue thresholds being met or by the number of providers affiliated with the parties, and may often look to the relevant parent entities to determine whether these tests are satisfied, including out-of-state entities several levels above the entities involved in the transaction. In a worst-case scenario for parties, there may be a legal challenge to the transaction stemming from the investigation, resulting in a settlement with conditions or the deal being blocked.

Many of these provisions are modeled after the Massachusetts Health Policy Commission Notice of Material Change requirement, which has been in place for nearly a decade.[21] Connecticut passed a law requiring notice for physician transactions soon after Massachusetts,[22]

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18 See e.g. Richard Scheffler, Neal Adams, Daniel Arnold, *The Competitive and Quality Impact of the Proposed Acquisition of Adventist Vallejo by Acadia Healthcare* (Sept. 25, 2021), https://www.oag.ca.gov/system/files/media/ahv-cqi.pdf.

19 Press Release, DOJ, Justice Department's Antitrust Division and the Office of the Inspector General of the Department of Health and Human Services Announce Partnership to Protect Health Care Markets (Dec. 9, 2022), https://www.justice.gov/opa/pr/justice-department-s-antitrust-division-and-office-inspector-general-department-health-and.

20 Holly Vedova, Director, FTC Bureau of Competition, FTC's Criminal Liaison Unit is Off to the Races Blog Post (March 24, 2023), https://www.ftc.gov/enforcement/competition-matters/2023/03/bcs-criminal-liaison-unit-races.

21 M.G.L. c. 6D § 13, https://malegislature.gov/Laws/GeneralLaws/PartI/TitleII/Chapter6D/Section13.

22 Public Act 14-168, https://www.cga.ct.gov/2014/act/pa/pdf/2014PA-00168-R00SB-00035-PA.pdf.

followed by Washington in 2019[23] and Oregon[24] and Nevada[25] in 2021. In 2022, California passed a statute covering a very broad range of transactions that goes into effect in 2024,[26] and on May 3, 2023, New York passed its own statute, with an effective date of August 1, 2023.[27] Currently, legislatures in Illinois,[28] Minnesota,[29] and North Carolina[30] are considering similar statutes that, if passed, could go into effect within the next few months, and the Maine legislature will likely pick up consideration of its version of a healthcare transactions review law when it next convenes later this spring in a special session.[31]

With healthcare deal values remaining relatively high and physician practice size increasing, [32] transactions are more likely to meet revenue and other size thresholds. And with four of the ten most populous states potentially being added to the list of jurisdictions requiring pre-close notice in the near future, it will become increasingly necessary to make filings or at the very least "run the traps" on multiple states' varying requirements. Although healthcare markets have long been a stated priority for state attorneys general, recent speeches and comments on the FTC/DOJ "Request for Information" related to the revision of the merger guidelines show that interest in investigating healthcare transactions of all sizes and bringing enforcement actions remains high.[33]

B. Controversy Regarding COPAs

At the same time that more states are passing legislation that would make it easier to detect potentially anticompetitive transactions, several states continue to have certificate of public advantage ("COPA") laws that allow qualifying transactions to enjoy some degree of immunity from federal antitrust laws. In April 2023, the question of whether a state COPA can confer immunity from the HSR Act and its filing requirements came into high relief in a pair of dueling complaints filed in federal court: One by LCMC Health, seeking "a declaratory judgment that the [HSR Act] does not apply to transactions that are immune from federal antitrust laws under the doctrine of state action immunity … to vindicate an important policy choice of the State of Louisiana concerning the health care services available to its citizens;"[34] and another by the FTC, asking for an order that the January 2023 transaction was reportable and that a filing was still required.[35] LCMC argued that:

> [i]f the FTC succeeds in subjecting state authorized mergers to Section 7A of the Clayton Act, it will permanently hamper the ability of States to authorize and approve time-sensitive mergers, even in instances where, as here, the State has concluded that a given transaction serves its critical interest in providing affordable, quality health care to its citizens.

As for the FTC, it alleged that the idea that at COPA could exempt a transaction:

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23 Wash. Rev. Code Ann. § 19.030 (2019), https://app.leg.wa.gov/RCW/default.aspx?cite=19.390.

24 ORS 415, https://www.oregonlegislature.gov/bills_laws/ors/ors415.html.

25 Nevada AB47, https://www.leg.state.nv.us/App/NELIS/REL/81st2021/Bill/7300/Text; *see also* Nevada SB239, https://www.leg.state.nv.us/App/NELIS/REL/81st2021/Bill/7964/Overview.

26 Cal. Health and Safety Code § 127507, https://legiscan.com/CA/text/SB184/id/2600107.

27 *See* Omnibus Budget Bill S. 4007/A. 3007, extension://elhekieabhbkpmcefcoobjddigjcaadp/https://legislation.nysenate.gov/pdf/bills/2023/S4007 (starting at p. 137) .

28 HB 2222, https://www.ilga.gov/legislation/fulltext.asp?DocName=&SessionId=112&GA=103&DocTypeId=HB&DocNum=2222&GAID=17&LegID=146481&SpecSess=&Session=.

29 Minn. HF 402 4th Engrossment - 93rd Legislature (2023 - 2024), www.revisor.mn.gov/bills/text.php?number=HF402&type=bill&version=4&session=ls93&session_year=2023&session_number=0.

30 House Bill L DRH40194-MGf-112, https://webservices.ncleg.gov/ViewBillDocument/2023/4114/0/DRH40194-MGf-112.

31 HP 894, An Act to Improve State Oversight of Proposed Health Care Entity Transactions, https://legislature.maine.gov/legis/bills/getPDF.asp?paper=HP0894&item=1&snum=131.

32 See e.g. American Medical Association Policy Research Perspective (2021), Carol K. Kane, PhD ("Since 2012 the share of physicians in small practices has fallen continuously, with 61.4 percent of physicians in practices with 10 or fewer physicians in 2012 and 56.5 percent in 2018. This appears to be driven by movement away from the smallest practices, those with fewer than 5 physicians.").

33 Public Comments of 23 State Attorneys General (April 21, 2022), https://www.naag.org/wp-content/uploads/2022/08/Public-Comments-of-23-State-Attorneys-General-.pdf (describing state efforts to investigate healthcare transactions and urging more vigorous enforcement by FTC and DOJ).

34 Complaint, *LCMC v. Garland, FTC, DOJ*, Dkt. No. 1, Civ. No. 23-1305 (E.D. La. April 19, 2023).

35 Petition, *FTC v. LCMC ad HCA*, Dkt. No. 1, Civ. No. 23-1103 (D.D.C. April 20, 2023).

appears nowhere in the text of the HSR Act and has never been recognized as an exemption from the HSR Act's notification requirements by any court in the HSR Act's forty-seven-year history. Additionally, neither the FTC nor the DOJ has promulgated an interpretation of the HSR Act exempting parties from filing where those parties received a similar certificate.

In its prayer for relief, the FTC asked the court not only to order LCMC to make a filing, but to force LCMC to halt integration to give the FTC time "to determine, along with the potential competition issues, the parameters of the COPA and whether it shields the Acquisition from liability under Section 7 of the Clayton Act." This appears to leave the door open to a scenario in which the FTC may find the COPA to confer immunity from ultimate liability, but only after it has received an HSR filing and used the waiting period to investigate. As an exhibit to its complaint, LCMC included email exchanges between its outside counsel and counsel in the FTC Premerger Notification Office, reflecting some uncertainty about whether the FTC had in the past perhaps informally declined to pursue parties that elected not to file HSR where the transaction in question had been granted a COPA. To the extent that there was any question about the FTC's *current* position, its decision to file litigation should resolve it. But ultimately the court may decide whether COPAs can shield parties from the burden, expense, and delay of having to file HSR — one of the primary benefits of COPA immunity to many parties.

III. A CALL TO ACTION FOR PRACTITIONERS, PARTICIPANTS

In order to provide effective advice to provider and payor clients or investors in the healthcare space it will be necessary to coordinate among healthcare regulatory, transactional, and antitrust teams, whether within a single firm or across multiple firms that service common clients. Because reporting requirements in the U.S. have remained relatively static for some time, tracking these developments may require new "muscles" for U.S.-focused transactional antitrust practitioners in particular.

· **Designate a team to track state laws and understand when they go into effect and what transactions may be affected**. State lawmakers are moving fast in this area and the window within which new laws may be in effect can be as shorter than the timeline for some sale processes and acquisitions. With several pending state bills targeting effective dates early in 2024 or even within 2023, and the expectation that new HSR rules will be in effect at the end of the year, keeping an eye on changes in real time will be important.

· **Designate a team to track developments, rulemaking and other guidance from state regulators related to existing laws**. Whether the responsibility sits with a healthcare regulatory, transactional, or antitrust team, monitoring developments and the evolution of guidance from state regulators will be critical to determining how state laws may affect transactions. What was true last time you looked at the details of a particular requirement may no longer be true: Particularly where a regulatory scheme is new and developing, revisions to implementing rules and issuance of FAQs may reveal critical changes in how the law applies. In addition, clients may wish to contribute comments to rulemaking processes to provide perspective, lobby for changes, request clarification, or even challenge the laws in court.[36]

· **Provide for regular touchpoints among the healthcare regulatory, transactional, and antitrust teams to share intelligence**. Having a crack antitrust team assigned to keeping up with developments will be meaningless if transactional team is not aware of new waiting periods that affect timelines and filing requirements that will affect budgets and strategic considerations such as antitrust risk-shifting provisions in definitive agreements. Conducting an initial orientation and then establishing an expectation of check-ins when transactions potentially involve

· **Buyers and sellers should involve antitrust counsel in early phases of business and pipeline planning on the buy side as well as reverse due diligence on the sell side**. In the current environment, understanding regulatory risk by jurisdiction should be part of determining where to deploy capital as a buyer and spend time as a seller. As a buyer, being in a position to identify targets that, all other things being equal, are not going to present antitrust issues because of a lack of concentration or other factors that might trigger an extended investigation by a state or federal agency is a strategic advantage. As a seller kicking off an auction process, asking questions regarding presence in individual states and service lines, for example, should allow for informed comparison of potential buyers' relative merits.

· **In-house and external counsel should manage expectations of business leaders by providing education about proliferating and shifting reporting requirements**. For many business leaders in the healthcare space, particularly those who have experience with transactions below HSR and state law thresholds, the reaction to new or expanded reporting requirements will range from irritation to dismay over additional expense, time, and disruption of what may be well-worn paths from LOI to close. But under any circumstances, it is better for everyone to know about these changes as far in advance as possible as opposed to the middle of a negotiation, after an agreement has been signed, at the time that a regulator seeks to apply what feels like an out-of-left-field condition, or, worst of all, after a transaction has closed.

36 See *Oregon Ass'n of Hosps. v. Oregon*, Civ. No. 22-01486 (D. Or.) (challenging the constitutionality of Oregon's Health Care Market Oversight regime).

HEALTH CARE ANTITRUST WITHOUT THE HEALTH CARE GUIDELINES: WHAT WILL THE FUTURE HOLD?

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I. INTRODUCTION

In a largely unheralded announcement on February 3, 2023, the Department of Justice Antitrust Division ("DOJ") withdrew three major antitrust policy statements applying to the health care industry (the "Health Care Guidelines").[2] The announcement has been met with widespread concern about the impact of the withdrawal on the industry, which over the last 30 years has arranged its affairs in the context of this guidance.

The stated motivation for the DOJ's withdrawal of the Health Care Guidelines is the significant changes in the health care industry over the period they have been in place. However, the DOJ did not engage in any industry consultation around how the Guidelines operated in practice and the potential impact of their withdrawal. Over the years in which the Guidelines were in place, there have been calls to modernize them to reflect changes in the industry. But rather than take this approach, the DOJ has jettisoned the Guidelines in their entirety, forcing the industry to reconsider longstanding practices in light of general antitrust guidelines, some of which themselves are in a state of flux.[3]

The withdrawal of the Guidelines raises important questions about the future of antitrust enforcement policy in the health care industry. What can companies expect with respect to ongoing benchmarking activities, clinically integrated networks, joint purchasing arrangements, and other practices that are core to many organizations in the health care space and beyond? Will withdrawal of the Guidelines smother procompetitive activities as health care organizations retreat into conservative positions to avoid antitrust risk?

II. OVERVIEW OF THE HEALTH CARE GUIDELINES

A. Health Care Industry Landscape Before the Guidelines

The U.S. health care system has been in a constant state of evolution over the last 50 years. Through the 1970s, Health Maintenance Organizations ("HMOs") emerged and gained legitimacy at a time when health care services were primarily paid for on a fee-for-service basis.[4] The 1980s were characterized by emerging technologies and rising health care costs that caused employers to find ways to combat cost increases and providers to begin exploring ways to provide care more efficiently. At the same time, health insurers began to develop different types of benefit plans (for example, PPOs), driven in part by employers seeking to have employees share more of the ever-increasing health care costs as well as by reluctance among physicians to adhere to gatekeeper models that they perceived as limiting their autonomy.[5] From the mid-1980s and throughout the 1990s, risk-based contracting models emerged, and providers began to seek ways to coordinate care through hospital mergers, Independent Practice Associations, joint ventures, and other collaborative arrangements.

Throughout this evolution, the antitrust enforcement agencies investigated and challenged anticompetitive mergers as well as conduct they viewed as obstructing innovative forms of health care delivery or financing.[6] In the 1990s, the agencies engaged in extensive industry consultation and developed guidelines to bring clarity to their antitrust enforcement goals and policies in the health care industry, and more importantly, their approach regarding applying the antitrust laws to certain activities by health care market participants.

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2 Press Release, U.S. Dep't of Just., Justice Department Withdraws Outdated Enforcement Policy Statements (Feb. 3, 2023), https://www.justice.gov/opa/pr/justice-department-withdraws-outdated-enforcement-policy-statements. While the FTC has not withdrawn the Guidelines, they are widely expected to do so.

3 For example, since January 2022 the DOJ and FTC have been engaging in a consultation around new merger guidelines which, at time of writing, have not been released.

4 This was due in large part to the Health Maintenance Organization Act of 1973, which provided funding to encourage the development of HMOs, overrode state laws that prohibited the development of HMOs, and required large employers to offer HMO products as an option to their employees. See U.S. Dep't of Just. & Fed. Trade Comm'n, Improving Health Care: A Dose of Competition 11 (2004), https://www.ftc.gov/sites/default/files/documents/reports/improving-health-care-dose-competition-report-federal-trade-commission-and-department-justice/040723healthcarerpt.pdf.

5 See Ellen M. Morrison & Harold S. Luft, *Health Maintenance Organizations in the 1980s and Beyond*, 12 Health Care Fin. Rev. 81 (1990), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4193099/pdf/hcfr-12-1-81.pdf. Employers also began to develop self-insured health plans in an effort to control their spending on health care.

