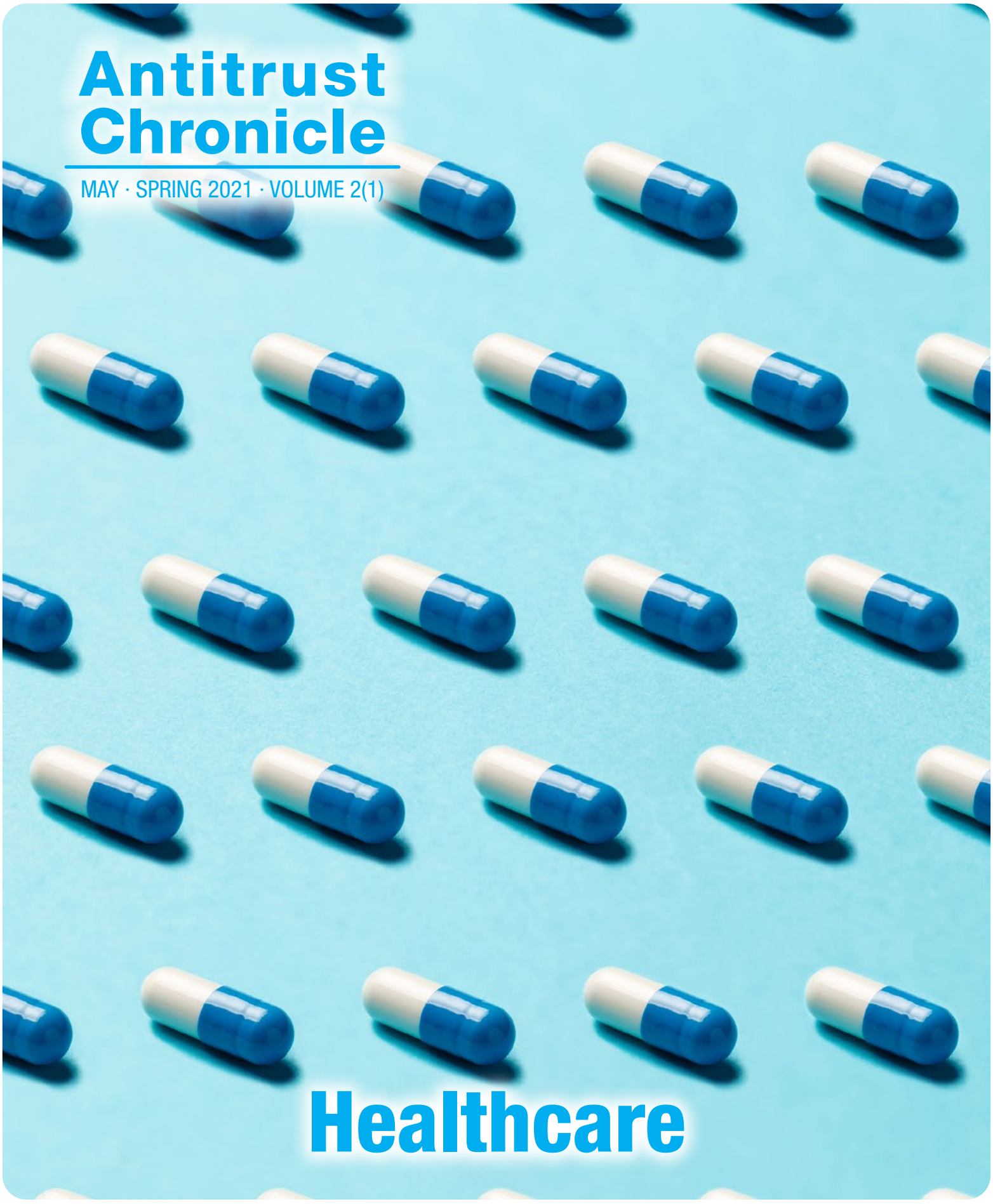

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CPI COMPETITION POLICY INTERNATIONAL

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LETTER FROM THE EDITOR

Dear Readers,

Since 2020, more than ever, healthcare has risen to near the top of the political agenda. Inevitably, the topics that define politics attract enhanced antitrust scrutiny, and healthcare is no exception.

Even before the COVID-19 pandemic, antitrust debates have raged in various aspects of the healthcare industry, from the provision of medical services, to patent-related practices in the pharmaceuticals industry.

Practices in healthcare vary considerably throughout the world. The