6 The DOJ sued the Utah Society for Healthcare Human Resource Administration for conspiring to exchange nonpublic prospective and current wage information about registered nurses and settled via a consent order. See Judgment, *United States v. Utah Soc'y for Healthcare Hum. Res. Admin.*, No. 94-C-282G (D. Utah Sept. 9 1994), https://www.justice.gov/atr/case-document/file/628496/download. The FTC sued the Michigan State Medical Society alleging it sought to "[f]ix, stabilize, or otherwise tamper with the fees which physicians in Michigan receive for their services." See *In re Mich. State Med. Soc'y*, 101 F.T.C. 191 (1983), https://www.ftc.gov/sites/default/files/documents/commission_decision_volumes/volume-101/ftc_volume_decision_101_january_-_june_1983pages_191-315.pdf.

B. The Health Care Guidelines

Between September 1993 and August 1996, the Department of Justice and Federal Trade Commission issued several policy statements related to antitrust enforcement in health care markets. These statements addressed antitrust enforcement policy in a variety of hospital and health insurer transactions and conduct, and provided "antitrust safety zones" under which the Agencies would not, absent extraordinary circumstances, pursue antitrust enforcement against health market participants. In essence, the statements gave market participants some comfort around certain categories of conduct when such conduct occurred in circumstances that did not raise concerns about market power and/or occurred in a way that was designed to minimize the risk of anticompetitive effects.

The 1993 policy statements[7] provided guidance to hospitals and health care providers on: hospital mergers; hospital joint ventures; physicians' provision of information to purchasers of health care services; hospital participation in exchanges of price and cost information; health care providers' joint purchasing arrangements; and physician network joint ventures. As health care markets continued to evolve, the 1993 policy statements were revised and supplemented first in 1994, and then by the 1996 Health Care Statements.[8] The 1996 policy statements consolidated earlier guidance and made notable updates to the statements regarding network joint ventures and multiprovider networks.

After a long hiatus in health care guideline-making, shortly after the passage of the Affordable Care Act,[9] in 2011 the FTC and DOJ issued the Affordable Care Organization ("ACO") Policy Statement,[10] which applied to collaborations among independent providers and provider groups participating in the Medicare Shared Savings Program, and provided an antitrust safety zone for such ACOs that also operate in the commercial market.

C. Summary of the Health Care Guidelines

The 1996 Health Care Statements set forth safety zones in the following areas where, absent extraordinary circumstances, the federal antitrust agencies would not pursue antitrust enforcement:

· *Small hospital mergers*: "any merger between two general acute-care hospitals where one of the hospitals (1) has an average of fewer than 100 licensed beds over the three most recent years, and (2) has an average daily inpatient census of fewer than 40 patients over the three most recent years…"[11]
· *Hospital joint* ventures to purchase, operate, and market high-technology or other expensive medical equipment where the participants count not individually bear the cost;[12] and to jointly recruit and train specialized personnel for clinical care.[13]
· *Providers' collective provision of non-fee information to purchasers of health care* services providing a safe harbor for a "medical society's collection of outcome data from its members about a particular procedure that they believe should be covered by a purchaser and the provision of such information to the purchaser" and "providers' development of suggested practice parameters--standards for patient management developed to assist providers in clinical decision-making--that also may provide useful information to patients, providers, and purchasers."[14]
· *Provider collective provision of fee-related information*. Providers can collectively provide purchasers of health care services with information about current or historical fees or other aspects of reimbursement where (1) the collection is managed by a third-party (e.g. a purchaser, government agency, health care consultant, academic institution, or trade association); (2) the information shared among competing providers provided data is more than 3 months old; and (3) there are at least five providers reporting data upon which each disseminated statistic is based, no individual provider's data represents more than 25 percent on a weighted basis of that statistic, and

7 U.S. Dep't of Just. & Fed. Trade Comm'n, Antitrust Enforcement Policy Statements Issued for the Health Care Industry (1993), https://www.justice.gov/atr/page/file/1197731/download.

8 U.S. Dep't of Just. & Fed. Trade Comm'n, Statements of Antitrust Enforcement Policy in Health Care (1996), https://www.justice.gov/atr/page/file/1197731/download [hereinafter Health Care Statements].

9 Patient Protection and Affordable Care Act, Pub. L. No. 111-48, 124 Stat. 119 (2010).

10 U.S. Dep't of Just. & Fed. Trade Comm'n, Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (2011), https://www.justice.gov/sites/default/files/atr/legacy/2011/10/20/276458.pdf [hereinafter 2011 ACO Policy Statement].

11 Health Care Statements, supra note 8, at 8 (Statement 1).This safety zone did not apply to hospitals less than five years old. *Id.* at 9.

12 *Id.* at 13 (Statement 2).

13 *Id.* at 31 (Statement 3).

14 *Id.* at 40 (Statement 4).

any information disseminated is sufficiently aggregated such that it would not allow recipients to identify the prices charged by any particular provider.[15] A similar safety zone applies to provider participation in surveys of prices for health care services or surveys of salaries, wages, or benefits of personnel.[16]

· *Joint purchasing arrangements* among health care providers where: (1) the purchases account for less than 35 percent of the total sales of the purchased product or service in the relevant market; and (2) the cost of the products and services purchased jointly accounts for less than 20 percent of the total revenues from all products or services sold by each competing participant in the joint purchasing arrangement.[17]

· *Certain physician network joint ventures:*

- "[A]n exclusive physician network joint venture whose physician participants share substantial financial risk and constitute 20 percent or less of the physicians in each physician specialty with active hospital staff privileges who practice in the relevant geographic market."[18]
- "[A] non-exclusive physician network joint venture whose physician participants share substantial financial risk and constitute 30 percent or less of the physicians in each physician specialty with active hospital staff privileges who practice in the relevant geographic market."[19]

The 2011 ACO Policy Statement established a safety-zone for ACOs meeting CMS eligibility criteria, presuming that an ACO is unlikely to raise significant competitive concerns if the combined share of services in a professional services agreement ("PSA") for the ACO is 30 percent or less of each common service in a PSA.[20] Hospitals and ambulatory surgery centers must be non-exclusive to the ACO to fall within the safety zone, regardless of share.[21] Even for ACOs not falling within the safety zone, the statement provides that the Agencies will not challenge as per se illegal a Medicare Shared Savings Program ACO that jointly negotiates with private insurers to serve patients in commercial markets if the agreement is reasonably necessary to accomplish the procompetitive benefits of the integration.[22] Finally, the ACO Statement highlights conduct that could raise competitive concerns and recommends safeguards to protect against conduct that may facilitate collusion between ACO participants in the sale of competing services outside the ACO.[23]

III. PURPOSE AND IMPACT OF THE HEALTH CARE GUIDELINES

Collectively, the Health Care Guidelines were designed to facilitate procompetitive interactions and activities in the health care industry. In announcing the 1993 Health Care Statements, the FTC and DOJ noted they were "designed to provide information to the health care community in a time of tremendous change, and to resolve, as completely as possible, any antitrust uncertainty that might deter beneficial mergers or joint ventures that promise to reduce health care costs."[24] The guidance in the 2011 ACO Statement was intended to "help health care providers form procompetitive ACOs that benefit both Medicare beneficiaries and patients with private health insurance, while protecting health care consumers from higher prices and lower quality."[25]

Did the Guidelines accomplish their goals? In many respects, yes. Over the past 30 years, the Health Care Guidelines have provided a basis for structuring collaborations and conduct across the health care industry. Health care providers turned to the Health Care Guidelines to

15 *Id.* at 43 (Statement 5).

16 *Id.* at 49 (Statement 6).

17 *Id.* at 53 (Statement 7).

18 *Id.* at 64-65.

19 *Id.* at 65.

20 2011 ACO Policy Statement, *supra* note 10, at 7.

21 *Id.* at 8.

22 *Id.* at 4.

23 *Id.* at 10-11.

24 Press Release, U.S. Dep't of Just., Antitrust Enforcement Policy Statements Issued for Health Care Industry (Sept. 15, 1993), https://www.justice.gov/archive/atr/public/press_releases/1993/211661.htm.

25 Press Release, Fed. Trade Comm'n, Federal Trade Commission, Department of Justice Issue Final Statement of Antitrust Policy Enforcement Regarding Accountable Care Organizations (Oct. 20, 2011), https://www.ftc.gov/news-events/news/press-releases/2011/10/federal-trade-commission-department-justice-issue-final-statement-antitrust-policy-enforcement.

determine how to work together with other providers in ways that would steer clear of potential antitrust pitfalls. At a time when many hospitals were seeking productive ways to battle the medical arms race — which many blamed for burgeoning health care costs — the Guidelines allowed providers to explore joint ventures and similar collaborative arrangements without the risk that such arrangements might later need to be abandoned due to antitrust concerns. The guidance on financial and clinical integration, further enhanced by the ACO Statement, encouraged the development of ACOs and other structures that shared risk and coordinated care, which is a significant goal of health policy.

The Health Care Guidelines have been widely relied upon in the health care industry and beyond. For example, they have formed the basis for much of the analysis in other agency guidance on specific instances of clinical integration,[26] and those opinions have been used as benchmarks for a large number of similarly configured networks. The guidance on group purchasing organizations and the antitrust safety zone for such arrangements in Statement 7 of the 1996 Health Care Statements has also been widely consulted in structuring such arrangements in health care and beyond.

Perhaps the most well-known and widely utilized guidance was regarding the exchange of price and other competitively sensitive information in the 1996 Health Care Statements. The information-exchange safe harbor was particularly popular as it provided bright lines for parties to avoid the risk of criminal prosecution for sharing information that risked being viewed as *per se* unlawful. Companies outside of the health care industry, such as trade associations and others that provide benchmarking services, looked to the guidance to establish parameters for information sharing that encouraged and expanded participation, enhancing the utility of benchmarking activities.[27] The agencies encouraged the extension of this guidance beyond the health care arena. For example, when the agencies issued their *Antitrust Guidance for Human Resource Professionals* in 2016, they referenced the information exchange guardrails as a useful tool for HR managers when engaging in information exchanges, such as surveys involving wages and compensation.[28] The agencies also referenced the guidance in informal statements regarding the treatment of information exchanges in other industries.[29]

In some respects, however, the Statements have been overtaken by events and fallen by the wayside. Apart from the ACO Statement, there have been no updates to the original guidance since 1996, and few if any references to the Health Care Guidelines have been made in agency materials since 2013. A host of other antitrust guidelines — for example, the Horizontal Merger Guidelines,[30] and the Antitrust Guidelines for Collaborations Among Competitors[31] — supersede some of the guidance. And other aspects of the Statements — such as the safe harbor for small hospital acquisitions — may be at odds with prevailing enforcement philosophy. Further, new areas of antitrust concern in the health care system — such as steering restrictions in hospital-payer contracts — are not addressed in the Statements at all.[32] In many respects, the federal antitrust agencies' active health care industry enforcement agenda can provide more recent and concrete direction in evaluating transactions and conduct that crosses the lines. And the federal government through CMS and state governments have their own health care agendas and regulatory processes that may displace federal antitrust enforcement policy, such as CMS' price transparency rules[33] and certificates of public advantage.[34]

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26 E.g. Fed. Trade Comm'n, Advisory Opinion on Norman PHO (Feb. 13, 2013), https://www.ftc.gov/sites/default/files/documents/advisory-opinions/norman-physician-hospital-organization/130213normanphoadvltr_0.pdf.

27 "Statement 6, concerning the exchange of price and cost information among providers, has often been consulted concerning how to structure wage and salary surveys, both in and outside of the health care industry." Peter Mucchetti & Eva Kurban, *On Their Silver Anniversary, It's Time to Burnish the Healthcare Guidelines*, CPI Antitrust Chronicle (May 11, 2021), https://www.competitionpolicyinternational.com/on-their-silver-anniversary-its-time-to-burnish-the-healthcare-guidelines/.

28 See U.S. Dep't of Just., Antitrust Div., & Fed. Trade Comm'n, Antitrust Guidance for Human Resource Professionals 1, 4-5 (Oct. 2016), https://www.justice.gov/atr/file/903511/download (issuing the guidance in an effort to "alert human resource (HR) professionals and others involved in hiring and compensation decisions to potential violations of the antitrust laws" and to encourage HR professionals to "implement safeguards to prevent inappropriate discussions or agreements with other firms seeking to hire the same employees").

29 See U.S. Dep't of Just., Antitrust Div., *Participating in Information Sharing and Trade Associations* (Nov. 12, 2020), https://www.justice.gov/atr/antitrust-issues-and-your-small-business/participating-information-sharing-and-trade-associations (listing various sources of useful guidance, including an FTC resource issued in December 2014 titled: "Information Exchange: Be Reasonable," which cites the information sharing safe harbor in Statement 6).

30 U.S. Dep't of Just. & Fed. Trade Comm'n, Horizontal Merger Guidelines (Aug. 19, 2020), https://www.justice.gov/sites/default/files/atr/legacy/2010/08/19/hmg-2010.pdf.

31 Fed. Trade Comm'n & U.S. Dep't of Just.: Antitrust Guidelines on Collaborations Among Competitors (Apr. 2000), https://www.justice.gov/atr/page/file/1098461/download.

32 See e.g. Mucchetti & Kurban, *supra* note 27.

33 See https://www.cms.gov/hospital-price-transparency.

34 See e.g. Lisl Dunlop, *Certificates of Public Advantage: Bypassing the FTC in Healthcare Mergers?*, 27 Competition (Cal. Lawyers Ass'n), No. 1, 2017-18, https://calawyers.org/publications/antitrust-unfair-competition-law/competition-winter-2017-18-vol-27-no-1-certificates-of-public-advantage-bypassing-the-ftc-in-health care-mergers/.

IV. HEALTH CARE GUIDELINES: REVISION OR ELIMINATION?

Most would agree that the world has changed significantly since the Health Care Guidelines were issued. Changes in the competitive landscape — such as the growth of value-based care and population health management, price transparency rules, and increasing vertical integration in the health care industry — have transformed the health care industry. Health care antitrust also has evolved significantly: our understanding of health market economics has developed, generalized antitrust policy statements have proliferated, and there are new theories of anticompetitive harm. Moreover, federal health care policies have been overhauled.

But there is not agreement about how to address this state of affairs: should we revisit, revise, and supplement the existing guidance, or repeal the guidance in its entirety and go back to first principles? And, given the age, complexity, and scope of the Guidelines, should a debate about these topics be more extensive and transparent?

According to the DOJ, the Guidelines were outmoded and no longer necessary, and their withdrawal "best serves the interests of health care competition" and "the interest of transparency with respect to the Antitrust Division's enforcement policy in health care markets."[35] In lieu of a replacement policy, the DOJ stated that a "case-by-case enforcement approach will allow the Division to better evaluate mergers and conduct in health care markets that may harm competition." The DOJ's view that health care should be addressed case-by-case according to general antitrust principles is consistent with the policy position expressed by both agencies in the past that industry-specific guidance is unwarranted because health care is no different from other industries.

The FTC's position on the Guidelines is not clear. Although widely expected to withdraw the Guidelines shortly after the DOJ, at time of writing it has not yet done so. Perhaps even more than DOJ, the FTC has utilized the Guidelines when advising the industry about collaborative practices, with the various advisory opinions on clinically integrated networks forming the backbone of many existing structures. Without that guidance, do we need to reconsider those organizations?

The DOJ's wholesale withdrawal of the Guidelines in a single swoop has drawn concern from many industry participants. The American Hospital Association viewed the withdrawal of all the guidance without consultation as "both unnecessary and reckless."[36] Withdrawing Guidelines that cover such a broad array of conduct and practices without notice or industry engagement, and not specifically addressing how the different aspects of the Guidelines fall short, has left the health care industry in a state of uncertainty and confusion.

Further, the health care industry has operated under the Guidelines for many years, and many structures and practices — particularly around ACOs and clinical and financial integration — are based on the Guidelines. As noted above, FTC policy statements contained in advisory opinions on these topics are grounded in the principles articulated in the Guidelines, as well as other industry-specific materials.[37] The DOJ also has issued business review letters based on the guidance that reference the Guidelines. Enforcement policy relating to the specific examples as well as structures based on those examples will now be called into question.[38]

The DOJ's withdrawal of the guidelines appears to be motivated in no small part by a desire to repeal the information-exchange safe harbor, which has expanded widely beyond the health care context, and which the DOJ believes are "overly permissive." In a recent speech, Principal Deputy Attorney General Doha Mekki described maintaining the safety zones as "like developing specifications for audio cassette tapes and applying them to digital streaming."[39] The DOJ appears to be motivated by industry developments relating to data, particularly machine learning, AI, and other advanced tools, that may undermine the efficacy of the old safeguards to anonymize information and prevent coordination. But while advances in technology and data practices may justify the repeal of safe harbors, those issues deserve to be discussed in an open and broad forum. While ultimately the result may be the same — elimination of the safe harbor — organizations engaged in information exchanges will gain insights into the agencies' concerns and identify acceptable safeguards to address antitrust risk.

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35 See Press Release, *supra* note 2.

36 Press Release, Am. Hosp. Ass'n, DOJ Withdraws Certain Health Care Antitrust Enforcement Guidance (Feb. 3, 2023), https://www.aha.org/news/headline/2023-02-03-doj-withdraws-certain-health-care-antitrust-enforcement-guidance.

37 Such as the joint FTC and DOJ 2004 report, Improving Health Care: A Dose of Competition, *supra* note 4.

38 See e.g. U.S. Dep't of Just., *Response to Greater New York Hospital Association's Request for Business Review Letter* (Jan. 16, 2013), https://www.justice.gov/atr/response-greater-new-york-hospital-associations-request-business-review-letter.

39 Doha Mekki, Principal Deputy Assistant Att'y Gen., Remarks at GCR Live: Law Leaders Global 2023 (Feb. 2, 2023), https://www.justice.gov/opa/speech/principal-deputy-assistant-attorney-general-doha-mekki-antitrust-division-delivers-0.

Will general DOJ and FTC guidelines and enforcement actions provide sufficient coverage? This will likely be inadequate for the health care industry at least. General guidelines fail to account for the specific challenges faced by the health care industry, as well as the impact of federal and state health policy. And while we can always look to examine the rationale behind antitrust enforcement actions for guidance as to how the FTC or DOJ might examine particular conduct, there is still a need for comprehensive guidance that is not couched in the particular facts and circumstances of a particular case.

In the health care industry, the Guidelines have encouraged market participants to act creatively in seeking to address challenges in health care and its extension to community health equity and access. Antitrust policy in health care needs to be nuanced to account for the complex set of political and regulatory factors applying to the industry. To date, government policy has encouraged collaborations, and the Guidelines have provided an important foundation upon which many of those collaborations are built. Before dismantling that scaffold, the agencies should engage in research, consultation, and provide clear and transparent guidance for the industry going forward.

UNRAVELING ARIADNE'S THREAD: ANTITRUST AND THE BIG DATA REVOLUTION IN HEALTHCARE

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I. INTRODUCTION

Healthcare markets are forming in Europe. Indeed, some European countries, such as the Netherlands, have adopted the choice and competition model for healthcare delivery. This choice and competition model is mainly based on the quasi-market system where patients can exercise choice and the money follows the patients.[2] This model creates incentives for patients, physicians as well as health insurers to choose providers based on quality information that is publicly available. The choice and competition model is one of the four core models for providing public services. The other available models are models that (a) rely on trust, when professionals and others who are involved in public service delivery are simply trusted to provide high-quality services, with no government intervention (b) use command and control or else hierarchy, where either the state or a state agency is involved in the provision of public services through managerial hierarchy in which senior officers monitor their subordinates with regards to public service delivery; and (c) rely upon voice, where users wish to receive a high-quality service, by sharing their views with providers.[3]

Why do health systems in Europe move towards market- driven healthcare delivery? EU health systems strive to meet various goals, among which the following are considered essential: (a) equitable access to good care, (b) cost-effectiveness in service organization and delivery, and (c) accountability and transparency. These systems, however, also share common concerns, notably increasing costs that are due mainly to three factors: rising life spans, increasing expectations and technological developments.[4] Undoubtedly, while these factors significantly contribute to the quality of life of EU citizens and lead to health improvements, they also constrain national health budgets. In this light, some countries in Europe have started to introduce the choice and competition model in healthcare to cut unnecessary costs.

The role of competition in healthcare has sparked heated debate. Critiques of the choice and competition model in healthcare point to "the lack of genuine competition in the real world," the challenge of providing trustworthy information to patients to help them choose providers, and the fact that patients do not necessarily have the ability and the knowledge to make good and rational choices that will improve their welfare. Critiques also warn that the risk of cream skimming is a serious one and that introducing the choice and competition model as a means to improve efficiency may inevitably harm equity. In brief, the argument goes, the introduction of the choice and competition model for delivering public services may undermine a health system's quality, defined from a health policy perspective as a multidimensional concept encompassing, among others, the notions of safety, access, equity, continuity, and effectiveness.[5] Is this risk real?

The answer to this question is a positive one. For instance, when competition among hospitals is introduced, governments often publish some quality indicators that offer patients, physicians and health insurers more detailed information on hospitals' performance and the quality of the services they provide. In the U.S., for instance, the Agency for Healthcare Research and Quality publishes the Inpatient Quality Indicators that provide important information on the quality of care inside hospitals, including inpatient mortality rates for surgical procedures. However, quality indicators evaluating hospitals' performance based on health outcomes, such as mortality rates, may in certain cases be misleading and thus fail to adequately inform the public on the true quality of the services hospitals offer to patients. This is because differences in outcome measures, such as mortality rates, may not necessarily relate to differences in quality of care among providers. Indeed, in certain cases, differences in outcome measures may relate to differences in the type of patients that different providers treat.

For instance, due to the social determinants of health, hospitals that operate in disadvantaged areas may treat more high -risk patients. People living in rural areas are more likely to experience poverty or suffer from chronic conditions. For this reason, hospitals operating in rural areas may have higher mortality rates than hospitals operating in urban areas not because they provide inferior care but because of the lower socio- economic status of the patients they treat. Because they may have higher mortality rates, hospitals operating in rural areas may experience lower patient volumes. Hence, they may be more financially vulnerable and face an increased risk of closure than hospitals in metropolitan areas. Should competition authorities allow a hospital merger, although it may further increase market power in the relevant market on the basis that it may ensure the financial stability of the merging parties in rural and disadvantaged areas and therefore guarantee access to health services for all citizens irrespective of their socioeconomic status?

2 S. Nuti, F. Vola, A. Bonini & M. Vainieri, "Making governance work in the health care sector: evidence from a 'natural experiment' in Italy" (2016) 11, *Health Economics, Policy and Law*, 18.

3 G. Le Grand, *The Other Invisible hand, Delivering Public Services through Choice and Competition* (Princeton University Press, 2007), 14.

4 W. Sauter, "The Impact of EU Competition Law on National Healthcare Systems" (2013) 38(4) *European Law Review* 457, 458.

5 Theodosia Stavroulaki, Healthcare, Quality Concerns and Competition law: A systematic Approach (Hart Publishing, 2022), IX.

Competition authorities around the globe would be unable to adequately examine this and analogous competition concerns that may arise due to conflicts between the goal of competition and the pursuit of health equity if they did not address a fundamental question first: how should we define and take into account the notion of healthcare quality when we apply antitrust in healthcare?[6]

This question, albeit crucial, is far from easy to address mainly because the notion of quality from an antitrust perspective and the notion of quality from a health policy perspective do not necessarily align.

While from an antitrust perspective quality is mainly defined as choice, variety, and innovation, from a health policy perspective quality is a multidimensional concept that encompasses also the notions of safety, access, equity, continuity, efficiency and acceptability or else the notion of trust in the doctor-patient relationship.

More than that, the antitrust scholarship claims that the pursuit of public policy goals and objectives, such as equity, is not and should not become part of the antitrust agenda. Should competition authorities transform the notion of quality when they apply competition law in healthcare so that their competition assessment is in line with the social objectives their health systems strive to attain, such as equity and access?

By examining the notion of quality from antitrust, health policy and medicine perspectives, and by analyzing and assessing numerous U.S., UK, and EU antitrust and merger cases mainly in hospital and medical markets, my research identifies the three different models and approaches under which antitrust enforcers around the globe can actually assess how a specific merger or agreement among providers may impact on healthcare quality. These are: (a) the U.S. "Market Approach" under which competition authorities may define quality in healthcare as they define it also in other sectors, namely as choice, variety, and innovation; (b) the "Holistic Approach" under which competition authorities may extend the notion of quality and consumer welfare in healthcare so that it encompasses not only the notions of choice, innovation and variety, but also the wider objectives and values health systems, generally pursue, pursue, such as access, equity and safety; and (c) the "Regulatory Approach" under which competition authorities may cooperate with health authorities when they assess the impact of a specific transaction (merger or agreement) on healthcare quality so that their competition assessment is in line with the social objectives their health systems try to attain.[7]

Competition authorities around the globe may benefit from the application of these models especially in light of the complex transactions that they increasingly examine in the age of big data revolution in healthcare. How? By focusing on the Google/Fitbit merger case, the section that follows delves into this question.

II. ANTITRUST IN THE AGE OF BIG DATA REVOLUTION IN HEALTHCARE: THE GOOGLE/FITBIT MERGER CASE

In December 2020, the European Commission approved the acquisition of Google by Fitbit.[8] The approval, however, was conditional on full compliance with certain commitments offered by Google. How can this merger harm competition and consumers?[9]

After a thorough examination of the proposed deal, the Commission raised the concern that the transaction at stake may restrict competition in several markets. In particular, the Commission explained that the Google/Fitbit deal had the potential of eliminating competition in: a) advertising; b) digital healthcare; and c) creation of wrist-worn wearable devices.[10] How?

A merger between Google and Fitbit would enable Google to gain access to numerous users' health and fitness data; it would also allow the tech giant to acquire access to technology necessary for the development of a data-base similar to that of Fitbit. Because the deal would allow Google to expand the already vast amount of data that can be used for the creation of personalized ads, Google's rivals would be unable to compete in the online search advertising market, online display advertising market, and the entire "ad tech" ecosystem. Ultimately, the

6 *Ibid.* X.

7 *Ibid.* XI.

8 European Commission, "Mergers: Commission Clears Acquisition of Fitbit by Google, Subject , to Conditions" (Press release, December 17, 2020), available at https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2484.

9 For a thorough discussion on the application of antitrust in the age of big data revolution in healthcare see: Theodosia Stavroulaki, *supra* n. 5, 245.

10 *Ibid.*

Commission explained, the envisaged transaction could harm advertisers who would run the risk of facing increased prices, reduced choice, and less innovation.[11]

The deal, the Commission also alleged, could also reduce competition in the digital healthcare space. Currently, several players have access to fitness, and health data provided by Fitbit through a web application programming interface ("Web API"), in order to offer services to Fitbit users and use their data in return. The Commission was concerned that following the transaction, Google would be encouraged to reduce competitors' access to the Fitbit Web API. If Google implemented this strategy, the Commission also said, start-ups' ability to compete in the emerging European digital healthcare space would be undermined.[12]

Finally, the Commission also raised the concern that following the transaction, Google may have strong incentives to put rival producers of wrist-worn wearable devices at a competitive disadvantage. Google, the Commission contended, could successfully attain this goal by undermining their interoperability with Android smartphones. But are these the only ways through which the transaction may hurt competition and consumers?

As several antitrust experts indicated, the answer to this question should be a negative one. Indeed, the proposed deal may also harm consumers and competition across markets, most crucially the health insurance/healthcare markets.[13] By acquiring control of Fitbit's sensitive and individualized health data and by combining this data with data from its current services in the online search and advertising markets, Google would be able to use its advanced health analytics to classify consumers into broader health-related categories: the ones who are expected to remain fit and healthy and the ones who might soon get sick; those who religiously adhere to a healthy diet and those who cannot resist junk food and sugar; the consumers that go for a run when they are stressed and the ones that drink more beers when they feel overwhelmed.[14] Moreover, Google could also use its sophisticated health analytics to predict people's future health status. For instance, Google would be able to identify "the diabetic-concerned," "the depression-concerned," and "cancer-concerned" consumer groups.

Google could make enormous profits out of these predictions. For instance, to the extent Google offers services in the health insurance services market, Google could use these analytics to identify the types of high- risk consumers that it is likely to attract. Then, it could design its health plans to be attractive to "profitable" consumers and less attractive to the high-risk "unprofitable" ones. For instance, if Google can predict that it is likely to increasingly attract the "diabetic-concerned" consumer groups, it could avoid cooperating with specific healthcare providers that have a strong reputation for treating patients with diabetes. At the same time, Google would try to attract the low-risk, healthier consumers by offering them a health insurance product at more advantageous terms.

But even if Google chooses not to enter the health insurance services market, it may still make enormous profits by taking advantage of its advanced health analytics. Specifically, it could sell these analytics to health insurers or to providers. By using these analytics in a discriminatory fashion, they could restrict access to healthcare and health insurance services to high-risk consumers that need access to their services. Such discriminatory strategies may cause harm not only to high-risk consumers but the society as a whole. This is because to the extent high-risk consumers face barriers to accessing health insurance, low-risk consumers also suffer. First, because such discriminatory policies may further increase health disparities and undermine society's social fabric. Second, because of the negative externalities pervading healthcare markets. As COVID-19 clearly demonstrated, if citizens lack access to adequate health insurance and healthcare services, a pandemic cannot be combatted and all people – rich and poor, healthy and sick – suffer.

Did the Commission consider these risks? The answer should be "not necessarily." Although antitrust experts expressed the worry that by further strengthening its ability to gain access to consumers' health data, and by undermining its competitors' ability to do so, Google may be able to increase its market power across markets, such as the health insurance or even the housing market, the Commission did not examine these less visible harms. Raising the concern that privacy concerns do not necessarily amount to competition concerns, as well as that any harms to privacy emerging from the deal would be addressed by the fact that Google is bound by the principles of the General Data Protection Regulation ("GDPR"), which provides that "the processing of personal data concerning health shall be prohibited, unless the person has given explicit consent," the Commission refused to allow any privacy concerns to enter the equation. By not integrating, however, such concerns into

11 *Ibid.*

12 *Ibid.*

13 See for instance M Bourreau, et al, "Google/Fitbit Will Monetise Health Data and Harm Consumers" (Centre for Economic Policy Research, September 2020) 8, available at https://cepr.org/voxeu/columns/googlefitbit-will-monetise-health-data-and-harm-consumers.

14 T. Stavroulaki, "Mergers that Harm Our Health" 19 (2022) *Berkeley Business Law Journal*, 89.

its merger analysis, and by not examining how Google's access to health data may harm competition and consumers in less visible ways, the Commission omitted to consider how the proposed deal may undermine the quality of the health insurance services and contribute to the existing health disparities in Europe. This however may not necessarily be the case if the Commission had grasped the opportunity to assess this deal in a manner analogous to the Holistic and the *Regulatory* Approach as described in the section above.

For instance, in the context of "the Regulatory Approach" the Commission could examine this merger in cooperation with the European Data Protection Board, the body that advises the European Commission on the application of EU data protection law. Although there is not regulatory framework obliging the Commission to examine mergers in cooperation with the Board, there may be several reasons why this may be a good idea, especially in the case of data- driven mergers in the healthcare field. First, because of the special value European health systems attach to health and healthcare. Second, because to the extent big tech players continuously increase their access to consumers' health data, they can exercise their market power across markets, including health insurance, housing, and labor markets. Not surprisingly, the European Data Protection Board had issued a statement before the Commission's final word, noting that "the possible further combination and accumulation of sensitive personal data regarding people in Europe by a major tech company could entail a high level of risk to the fundamental rights to privacy and to the protection of personal data." [15] Had the Commission cooperated with the European Data Protection Board and received its advisory opinion in the context of its merger assessment, the Commission may not have applied merger law in a way that disregarded the merger's impact on access to health insurance and healthcare services. By doing so, however, it applied a merger assessment that risks undermining essential EU health policies and objectives.

In the context of the "Holistic Approach," the Commission may also successfully consider the merger's impact on access to health insurance and healthcare services. This is because if the Commission examined this merger in a manner similar to the *Holistic Approach*, the Commission would also assess how the proposed deal may affect the health systems' main objectives. Specifically, the Commission would examine how, by gaining increasing access to consumers' health data, core facets of the healthcare quality notion and core objectives of EU health systems may be undermined. Arguably, the goals of access and equity are vital goals of EU health systems. The reduction of health inequities and inequalities are also essential goals of EU Member States. Hence, by applying the *Holistic Approach*, the Commission may further expand its analysis, assess the merger's impact across markets, including healthcare and health insurance services markets and apply merger law in a way that conforms with Europe's health values.

Surely, the Commission could also combine the Regulatory and the Holistic Approach. Indeed, it could (a) explore in cooperation with the European Data Protection Board how the proposed deal may harm people's privacy and (b) also explore how potential harms to privacy may also harm people's access to health- care and health insurance services and contribute to the rising health inequalities.

Some could argue in accordance with the Commission's point of view that to the extent Google cannot use people's health data without their explicit consent on the basis of the GDPR, the above risks are not real. However, this point of view underestimates that if it is more profitable for any giant tech player to breach the GDPR and pay a fine than obey the GDPR and not use people's health data, the tech player will breach the GDPR. Google and any big tech player may take this risk, especially knowing that a violation of the GDPR may not necessarily be detected.

The *Facebook/WhatsApp* merger story illustrates this risk. That merger ended with an unconditional clearance after a Phase 1 review on the basis that no traditional competition concerns were raised. Facebook at the time also gave the empty promise not to exploit WhatsApp data following the proposed deal. Although Facebook was fined €110 million for having misled the European Commission, it still got to combine and exploit the data.[16] Crucially, Facebook successfully prevented another rival social network platform from entering the market and threatening its dominance.

III. CONCLUSION

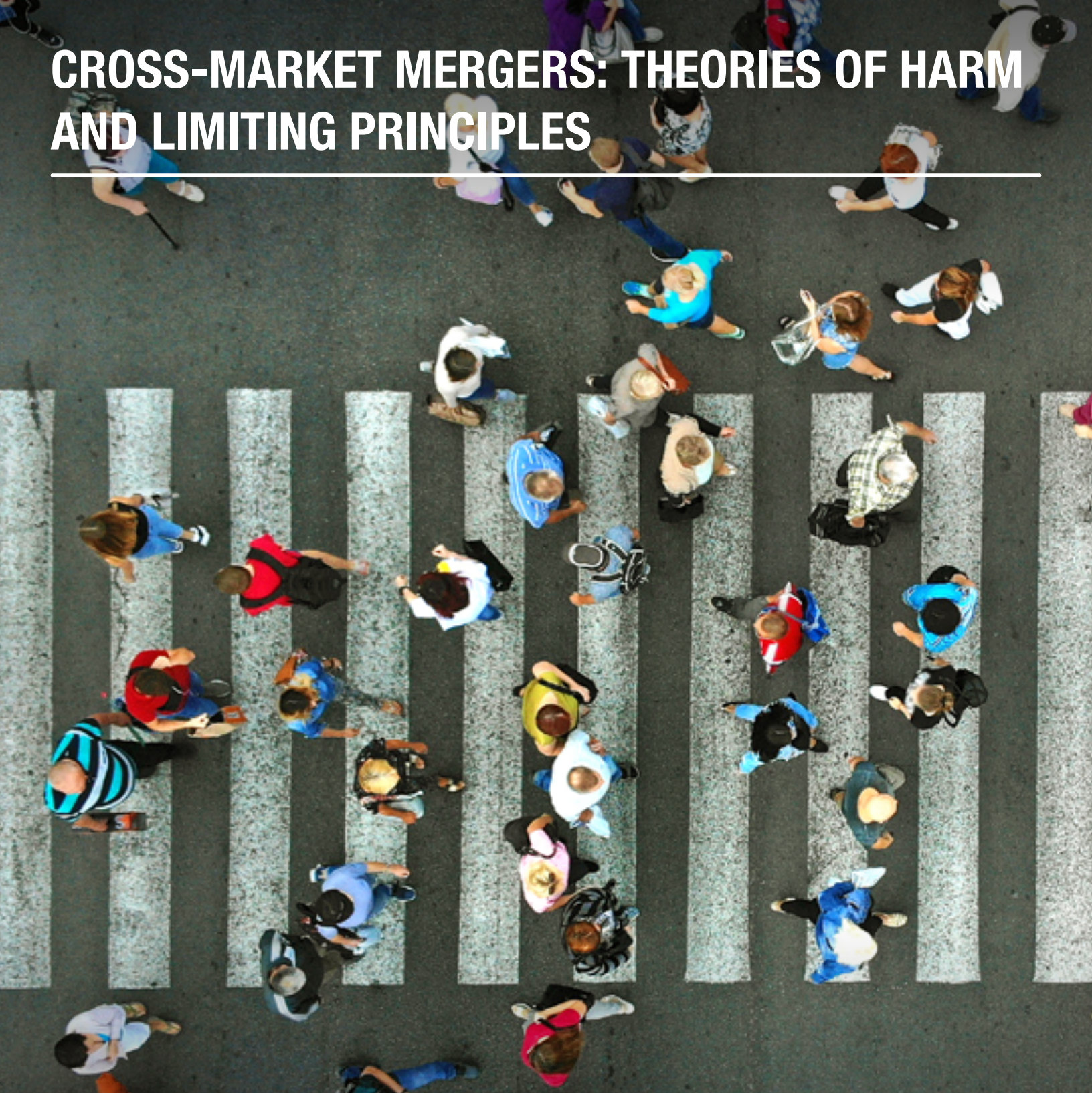
More and more European countries have introduced competition in their healthcare sectors to cut costs and improve quality. The goal of competition in healthcare, however, may in certain cases conflict with essential goals of EU health systems including access to care and health equity. Such conflicts may create new competition concerns that competition authorities around the globe may not be well equipped to address unless

15 C. Caffarra & T. Valletti, "Google Gobbling Fitbit is a Major Privacy Risk, Warns EU Data Protection Advisor" (*Techcrunch*, February 20, 2020), available at: https://techcrunch.com/2020/02/20/google-gobbling-fitbit-is-a-major-privacy-risk-warns-eu-data-protection-advisor/?guccounter=1&guce_referrer=aHR0cHM6Ly93d3cuZ29vZ2xlLmNvbS8&guce_referrer_sig=AQAAANv4xTcu1iznlLQ7QkgKUVO7TgqcnnBxfhFzqlmJ2978xmJZAgJSq-j4coE-gvBuQ5UG68olwRJJdFB3ElOawvwZESO5vyVIehnhyRljeqieGyjyW-DoriKfTRvfD_x5uOQk89-KByYh2b18TTcPD16SO2JVmYFrulhYlQ_lK1aLL.

16 *Ibid.*

they ask the question of how to define healthcare quality. This article indicates that quality of care can be measured and assessed under three different models: the *Market Approach*, the *Holistic Approach*, and the *Regulatory Approach*. Competition authorities may benefit especially from the application of the *Regulatory Approach* and *the Holistic Approach* when they examine the complex transactions that increasingly emerge in the age of big data revolution in healthcare. Taking as an example the Google/Fitbit deal, this piece alleged that if the Commission had examined this deal under the *Regulatory* and the *Holistic Approach* it might have been better able to detect the less visible harms such data-driven deals may cause to vulnerable populations and high-risk consumers.

CROSS-MARKET MERGERS: THEORIES OF HARM AND LIMITING PRINCIPLES



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Several studies find evidence of systematic price increases following specific types of "cross-market" hospital mergers and acquisitions — combinations of hospitals that are too distant to be close substitutes or in the same relevant antitrust market as traditionally defined. The literature on cross-market healthcare mergers continues to grow, and in recent years antitrust agencies have investigated transactions on the basis of cross-market concern. As yet, however, no agency has fully litigated a cross-market challenge.

We review the mechanisms by which a cross-market merger could lead to price increases, the logical predicates for each mechanism, and factors that may increase or decrease antitrust concern. We focus in particular on the *common customer* mechanism, which posits that hospitals can be substitutes from the perspective of employers and the health insurers that market products to them, even if the hospitals are not substitutes for individual patients. This mechanism appears to have been the primary subject of the investigations to date and most closely relates to a potential lessening of competition. Finally, we discuss the important distinction that, while complementarity between sellers is ruled out by definition for in-market mergers, parties to a cross-market merger can be complements or substitutes.

I. INTRODUCTION

A "cross-market" merger is one that combines firms that do not directly sell the same products to the same end customers yet could, nonetheless, potentially lead to price increases. In healthcare, where geographic markets tend to be localized (e.g. a portion of a large metropolitan area or one or several counties), cross-market concerns could apply to mergers of sellers in different but related markets, such as hospitals in distinct regions of a metropolitan area. For example, even if end consumers — patients — in one market do not view hospitals in other markets as substitutes to their local hospitals, those hospitals still may be substitutes from the perspective of health insurers, which act as intermediaries offering networks of healthcare providers to individuals and firms.[2]

The federal antitrust agencies as well as some state agencies have, in recent years, begun to investigate hospital transactions that are or might be cross-market mergers. Figure 1 summarizes the investigations to date that are a matter of public record. So far, the Federal Trade Commission ("FTC") and Department of Justice ("DOJ") have not brought a challenge, while the California Attorney General has negotiated consent decrees but not litigated a challenge, leaving the theory untested in court. In part, this may reflect the nascent, though slowly growing, body of *empirical* research into whether and when mergers and acquisitions are likely to increase prices through cross-market effects.

There are some high-level consistencies within the literature as to the three primary mechanisms that could lead to price increases from a cross-market merger: *change-in-control, tying,* and *common customers*. But there is no consensus on the conditions necessary for a merger that combines hospitals in distinct but related markets to generate a substantive risk of competitive harm through cross-market effects; nor is there a consensus on limiting principles or safe harbors that indicate when cross-market competitive harm is unlikely. In short, there is no consensus on when the agencies *should* investigate a cross-market transaction, and uncertainty regarding when the agencies will investigate a cross-market transaction is high. Further, given that no cross-market case has been litigated yet, uncertainty over when the agencies would be likely to sue is also high.[3]

In this paper, we first overview the aforementioned three mechanisms. We then discuss in more detail the common customers mechanism, which appears to have been the primary focus of the known investigations to date and is the mechanism that most closely relates to a potential lessening of competition. We review logical predicates for the common customer mechanism to create harm, limiting principles, and an important distinction between traditional in-market mergers of horizontal substitutes and cross-market mergers — namely, that complementarity between the sellers is ruled out by definition for in-market mergers whereas parties to a cross-market merger can be complements or substitutes.

2 Nevo (2014) discusses other industries with intermediaries or platforms, such as cable companies offering bundles of content and smartphones offering bundles of technology and applications, in which a similar logic could apply. Aviv Nevo, "Mergers That Increase Bargaining Leverage," Speech, Stanford Institute for Economic Policy Research, January 22, 2014, https://www.justice.gov/atr/file/517781/download. Vistnes & Sarafidis (2013) observe that the predicates of the cross-market theory could also apply to general combinations of inputs, such as hospitals and physicians, into health insurers' provider networks. Gregory S. Vistnes & Yianis Sarafidis, "Cross-Market Hospital Mergers: A Holistic Approach," *Antitrust Law Journal* 79, no. 1 (2013): 289.

3 For a detailed discussion of these and other issues, *see* Gregory S. Vistnes, "Cross-Market Hospital Mergers: Assessing Likely Harm and Implications for Future Government Action," working paper (2022) ("Vistnes (2022)"). See also Keith Brand & Ted Rosenbaum, "A Review of the Economic Literature on Cross-Market Health Care Mergers," *Antitrust Law Journal* 82, no. 2 (2019): 533–549; Jamie S. King, Alexandra D. Montague, Daniel R. Arnold, & Thomas L. Greaney, "Antitrust's Healthcare Conundrum: Cross-Market Mergers and the Rise of System Power," *Hastings Law Journal* 74, no. 4 (2023): 1057–1120.

Figure 1. Summary of Known Cross-Market Agency Investigations and Outcomes

Transaction	Year	Market	Agency	Outcome
Cedars-Sinai / Huntington	2020	Los Angeles, CA. 30-minute drive between Huntington and largest Cedars-Sinai hospital.	CA AG	Consent decree
Beaumont / Spectrum	2021	Michigan, approximately 100 miles away from each other.	FTC	No challenge
Adventist / Acadia	2021	Northern California, approximately 76 miles away from each other.	CA AG	Consent decree
Atrium / Advocate Aurora	2022	Merging parties in different states, with no hospitals in adjacent states.[1]	FTC	No challenge
USC / Methodist	2022	Los Angeles, CA. Methodist located 20-to-30-minute drive from closest USC hospital.	CA AG	Consent decree
Sanford / Fairview	2023	South Dakota-based Sanford Health is seeking to combine with Minnesota's Fairview Health Services.	MN AG	Under review[2]

Notes:
[1] Atrium had hospitals in North Carolina, South Carolina, Georgia, and Alabama, while Advocate Aurora Health was based in Wisconsin and Illinois.
[2] In April 2023, Sanford and Fairview postponed closing their merger a second time, citing the ongoing review by the Minnesota Attorney General. It is unclear whether the FTC or DOJ is investigating the proposed transaction. Alex Kacik, "Sanford, Fairview delay merger a second time," *Modern Healthcare* (April 3, 2023), https://www.modernhealthcare.com/mergers-acquisitions/sanford-health-fairview-health-services-delay-merger-again.

II. POTENTIAL MECHANISMS OF CROSS-MARKET PRICE INCREASES

The literature has identified several mechanisms by which a merger of hospitals that do not compete in the same relevant antitrust market could lead to price increases: (1) *change-in-control*, (2) *tying*, and (3) *common customers*.[4] In this section, we briefly describe each of these mechanisms. We then describe the common customers mechanism in more detail, as that is both most closely related to a theory of lessened competition and appears to have been the main focus of agency investigations to date.

A. Change-in-Control

The change-in-control mechanism refers to the potential for higher prices to result from a system that is a more effective bargainer — e.g. it may be more experienced, better financed and more patient, or simply more skilled — acquiring a hospital or system that is a less effective bargainer.[5] With a better bargaining team at the helm, prices may increase post-acquisition, whether the hospitals are close together or distant, and whether they have common customers or not. Any price increases likely would be observed at the acquired hospitals or systems, which may be less sophisticated or have fewer resources than the acquirer. Another distinction is that, while systems with greater market power could also be more effective negotiators, the change-in-control mechanism does not require market power in either party's market.

Lewis & Pflum (2017) study out-of-market acquisitions and find evidence of significant post-transaction price increases on average, despite the acquiring system and target hospital being quite far apart.[6] Their results provide support for the existence of the change-in-control mechanism but do not rule out the other mechanisms. They also note, and we agree, that it is unclear whether a price increase caused by replacing a less effective bargaining team with a more effective bargaining team constitutes an antitrust violation — i.e. it is not clearly a factor whose

4 Schmitt (2018) evaluates cross-market mergers that increase multimarket contact between competing hospital systems and finds evidence of general price increases rather than increases in the specific market(s) where the combination occurred. This result is consistent with increased multimarket contact facilitating coordination between systems that compete across multiple markets. Matt Schmitt, "Multimarket Contact in the Hospital Industry," *American Economic Journal: Economic Policy* 10, no. 3 (2018): 361–387.

5 Lewis & Pflum (2015) describe this mechanism as follows: "[S]ystem membership may alter a hospital's bargaining power allowing the hospital to extract a higher share of the surplus generated by contracting with an [insurer], resulting in a higher reimbursement rate. This latter channel is of particular interest because it allows for an increase in prices after merger (through higher bargaining power) even when merging hospitals are located in different patient markets and thus experience no change in bargaining position." Matthew S. Lewis & Kevin E. Pflum, "Diagnosing Hospital System Bargaining Power in Managed Care Networks," *American Economic Journal: Economic Policy* 7, no. 1 (2015): 244.

6 They also find that nearby rivals of the acquired hospitals also increase prices on average, but to a lesser extent. Matthew S. Lewis & Kevin E. Pflum, "The Price Effects of Cross-Market Mergers: Theory and Evidence from the Hospital Industry," *RAND Journal of Economics* 48, no. 3 (2017): 579–610.

effect "may be substantially to lessen competition, or to tend to create a monopoly."[7] In addition, leadership at hospitals with less sophisticated bargaining teams may also be less effective in other respects. The potential for mergers and acquisitions to cause less effective management teams to be replaced by more effective leadership is generally pro-competitive. It is unclear whether antitrust policy could restrict the scope for the change-in-control mechanism to lead to price increases without also weakening the generally beneficial competitive pressure that the risk of takeovers and managerial terminations creates.

B. Tying in the Presence of Non-Market Constraints on Pricing

Tying refers to the practice of selling two distinct though commonly related goods or services only together, rather than *a la carte*. Tying may raise competitive concern when a seller that has market power in one market but faces competition in a second market requires customers who want to purchase the former product to also purchase its version of the competitively supplied product.[8] In the hospital industry, it is ubiquitous for hospital-insurer contracts to include both inpatient and hospital-based outpatient services. To our knowledge, this has not been challenged as anticompetitive, presumably because inpatient and outpatient services within a hospital are produced using common physical and human capital such that separate contracting and sale would be unwieldly and inefficient. Hospital systems may also tie across their locations by requiring an insurer that wants to contract with any of the system's hospitals to contract with all of its hospitals — a practice often referred to as all-or-nothing contracting.[9] In general, tying can be viewed as a form of cross-market conduct, because there are necessarily two markets at issue: one for the tying product and another for the tied product. Because tying of this sort has a long history in antitrust that predates the recent literature on cross-market hospital mergers, we do not discuss this in detail.

One variant of tying that could arise, under certain conditions, in a cross-market hospital merger involves a firm with market power that faces overt or implicit non-market constraints on its pricing. Suppose a hospital system has substantial market power that would enable it to negotiate exceptionally high prices from health insurers but that some external constraint makes it impossible or unattractive for the system to charge such a high price. The constraint could be overt price regulation, though that is rare. Alternatively, the constraint could be a desire to avoid negative press, negative attention from state legislators, or conduct investigations by state attorneys general and other agencies.[10]

If the system were unable to fully raise its prices to the level it could negotiate absent external constraints, it could use acquisitions and a tie to effectuate a price increase. Specifically, it could acquire one or more other hospitals and use all-or-nothing contracting to require health insurers to contract with those hospitals as a condition of contracting with its existing, price-constrained hospitals. The system could then raise prices at the acquired locations.[11] If those new locations are in markets distinct from the system's existing hospitals, the result would be a price increase from a cross-market merger.

Several factors distinguish this tying theory from other cross-market mechanisms. First, the acquirer, but not necessarily the target, must have market power — this is in contrast to the common customers mechanism, where, as we discuss below, both parties must possess some degree of market power. Second, the tying mechanism does not require the existence of common customers, only a common insurer (if an insurer does not sell insurance in the geography of the tied hospitals, a tie would be moot). Third, there must be some non-market constraint on the prices the acquirer can set at its existing hospitals. This last factor likely limits the set of cross-market transactions to which this tying mechanism might apply. Finally, tying would be an atypical basis for a prospective merger challenge, though it certainly has been a significant basis for retrospective conduct investigations and enforcement actions.[12]

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7 FTC, "The Antitrust Laws," https://www.ftc.gov/advice-guidance/competition-guidance/guide-antitrust-laws/antitrust-laws.

8 FTC, "Tying the Sale of Two Products," https://www.ftc.gov/advice-guidance/competition-guidance/guide-antitrust-laws/single-firm-conduct/tying-sale-two-products.

9 The California Attorney General filed an antitrust lawsuit against Sutter Health, which ultimately settled. One condition of that settlement requires Sutter to "stop all-or-nothing contracting." California Department of Justice, "Attorney General Becerra Secures Preliminary Approval of Settlement with Sutter Health Resolving Allegations of Anti-Competitive Practices," March 9, 2021, https://oag.ca.gov/news/press-releases/attorney-general-becerra-secures-preliminary-approval-settlement-sutter-health.

10 The aforementioned Sutter case provides one example. In another, the Pennsylvania Attorney General filed a lawsuit, ultimately settled, against UPMC that asked a state court to "[p]rotect against UPMC's unjust enrichment by prohibiting excessive and unreasonable billing practices inconsistent with its status as a non-profit charity providing healthcare to the public." Pennsylvania Attorney General, "Attorney General Josh Shapiro Announces Legal Action against UPMC for Violating Pennsylvania's Charities Laws," February 7, 2019, https://www.attorneygeneral.gov/taking-action/attorney-general-josh-shapiro-announces-legal-action-against-upmc-for-violating-pennsylvanias-charities-laws/.

11 The theory of using a tie to avoid price caps dates back at least to the 1950s. See Ward S. Bowman Jr., "Tying Arrangements and the Leveraging Problem," *Yale Law Journal 67*, no. 19 (1957): 21–23.

12 King et al. (2023) argue that "[a] merger that provides a health system with the incentive and opportunity to tie its facilities together to coerce payers into higher prices and foreclose lower-priced hospitals from those payers' networks should be within the reach of the Clayton Act." King et al. (2023), 1090.

C. Common Customers

The foremost mechanism behind potential cross-market price increases is the presence of *common customers*, meaning large employers seeking to provide sufficient coverage in terms of choice and quality to their employees who live and work across multiple markets. These customers link the merging parties' separate geographic markets and can make the parties to a cross-market merger substitutes from the perspective of the *insurer*, despite not being substitutes for any individual health plan enrollees or patients.

As an example, consider an employer with a primary location in the center of a large metropolitan area that consists of a central city and multiple surrounding suburbs from which workers commute. For example, Manhattan workers commute from Brooklyn, The Bronx, Long Island, Hoboken, Westchester, etc. Likewise, San Francisco workers commute from the surrounding counties of Oakland, Marin, San Mateo, and Contra Costa. In general, few patients would consider hospitals in a distant suburb or county to be close substitutes for their local hospitals, meaning that a merger of hospitals in distant suburbs would likely not be a horizontal, in-market merger. The premise underlying the common customers mechanism is that, because larger employers need a health plan that offers *most* of its workers a reasonably attractive network of hospitals from which to choose, hospitals in disparate suburbs can be substitutes *from the perspective of health insurers* that market their products to such larger employers.

Continuing the example, suppose that an employer would not be disaffected by having a less attractive hospital network in one suburb where its employers live, but having two such gaps would be substantially more difficult, and having three gaps would be untenable.[13] If this pattern holds, then a merger of hospitals in two or more distinct suburbs could increase the combined entity's bargaining leverage. Each hospital on its own could create at most one network gap, which does not make an insurer's network difficult to market. But together, they may be able to create two gaps, and that would make the insurer's product difficult to market. That stronger threat would increase the combined entity's bargaining leverage over the insurer and allow it to increase price — even though few if any patients view the combining hospitals as substitutes.

III. COMPONENTS OF A COMMON CUSTOMERS CROSS-MARKET THEORY OF HARM

Vistnes & Sarafidis (2013) first identified the common customer mechanism as a potential driver of cross-market effects in an analysis that, while grounded in the structure of the industry, is theoretical.[14] In subsequent work, Dafny, Ho, & Lee ("DHL," 2019) provide additional theoretical analysis, along with empirical work to test the theory.[15] In their empirical work, they construct a sample of mergers involving hospitals located within the same state but more than 30 minutes apart. DHL's central result is that mergers among hospitals located within 30–90 minutes of each other and in the same state lead, on average, to price increases of 7 percent to 10 percent. They also evaluate mergers among hospitals that are more than 90 minutes apart but find no evidence of persistent price increases; they attribute this to the extent of common customers waning as distance increases.

DHL's results establish that cross-market hospital mergers can lead to price increases, but that raises practical questions for enforcers and merging parties alike. What types of cross-market hospital transactions are more or less likely to lead to price increases? Are there tangible criteria that establish when a transaction is unlikely to raise concern, akin to the HHI thresholds applicable to horizontal in-market mergers?[16]

For the common customer mechanism, as developed by Vistnes & Sarafidis and DHL, to raise a risk of increased bargaining leverage and higher prices from a cross-market merger, several conditions must be met. The following overview of necessary conditions is based on our review of their work, as well as subsequent commentary and agency investigations. The conditions we identify align closely with the discussion in Vistnes (2022).[17]

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13 The reduction in the value of a health insurer's network from having a second gap must be more than twice as large as the reduction from having a first gap (assuming the gaps are equally sized). This condition applies when the value function relating the quality of a health insurer's hospital network to the number of geographies with an attractive set of hospitals in-network is "concave."

14 Vistnes & Sarafidis, *supra* note 2.

15 Leemore Dafny, Kate Ho, & Robin Lee, "The Price Effects of Cross-Market Mergers: Theory and Evidence from the Hospital Industry," *RAND Journal of Economics* 50, no. 2 (2019): 286–325.

16 Under current agency policy, mergers in unconcentrated markets and mergers involving small changes in concentration are "unlikely to have adverse competitive effects and ordinarily require no further analysis." *Horizontal Merger Guidelines* (2010), § 5.

17 "Three necessary conditions drive the [] theory: the presence of common linked employers [i.e. common customers]; market power at the hospitals across which there are common linked customers; and concavity." Vistnes (2022), 20 and cites therein.

Two caveats apply to the factors we discuss below. First, the common customer mechanism does not embed any specified relationship between market shares of the merging parties within linked markets or the extent of common customers and the probability or magnitude of cross-market price increases. Consequently, we can identify factors that likely increase or decrease concern, but only qualitatively. This, of course, does not bar enforcement. For example, coordinated effects merger challenges commonly rely on qualitative assessments of the impact of a merger on the ability of firms to sustain higher prices through coordinated interaction, as opposed to quantitative indicia such as upward pricing pressure and merger simulations.[18] Second, in contrast to the large body of case law on horizontal mergers, there have been no litigated cross-market merger challenges. This means we cannot identify the factors that a court hearing an eventual cross-market challenge would prioritize.

A. Sufficient Volume of Common Customers

Common customers are customers that value the services of both of the parties to a cross-market merger. For example, while *enrollees* who live in an eastern suburb of a city would generally place little value on whether hospitals in a western suburb are in their insurance network, *employers* that have workers residing in both the eastern and western suburbs would place value on the hospitals in both suburbs. Only some employers in a given region would have workforces that are dispersed in this way.[19] In other words, for any given cross-market merger, some customers will be common and some will not, and the relative magnitudes of the two will depend on the specifics of the merger at hand. There are no theoretical or empirical thresholds for the extent of common customers that raise concerns. Directionally, a smaller set of common customers raises less concern and vice-versa.

Results in DHL support the conclusion that concern wanes as the extent of common customers declines.[20] In particular, DHL find evidence of price effects among cross-market mergers involving hospitals within 30–90 minutes, which they hypothesize are "precisely the sort of cross-market hospital mergers where common customers are likeliest to be present."[21] But they do not find evidence of sustained price increases beyond 90 minutes.

Although far from a bright line, this does identify several topics that hospitals considering a cross-market merger, or an agency evaluating such a merger (or deciding whether to do so), could explore. Public data on commuting patterns between markets may provide an indicator of the extent to which a full investigation would likely identify more than a handful of common customers. Whether or not the implicated markets are in the same metropolitan statistical area ("MSA") is also informative, as the US Census Bureau defines MSAs to include a core urban area "plus adjacent counties having a high degree of social and economic integration with the core as measured through commuting ties."[22] In addition, business records may identify the employers providing insurance coverage to patients of the respective merging hospitals, which could provide a direct measure of the presence and significance, or absence, of common customers.

B. Market Power and Market Shares in Two or More Component Markets

There is consensus in the literature that *at least one* merging party must possess market power in the linked market. For example, King et al. write, "Researchers and antitrust enforcers have been quick to note that there are definitely plus factors that make cross-market price effects more likely. One of these plus factors is almost always that one of the parties to the transaction has market power in at least one market."[23]

However, we believe that when premised on common customers the theory requires that some degree of market power be present in *at least two* component markets.[24] This is because the common customers mechanism operates through increased bargaining leverage. A hospital

18 *Horizontal Merger Guidelines* (2010), § 7.

19 The majority of firms in the country are small, but large firms account for the majority of employment. Nationwide, firms with fewer than 100 employees account for about 35 percent of employment while firms with more than 1,000 employees account for about 42 percent of employment. BLS, "Table F. Distribution of Private Sector Employment by Firm Size Class: 1993/Q1 through 2022/Q1, Not Seasonally Adjusted," https://www.bls.gov/web/cewbd/table_f.txt. Larger firms are much more likely to offer insurance coverage to their workers and so account for a disproportionate share of the commercially insured population. Kaiser/HRET, "2022 Employer Health Benefits Survey," October 27, 2022, https://www.kff.org/health-costs/report/2022-employer-health-benefits-survey/.

20 DHL, 315; see also DHL, 296 ("The price effects of a cross-market merger should be larger the more prevalent are common customers for the merging hospitals.").

21 Some confusion is evident in the literature regarding DHL's results for out-of-state mergers. DHL do not *test* whether out-of-state combinations that are within the 30- to 90-minute range lead to price increases, because their data include few such transactions. DHL, 311. They do test whether out-of-state combinations *overall* lead to price increases and find that they do not. Taken together, their results imply that out-of-state combinations involving distances greater than 90 minutes are unlikely to raise concern, but their results do not speak to out-of-state combinations at distances between 30 and 90 minutes. That said, the extent of common customers at any given distance would likely be no greater and may well be less for hospitals in different states, which would imply lesser concern.

22 US Census Bureau, "Glossary," https://www.census.gov/programs-surveys/metro-micro/about/glossary.html (*see* definition of "Core Based Statistical Areas").

23 King et al. (2023), 1088.

24 DHL (2019) do not include an explicit statement of the necessity of a significant market share or market power in two or more of the linked markets. However, that proposition is somewhat implicit in several statements in their paper. See DHL, 291, 296.

without market power (i.e. a hospital that faces ample substitutes) would not augment the bargaining leverage of the merged entity — even if one party does have existing market power. In this view, we agree with Vistnes (2022).[25]

However, there is no consensus and little evidence on how to operationalize a "market power in at least two markets" condition. Vistnes suggests examining the prices set by the hospitals in the linked markets as well as relying on interviews with health plans. Fulton et al. (2022) use a 30 percent cut-off, based on discharge shares within a commuting zone, to define a "large" market share that might raise cross-market concern.[26] Merger challenges when post-merger shares are 30 percent or less are rare, and FTC challenges to horizontal hospital mergers typically entail alleged post-merger shares of 50 percent or higher. In this respect, a 30 percent share could be a reasonable informal safe harbor, so long as the share is computed in an appropriate relevant geographic market. This, however, is not necessarily straightforward, especially at the deal consideration or agency screening stage. For example, a hospital could have a 15 percent share within its "commuting zone," a 25 percent share in its primary service area, and a 50 percent share in a relevant geographic market, as the FTC would ultimately define it in court.

Suppose the agencies were to adopt an X percent safe harbor for concern under the common customers mechanism. A transaction would be within the safe harbor if, in every pair of markets (one from each system) with significant common customers, one party *or* the other had a share below *X* percent.

C. Health Insurance Products Are Not Tailored to the Linked Markets

A cross-market hospital merger can increase the combined system's bargaining leverage if having network "gaps" in additional markets makes it increasingly difficult for health insurers to market their plans. For example, suppose that having a gap (i.e. not having an important hospital in-network) in Market A would reduce an insurer's sales by 10 percent and that a gap in Market B would likewise reduce sales by 10 percent. A cross-market merger of hospitals in Markets A and B would increase the system's bargaining leverage if the simultaneous absence of the system's hospitals in both markets would reduce the insurer's sales by more than 20 percent. This is a restatement of the "concavity" condition.

For a cross-market merger, the individual enrollees in Market A place little or no value on the appeal of the hospital network in Market B. Likewise, Market B enrollees care little about the hospital network in Market A. Substitutability, and potential increased bargaining leverage, arises insofar as *employers* with workers in both markets would be substantially less likely to buy an insurance product with a gap in both markets. This, however, presumes that the employer offers the same insurance product in both markets. If, instead, the employer offers insurance products that are tailored to each market — call them Plan A (for Market A) and Plan B (for Market B) — then the linkage between the two markets is sundered.[27]

If a cross-market merger combines important hospitals in the two markets but health plans are tailored to each market, the combined system would not gain bargaining leverage. This is because the reduction in the value of Plan A from a simultaneous termination in both markets by the combined system is identical to the reduction in the value of Plan A from losing just the hospitals in Market A. The same applies in Market B.

This identifies additional questions for parties to a cross-market merger, or agencies reviewing such a merger, to evaluate. Do most employers with workers in the component markets offer a common plan in both markets? Are the sets of insurers similar in the component markets? If employers do not offer tailored plans, would it be costly for them to do so?

D. From the Perspective of Insurers, the Combining Systems Are Substitutes Rather than Complements

By definition, horizontal mergers combine firms that offer substitutes. In contrast, complementarities between merging parties are an inherent possibility in cross-market mergers. For example, a better provider network for an insurer in one market will boost demand for that insurer's products, which will benefit all providers contracted with the insurer. As a hospital system accounts for a greater share of an insurer's network — such as by having hospitals located in more of the insurer's markets — the system will internalize those positive externalities to a greater degree.

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25 "Showing appreciable harm under the CLE [i.e. common customers] theory requires showing that both of the merging parties have substantial market power since, absent such market power, a merger would not make it more difficult for a health plan to drop the hospital from its provider network." Vistnes (2022), 21.

26 Brent D. Fulton, Daniel R. Arnold, Jaime S. King, Alexandra D. Montague, Thomas L. Greaney, & Richard M. Scheffler, "The Rise of Cross-Market Hospital Systems and Their Market Power in the US," *Health Affairs* 41, no. 11 (2022): 1652–1660.

27 DHL explain this as follows: "The simple model [of cross-market bargaining leverage effects on price] assumed that employers faced a cost of offering additional plans. If instead, employers could costlessly offer different plans in different markets, then markets would again be separable and no cross-market merger price effects would arise." They further observe that insurers commonly offer specific health plan products over broad markets. DHL, 317.

Complementarities of this sort could mitigate or even offset price increases that might arise from the common customer mechanism. DHL explain this as follow:

> [I]f the sum of the losses from excluding either hospital individually exceeds the loss from excluding both simultaneously . . . then a merger may potentially lead to a reduction in negotiated reimbursement rates under Nash bargaining. This can occur, for example, if the two merging hospitals are sufficiently strong complements so that an insurer can only obtain significant revenues . . . if it contracts with both hospitals as opposed to only one.[28]

The Massachusetts Health Policy Commission ("HPC") relied on a version of this complementarity logic in approving (subject to conditions) the merger of Beth Israel and Lahey Health, two systems that primarily operated hospitals in adjacent parts of the Greater Boston area.[29] The motivating premise was that, absent the merger, each system has an attenuated incentive to make investments or offer lower prices in order to become more competitive with the market leader, Partners Healthcare (now Mass General Brigham). For example, if a narrow network product that excludes Partners Healthcare requires both Beth Israel and Lahey to be marketable, then complementarity as described above would apply. One aspect of the HPC decision that would not apply generally in the case of cross-market hospital mergers is the presence of a market leader that was not part of the transaction.

IV. CONCLUSION

Cross-market hospital mergers can affect prices in multiple markets and through multiple mechanisms, not all of which clearly fall under the antitrust laws. Moreover, there is the potential for complementarity as well as substitutability between the merging parties. These factors make competitive effects analysis and enforcement in cross-market cases complex and uncertain. This ambiguity is likely to continue until and unless additional empirical research emerges and antitrust agencies establish precedents through fully litigated merger challenges.

The DOJ and FTC are currently revising the *Horizontal Merger Guidelines*, and a draft for public commentary may soon be available.[30] The new guidelines are expected to cover mergers of all types rather than just horizontal mergers and may include principles by which the agencies will evaluate cross-market mergers.[31]

In the meantime, two recent merger reviews suggest that transactions involving hospitals more than two hours apart may not be challenged, which is consistent with the 30- to 90-minute result from DHL. Specifically, the FTC issued second requests, reportedly on cross-market grounds, for the Beaumont-Spectrum and Advocate-Atrium mergers. In the former, all party hospitals were located within Michigan but were over two hours apart. In the latter, the parties' hospitals were in different states. Some additional guidance may come from three consent decrees in California, but it is unclear whether that will generalize to other states or to federal investigations.[32]

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28 DHL, 292.

29 "The core question is as follows: *If BILH becomes more attractive to payers and consumers [through complementarities for the combined system], would BILH become a true alternative to Partners in payer networks and thereby constrain Partners' 'must-have' status*, or would the result instead be a second 'must-have' system? If enough consumers (patients or employers) would have a strong preference for a plan that includes both systems, BILH could become a second 'must-have' system in the Commonwealth. . . . If, on the other hand, a combined BILH system were viewed as a true alternative to Partners, payers would have an increased ability to build a viable network without Partners, which would constrain Partners' bargaining leverage and reduce the price increases it would otherwise be able to negotiate." (Emphasis added.) Massachusetts Health Policy Commission Review of The Proposed Merger of Lahey Health System, etc., HPC-CMIR-2017-2, September 27, 2018, https://www.mass.gov/doc/final-cmir-report-beth-israel-lahey-health/download, 64–65. Two of the authors of this paper advised the Massachusetts HPC in its review of the BIDCO-Lahey merger.

30 DOJ & FTC, "Federal Trade Commission and Justice Department Seek to Strengthen Enforcement Against Illegal Mergers," press release, January 18, 2022, https://www.ftc.gov/news-events/news/press-releases/2022/01/federal-trade-commission-justice-department-seek-strengthen-enforcement-against-illegal-mergers.

31 In comments submitted in response to the announcement of the revision, Nancy Rose & Leemore Dafny offered the following recommendations regarding cross-market mergers:

- "When reviewing mergers among parties that serve different markets (e.g., cross-market mergers), the Agencies' review will emphasize the competitive effects of such a transaction over the formal delineation of relevant markets. . . . market definition may be uninformative or even misleading with regard to the potential for the merger to yield anticompetitive effects."
- "When performing a merger review, whether horizontal or nonhorizontal (including cross-market), the effects of prior mergers or acquisitions by the parties will explicitly be considered as sources of real-world evidence . . . such direct evidence may bolster the case for or against challenging a given transaction."

Leemore Dafny & Nancy Rose, "Response to DOJ-FTC Merger Guidelines Request for Information," April 21, 2022, https://tinyurl.com/5f4ahdwm. Professor Dafny is a co-author of DHL and Professor Rose is a former DOJ chief economist.

32 Vistnes (2022), section IV.C.

HEALTHCARE ADMINISTRATIVE COSTS AND COMPETITION POLICY

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Administrative costs in the U.S. healthcare sector represent between 25 percent to 31 percent of total expenditures,[2] a proportion twice that in Canada and significantly greater than in all other Organization for Economic Cooperation and Development member nations.[3] Moreover, the rate of growth in administrative costs in the United States has outpaced that of overall health care expenditures and is projected to continue to increase without reforms to reduce administrative complexity.[4]

The primary culprit of these wasteful administrative are costs are often attributed to billing and insurance-related ("BIR") activities.[5] BIR costs are now garnering greater attention for at least two reasons. One is the recent emergence of empirical evidence that quantifies the magnitude of BIR costs, including the particularly embarrassing feature that BIR costs in other nations are far lower.[6] A recent study estimates the amount of money lost to high transactions costs in the U.S. is at least $250 billion annually.[7] These are just the static costs lost during the transaction process and do not include the opportunity costs from ancillary innovation that would emerge from BIR solutions.

The second reason is that other industries have managed to execute financial transactions at far lower costs. For example, paying for services with a commercial credit card requires only 2-3 percent of the cost of the transaction.[8] Since transaction costs add no value to health-care delivery, they represent prime targets for reducing wasteful health care spending.

If high costs are invitations to entry, we believe the persistence of high costs – especially when other markets prove that lower costs are technologically possible – is an indication of entry barriers in this market. Unfortunately, until recently, the nation's high administrative costs in healthcare have not been deemed to be a problem that should be addressed through competition policy. We will argue that this is a mistake. Not only do we know that efforts to reduce administrative costs would be accelerated in the face of greater competition, but we also know, as we discuss below, that competition policy levers can meaningfully help achieve this result. In fact, addressing the enormous growth of administrative costs is one of the most attractive areas for innovation across the health sector.

I. BILLING COSTS IN HEALTHCARE

Transactions in healthcare are complex. Most services are paid for through public or private health insurance, so-called third-party billing, which means patient-consumers do not directly negotiate with providers for the cost of services. Although there are good reasons why most healthcare is purchased through intermediary payers (e.g. the provision of financial security, the inability of most consumers to identify necessary and valuable healthcare services), it means that financing healthcare must endure a complicated transaction sequence.

The typical healthcare payment goes through the following steps. First, a provider must establish that a patient is an eligible member of a health insurance plan — and thus a path to payment is secured — before the service is provided. Next, after delivering the healthcare service, the provider must then determine how to submit a bill to the patient's payer in accordance with the complex contract provisions that detail the unique payment process for that plan (each private health plan negotiates a contract with each healthcare provider in their network; the public plans can have national payment models administered through private health plans, or they can delegate plan administration to private health plans through Medicare Advantage or Medicaid Managed Care programs). After bill submission, the health plan then reviews the bill to make sure that they are financially responsible under the plan contract and for the amount billed, and it then pays the provider or denies payment based on its reading of the plan terms. Frequently, a cycle of rebilling and adjustments ensue.

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2 DU Himmelstein, M Jun, R Busse, et al. *A Comparison of Hospital Administrative Costs in Eight Nations: US Costs Exceed All Others By Far*. 33 Health Aff. 1586-1594 (2014).

3 *Id.*; A Jiwani, D Himmelstein, S Woolhandler & JG Kahn. *Billing and insurance-related administrative costs in United States' health care: synthesis of micro-costing evidence.* 14 BMC Health Serv Res. 556 (2014).

4 DM Berwick, AD Hackbarth. *Eliminating waste in US health care*. 307 JAMA. 1513-1516 (2012).

5 P Tseng, RS Kaplan, BD Richman, MA Shah & KA Schulman, *Administrative Costs Associated With Physician Billing and Insurance-Related Activities at an Academic Health Care System*, 319 JAMA 691-697 (2018); JG Kahn, R Kronick, M Kreger, DN Gans. *The cost of health insurance administration in California: estimates for insurers, physicians, and hospitals*. 24 Health Aff 1629-1639 (2005).

6 Barak D. Richman, Robert S. Kaplan, Japees Kohli, Dennis Purcell, Mahek Shah, Igna Bonfrer, Brian Golden, Rosemary Hannam, Will Mitchell, Daniel Cehic, Garry Crispin & Kevin A. Schulman, *Billing And Insurance–Related Administrative Costs: A Cross-National Analysis*, 41 Health Affairs 8, 1098-1106 (2022).

7 McKinsey & Company. *Administrative Simplification: How to Save A Quarter-Trillion Dollars in US Healthcare*. (Oct. 2021); Sahni NR, Carrus B & Cutler DM. Administrative Simplification and the Potential for Saving a Quarter-Trillion Dollars in Health Care. *JAMA*. 2021;326(17):1677–1678. doi:10.1001/jama.2021.17315

8 Daly L. Average credit card processing fees and costs in 2021. The Ascent, https://www.fool.com/the-ascent/research/average-credit-card-processing-fees-costs-america/ (Apr 13, 2021)

It is striking to contrast this transaction sequence with the typical credit card purchase. Credit cards also involve financial intermediaries, but any credit card user can readily and intuitively understand why the credit card intermediaries involve much lower transaction costs. At the point of sale, both the buyer and the seller in a credit card transaction are automatically verified, and the payment is instantly engineered. There is no technological barrier that prevents healthcare transactions from being similarly automated, but legacy decisions around the business processes of billing have prevented and still impede the implementation of common-sense digital strategies. In turn, these payer business decisions have prevented meaningful competition from improving our inefficient and expansive system for financing healthcare.

First, the U.S. healthcare sector lacks a digital infrastructure to manage healthcare transactions. Consider the obvious lack of digital tools imprinted on health insurance cards: they have no bar codes, no magnetic strips, and no EMV security chips. Nothing in these cards can do what credit cards do (critically, other nations do have health insurance cards with these capabilities[9]). Instead, the card is completely analog, and healthcare providers must manually enter the card's information onto their own electronic system. Although many of the billing processes have become digitized over the last decade – after all, healthcare providers enter insurance information into a computer, rather than into paper files – this digitized part of the billing process is built atop analog business processes that preceded the large-scale implementation of electronic health records ("EHRs").

Second, the U.S. healthcare sector lacks business models that can utilize new billing technologies. Policy and industry leaders have exhibited little understanding of how innovation can (and how it cannot) generate new payment processes that generate efficiencies. The presumption was that "paper kills" and that converting paper records to electronic records would automatically make transactions less costly and cumbersome.[10] There was little recognition that innovative business processes needed to emerge in order to achieve efficiencies and even less recognition of what is needed to foster those business process improvements.

Many of these errors can be placed at the feet of the Health Information Technology for Economic and Clinical Health ("HiTECH") Act, enacted as part of the American Recovery and Reinvestment Act of 2009. HiTECH invested $38 billion of government funds to make EHRs widespread, but it did nothing to replace the analog foundation of medical financing. Thus, despite promising to revolutionize medical billing,[11] HiTECH only transformed how many organizations stored their internal records while leaving the underlying analog transaction architecture unchanged. Consequently, the rise of electronic health records failed to reduce administrative costs for providers,[12] and it instead fostered the rise of legacy firms who quickly gained market share in the lucrative EHR industry without making transaction markets more efficient or open.[13]

II. COMPETITION POLICY TO REDUCE ADMINISTRATIVE COSTS IN HEALTHCARE

Policymakers can reverse the failures of the past. However, tackling the challenge of high transaction costs in healthcare requires an explicit recognition of the underlying market-wide problems and a cohesive strategy that addressees them.

Perhaps the real shortcoming in the HiTECH Act was its failure to identify the problem that needed to be solved. Many early analyses of electronic health records focused on their impact on medical record rooms and charge capture for providers, not changes in billing processes. Even a comprehensive analysis by the National Academy of Medicine after HiTECH implementation focused on the firm-level benefits, not market level benefits, of digital technology.[14] Policymakers failed to recognize that high administrative and billing costs are products of a market failure, one that requires a policy intervention.

9 https://en.wikipedia.org/wiki/Carte_Vitale.

10 David Merritt, ed., Paper Kills 2.0: How Health IT Can Save Your Life and Your Money (Forward by Newt Gingrich & Tom Daschle, 2010). (Center for Health Transformation, 2010).

11 https://www.whitehouse.gov/the-press-office/2011/09/12/presidential-proclamation-national-health-information-technology-week ("Health informatioin technology connects doctors and patients to more complete and accurate health records. Tools like electronic health records and elecrtreonic prescriptions help patients and provides make safer, smarter decisions about health care. This technology is critical to improving patient care, enabling coordination between provides and patients, reducing the risk of dangerous drug interactions, and helping patients access prevention and disease management services. … Better technology can also cut costs for providers by reducing paperwork and duplicative tests.").

12 Tseng (2018).

13 https://www.definitivehc.com/blog/most-common-inpatient-ehr-systems.

14 https://nam.edu/perspectives-2014-return-on-information-a-standard-model-for-assessing-institutional-return-on-electronic-health-records/.

The market failures that generate high billing costs stem from the organization of healthcare billing. Prior work has identified three factors that cause these market failures: architectural complexity, contractual complexity, and compliance costs.[15] Architectural complexity arises when each plan and each provider negotiate for a unique contract for health care services. The resulting massive redundancy — a form of prisoners' dilemma — is staggering. For example, United Healthcare alone loaded over 40,000 different health plans into their price transparency platform.[16] Contractual complexity is the detailed requirements outlined in each contract, and in their on-line coverage manuals and tools. For example, Blue Shield of California has a 450-page HMO/Medical Group Procedures manual for 2023, which was amended twice in the month it was published.[17]

Each payer similarly imposes its own set of contracts, payment mechanics, and financing infrastructure onto each provider with which it contracts. These are all separate, analog systems that individually are cumbersome to manage, and together multiply the collective administrative burden for providers who must navigate this complexity across the many different payers in a market. Finally, compliance costs are the costs of ensuring that the billing policies follow the rules for public and private health plans (non-compliance with rules for billing private health plans can trigger civil liability, but non-compliance in billing public health plans can bring more severe criminal penalties). Since 2010, providers who participate in the Medicare and Medicaid programs are required to establish billing compliance programs by statute.[18]

While it is easy to envision the factors driving up costs in this market model, few have understood the totality of these forces, and fewer still have developed strategies to bring these costs down. The source of costs is clearly not a firm level challenge but a market level challenge. The banking sector encountered similar market-wide inefficiencies until a regulator intervened. Local banks benefited from proprietary transaction models (you originally had to visit your bank branch to use your ATM card), but the development of a large-scale digital platform for efficient transactions has been a long-time goal of federal policy makers. When regulators established the protocols for a common payment system, industry was compelled to develop new business models in response. The efficiencies achieved in credit card transactions in the retail sector are due to collaborations and standard settings across banks, retailers, and other intermediaries. Moreover, the common standards invite other entities to provide innovations to supplant the technology of incumbents. In fact, this market is not static, with FinTech and digital payment models continuing to drive down costs and increase access to financial services for consumers.

The solution is coordination: establishing a common digital infrastructure, payment model, and technological standards for all payers and providers. But coordination will be hard to achieve because, like the health sector itself, healthcare policy is fragmented. No single organization in government owns or has oversight of the transaction platform in healthcare. While public and private insurance organizations largely use the same platform for payment, neither has oversight over the market.

For example, the Centers for Medicare and Medicaid services, provides insurance coverage to almost 150 million Americans. They have a statutory authority to address administrative simplification under the 1996 Health Insurance Portability and Accountability Act, but enforcement falls to the National Standards Group at the Center for Medicare and Medicaid Services ("CMS"). This office, policing transactions for a $4.7 Trillion market, monitors compliance with the Transactions and Code Sets ("TCS"); the National Employer Identifier Number ("EIN"); the National Provider Identifier ("NPI"); and the Operating Rules ("OPR").[19] Yet the only enforcement actions undertaken by this group are investigations of complaints and random compliance reviews. For the first quarter of 2023, the agency reported 17 valid complaints under its operating authority.[20] This is a sharp contrast to the world of banking, where the Federal Reserve has driven a seemingly relentless focus on transforming the transaction process.

Meanwhile, billing procedures in the insurance community are well established, and each health insurer touts its costly transaction model as a core feature of its business. Even new entrants into the market, such as highly touted Oscar, focused on a digital presence for patients but the same back-end administrative processes for providers.[21] Accordingly, no individual insurer can offer a digital model that can transform

15 Scheinker D, Richman BD, Milstein A & Schulman KA. Reducing administrative costs in US health care: Assessing single payer and its alternatives. Health Serv Res. 2021 Aug;56(4):615-625.

16 https://transparency-in-coverage.uhc.com/.

17 https://www.blueshieldca.com/bsca/bsc/wcm/connect/provider/Provider_Content_EN/Guidelines_ resources/manuals.

18 https://oig.hhs.gov/compliance/physician-education/compliance-programs-for-physicians/.

19 https://www.cms.gov/files/document/administrative-simplification-enforcement-slides-2021.pdf; https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/Enforcements/HIPAAEnforcementStatistics.

20 https://www.cms.gov/files/document/enforcement-data-first-quarter-2023.pdf.

21 https://www.hioscar.com/blog/our-post-election-thoughts-on-healthcare.

the sector. Until the entire sector – or our political leaders – identify transaction costs as a market-wide distortion, technology adoption will proceed with little or no productivity gains.[22]

These experiences suggest that a true common transaction platform, one with public protocols and allows entry from entrants, is an essential foundation for an efficient healthcare market. Such a platform would enable a transition from analog billing processes to a pure digital transaction payment model in healthcare, and enormous benefits would result. It would usher in new tools that can directly address the $250 billion in annual spending considered "waste" by researchers.[23] It would also lead to downstream savings through electronic methods of fraud detection (credit card fraud is detected by algorithms culling through transactions in real time; health care fraud is currently detected through manual review of paper charts). Finally, such a platform would drive competition in the market, reducing barriers to entry for firms by offering new service models for patients. The quality of services would also improve because it'd be easier for firms to develop novel technologies and services to access the payment system.

The banking sector has had the Federal Reserve as a quarterback for digital transformation, but healthcare lacks an obvious federal analog. While CMS has some statutory authority to address administrative simplification, it has never been an agency tasked with overseeing the entire health care market. In fact, CMS acts at times in ways that hurt value in the private health care market.[24] It is possible that CMS, together with the Office of the Assistant Secretary for Planning and Evaluation ("ASPE") could collaborate on novel governance efforts. More likely, Congress would need to delegate new authorities to HHS to accomplish this effort. Given likely resistance by incumbents in the market, there would need to be a strong push by employers and patient advocates to bring this concept forward. Scholarship from the newly awakened competition policy community could be critical to the success of such efforts.

III. CONCLUSION

Electronic health records were envisioned as a technological revolution, and the HiTECH Act was described as a transformative investment that would move us from hand-written notes to a digital process, thus accurately documenting patient encounters while reducing the administrative burden for providers. Yet, despite this massive public investment, the economic benefits envisioned were not achieved. This failure was not a failure of technology but a failure to understand the underlying factors driving up administrative costs in the U.S. healthcare market.

We are at an interesting juncture in healthcare policy. Digitization has spawned new waves of intermediaries that optimize pieces in an overwhelmingly complex process, but optimizing inefficient processes simply escalates costs and creates ever larger barriers to entry. It is time for those involved in competition policy to address the specific failings in the billing market, develop structures that force a new level of standardization, and foster an architecture that invites entry and competition. There are few opportunities in healthcare as important and as overlooked as the transaction platform underlying healthcare financing, and few areas where thoughtful competition policy could be so beneficial.

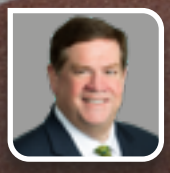
22 https://hbr.org/2017/11/the-it-transformation-health-care-needs.

23 Sahni. 2021.

24 Richman BD & Schulman KA. A cautious path forward on accountable care organizations. JAMA. 2011 Feb 9;305(6):602-3.

THE EVOLUTION OF ANTITRUST ANALYSIS FOR THE HEALTHCARE INDUSTRY: IS IT FOR THE BETTER OR WILL IT RESULT IN UNNECESSARY HURDLES

BY PATRICK D. SOUTER[1]



1 Gray Reed, Dallas, Texas.

I. INTRODUCTION

On July 9, 2021, the healthcare industry was provided the first official pronouncement by the Biden Administration of how antitrust analysis and enforcement would substantially deviate from that which industry participants had relied upon the previous three decades. The new analysis would be much more aggressive in its approach than that utilized from a historical antitrust perspective. The Executive Order on Promoting Competition in the American Economy[2] ("Executive Order") established a "whole-of-government effort" to promote competition in certain industries the Biden Administration asserts are the most pressing areas of problematic competition. The Executive Order includes 72 initiatives to be pursued by more than a dozen federal agencies when addressing concerns on negative impacts to the marketplace. Healthcare is spotlighted as one on those problematic industries where a drastic overhaul of antitrust enforcement is believed to be necessary to improve competition. It also encourages those federal agencies involved in antitrust matters to focus their efforts on key industries and underlying markets where there may be problematic competition issues and coordinates other agencies' ongoing response to consolidated business arrangements.

Healthcare was identified for new, heightened antitrust enforcement since "… lack of competition in healthcare increases prices and reduces access to quality care."[3] One of the four healthcare industry segments that was specifically focused on was hospital consolidations.[4] The United States Department of Justice ("DOJ"), and Federal Trade Commission ("FTC") (collectively, "Agencies"), like other governmental agencies, commonly issue guidance documents and other resources to educate and inform stakeholders on how these agencies will apply antitrust laws in certain arrangements. Much of this guidance will be applicable across a wide array of industries but there are instances where these materials will be industry-specific due to the differences in one industry versus the others. Healthcare is an example of a standalone industry due to the type of stakeholders involved in a patient's care and the unique way healthcare should be delivered for those patients to receive optimal results. The Executive Order was the precursor of the DOJ and FTC eliminating such guidance that was compiled through Agency policies ("Policy Statements") that established what was referred to as "Antitrust Safety Zones."

The guidance offered through each of these Policy Statements was not intended to create laws, regulations, or other legal doctrines. Rather, the purpose was to provide insight on how the Agencies would examine and apply existing antitrust laws and the interpretation by the courts in those instances where joint arrangements might be questioned. There are various methods of antitrust analysis based upon a particular arrangement and the impact of the Policy Statements allowed for consistent review and interpretation of the applicable laws and regulations:

> The Healthcare Statements provide for flexible analysis and allow for consideration of procompetitive justifications in appropriate cases of potentially procompetitive joint behavior that otherwise might receive per se condemnation. This approach illustrates the reluctance of Agencies, as well as the courts, to apply the per se rule to condemn collaborative conduct among health care providers where, despite the elimination of some price competition among providers, there also is a reasonable likelihood that the conduct may be part of a larger, potentially, procompetitive, endeavor.[5]

Therefore, when healthcare market participants were contemplating a proposed transaction that may result in antitrust scrutiny, the guidance allowed for established considerations to be taken into account and Policy Statements on how those considerations should be addressed. These authorities provided for a commitment by the Agencies not to challenge conduct that met the Policy Statements and provided consistency in antitrust analysis and enforcement.

However, in less than a year, the Biden Administration's antitrust overhaul initiative as set forth in the Executive Order has resulted in federal authorities completely dismantling a consistent approach to healthcare mergers, consolidations and working relationships. This guidance has been utilized for decades for not only hospitals and health systems but healthcare providers, suppliers, and payors. More specifically, antitrust guidance and safety zones authorities have been eliminated wholesale and new approaches to antitrust analysis and enforcement announced for a more stringent, case-by-case analysis and not just for hospital mergers as the Executive Order stated. Rather, the Agencies' actions due to the Executive Order will result negatively impact the entire healthcare industry.

2 Fact Sheet: Executive Order on Promoting Competition in the American Economy (July 9, 2021).

3 *Id.*

4 The other three industry segments were prescription drugs, hearing aids and health insurance.

5 Cristine L. White, Saralisa C. Brau & David Marx, Jr., Antitrust And Healthcare: A Comprehensive Guide 59 (2d. ed 2008).

II. THE CREATION OF ANTITRUST SAFETY ZONES

The Clinton administration, through the DOJ and FTC, initiated steps on September 15, 1993, to make healthcare more accessible and affordable for all by issuing guidance to healthcare facilities and providers for their use in structuring mergers, joint ventures, and other contractual arrangements.[6] Interestingly, the basis for the Clinton Administration initiatives are the same utilized for the Biden Administration initiatives but the end results are diametrically opposed from each other.

The Agencies issued their Policy Statements addressing six specific areas of healthcare arrangements: (i) hospital mergers; (ii) hospital joint ventures involving high-technology or other expensive medical equipment; (iii) physicians' provision of information to purchasers of health care services; (iv) hospital participation in exchanges of price and cost information; (v) health care providers' joint purchasing arrangements; and (vi) physician network joint ventures (collectively, the "1993 Statements"). These policy statements established Antitrust Safety Zones setting forth circumstances in which the Agencies would not challenge the certain aforementioned arrangements. Additionally, the Agencies also committed to expediting requests for FTC Advisory Opinions,[7] and DOJ Business Reviews[8] when requested by those contemplating arrangements that may implicate antitrust enforcement activity. The 1993 Statements were not intended to be static. Rather, they would be revisited with the evolution of the structure of the healthcare industry.

The Agencies revised the 1993 Statements one year later "… designed to encourage agreements that promote efficiency in the health care industry and lower health care costs to consumers."[9] These revisions expanded the guidance to nine enforcement policies that included new guidance on hospital joint ventures, the provision of fee-related information to purchasers and creating healthcare networks. It also provided additional guidance on the topics previously addressed in the 1993 Statements as well as creating new guidelines for hospital joint ventures involving specialized clinical services, analytical principles relating to multi-provider networks and providers' collective provision of fee-related information.

The Agencies issued the next set of Statements of Antitrust Enforcement Policy in Health Care in 1996[10] that expanded on the revised 1993 Statements safety zones and included guidance pertaining to physician network joint ventures, clarified and expanded the Agencies' 1993 guidance to new healthcare arrangements and business models, offered hypothetical scenarios to clarify the agencies' application of the enumerated safety zones, and explained how the agencies would analyze conduct falling outside of the safety zones.

The last significant development relating to the Agencies' policy statements occurred in 2011 with the issuance of Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (the "2011 Policy Statements").[11] The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively, the "Affordable Care Act")[12] allowed for healthcare providers to utilize an Accountable Care Organizations ("ACO") as a method of healthcare delivery system reform that allowed for healthcare providers and affiliated stakeholders to service Medicare fee-for-service beneficiaries and share in the savings generated if certain metrics were met from an organization participating in the Medicare Shared Savings Program.[13] The 2011 Policy Statement also provides more latitude so as to allow for ACO-type arrangements operating in a private sector such as similar types of arrangements with commercial payors when those stakeholders are participating in the Medicare Shared Savings Program.

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6 Press Release, U.S. Dep't of Justice, Antitrust Enforcement Policy Statements Issued for Health Care Industry (Sept. 15, 1993).

7 The FTC may issue Advisory Opinions that contains advice in the form of an opinion if it is practical for the FTC to render such a request, is made of an actual, proposed business arrangement and not require extensive investigation, clinical study, testing, or collateral inquiry. It may not issue an opinion if the request is based upon a hypothetical question.

8 The DOJ may issue a similar type of review like that of the FTC Advisory Opinion under similar circumstances.

9 Press Release, U.S. Dep't of Justice, New Antitrust Enforcement Policy Statements Issued for Health Care Industry (Sept. 27, 1994).

10 Statements of Antitrust Enforcement Policy in Health Care Issued by the U.S. Dep't of Justice and Federal Trade Commission (Aug. 1996).

11 Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program issued by the Federal Trade Commission and U.S. Dep't of Justice (Oct. 20, 2011).

12 The Patient Protection and Affordable Care Act, Pub. L. 111-48, 124 Stat. 119 (2010), and the Health Care and Education Reconciliation Act of 2010, Pub. L. 111-52, 124 Stat. 1029 (2010) commonly referred to as "ObamaCare."

13 Patient Protection and Affordable Care Act § 3022, 124 Stat. at 395-99.

III. DOJ'S WITHDRAWAL OF THE THREE HEALTHCARE POLICY STATEMENTS

On February 2, 2023, Principal Deputy Assistant Attorney General of DOJ's Antitrust Division, Doha Mekki, announced in a speech that the DOJ was withdrawing the three Policy Statements with no immediate plans to replace them.[14] Deputy AAG Mekki reasoned that such withdrawal was necessary since the Policy Statements "… no longer reflect market realities or the Division's current enforcement posture."[15] Specifically, the Deputy stated:

> Much has changed in the health care industry over the 30 years since these statements were issued. The delivery of health care products and services have changed. In many respects, our understanding of health care economics has evolved for the better. Increasingly health care is a data intensive industry that relies on the power of machine learning, artificial intelligence, and other advanced tools to develop or deliver products or services. Some markets are increasingly multi-sided. These realities affect how buyers or sellers transact business, which may bear on important dimensions of competition in this industry.
>
> Moreover, a wave of consolidation in the health care industry has brought together industry participants who once served distinct or adjacent functions. As just one example, large health insurance companies now own providers, PBMs, health data analytics companies, and acute care clinics. If the concept of industry roll up was not in our lexicon then, it is more commonplace now. In many cases, these combinations and other entanglements may have changed the underlying incentive structures in the industry.[16]

Deputy AAG Mekki reasoned that due to the evolution of the healthcare marketplace and outdated nature of many statements reflected in those documents, the DOJ was no longer confident that the guidance fully reflects market realities, the risk of serious competitive harm, or the full scope of liability under the antitrust laws.

The next day, following through on the Deputy's statements, the DOJ issued a press release formalizing the withdrawal of the Policy Statements.[17] The FTC, which usually is responsible for investigating healthcare related activities such as hospital mergers, has yet to withdraw its support for the three Policy Statements. However, the FTC did issue a new Policy Statement that will impact its analysis of healthcare transactions and seems to be an indicator that it will move another direction in analysis and enforcement of the antitrust laws in the healthcare industry.

IV. FTC'S NEW POLICY STATEMENT REGARDING UNFAIR METHODS OF COMPETITION

On November 10, 2022, the FTC issued its Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the FTC Act[18] that alters how the Agency will review arrangements that traditionally were analyzed under more traditional principles. The FTC has indicated its intent to use Section 5 of the Federal Trade Commission Act[19] ("Section 5") as the sole basis to pursue cases that are outside other antitrust laws such as the Sherman Act[20] and Clayton Act[21] where unfair methods of competition negatively impact competition. Additionally, the FTC indicates reviewing conduct that tends to foreclose or impair market participants opportunities, reduce competition, reduce opportunities for choice in the marketplace and otherwise negatively harm consumers. This method of analysis will result in the FTC moving away from utilizing the long-standing *rule of reason* analysis as utilized by the judiciary in reviewing Sherman Act violations and further evidence that one should be leery of relying upon the DOJ's withdrawn Policy Statements in addressing Section 5 antitrust concerns.

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14 Doha Mekki, Principal Deputy Assistant Attorney General, Antitrust Division, Remarks at GCR Live: Law Leaders Global 2023 (Feb. 2, 2023), https://www.justice.gov/opa/speech/principal-deputy-assistant-attorney-general-doha-mekki-antitrust-division-delivers-0.

15 *Id.*

16 *Id.*

17 Press Release, U.S. Dep't of Justice, Justice Department Withdraws Outdated Enforcement Policy Statements (Feb. 3, 2023).

18 Fed. Trade Comm'n, Policy Statement Regarding the Scop of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act (Nov. 10, 2022).

19 15 U.S.C. §45.

20 15 U.S.C. §§ 1–7.

21 15 U.S.C. §12-27.

V. WHAT DOES THIS MEAN FOR HEALTHCARE ANTITRUST ANALYSIS?

Healthcare marketplace stakeholders no longer have the level of guidance it previously had to rely upon when structuring transactions or even when contemplating whether they are advisable to consider. The "whole-of-government" approach referenced in the Executive Order forebodes many new, aggressive enforcement actions with a coordination among governmental authorities that traditionally have not jointly participated in such activities. These new initiatives should result in the following considerations to be contemplated early in the transaction process:

(i) Anticipation that there will be an expanded scope of scrutiny resulting in broader, more comprehensive investigations from one or more governmental authorities;
(ii) Recognize that a more focused investigation and analysis of the relevant geographic marketplace, including one that is much narrower than traditionally used, may be utilized in the analysis to ensure that an appropriate market analysis occurs;
(iii) Prepare in advance the need to present to the authorities more thorough information early in an antitrust review to assist in expediting the process;
(iv) Understand that a more individualized case-by-case analysis will result in greater uncertainty than what was encountered when the Policy Statements were in effect due to lack of Antitrust Safety Zones; and
(v) Expect to incur significant more expense in dealing with governmental authorities since it will be much more involved and time consuming.

While the healthcare industry has lost a valuable resource in consideration of and structuring transactions, it does not mean that traditional business arrangements that previously cleared antitrust scrutiny will not continue to do so. Rather, the Agencies will be more sensitive and focused of the impact of a healthcare transaction to ensure that not only at the time of the transaction but on a long-term going-forward basis it does not result in a negative impact in the delivery of healthcare.

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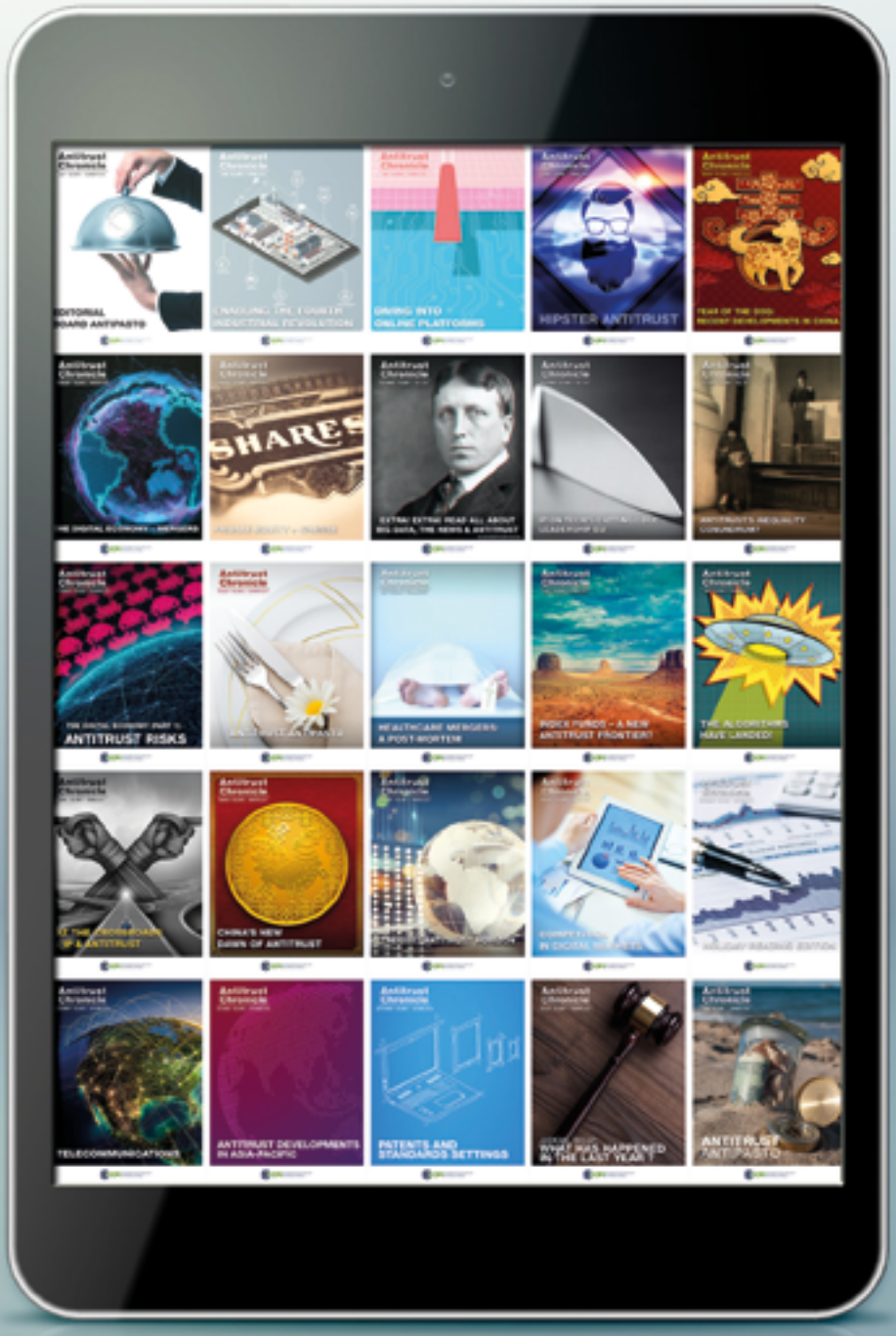


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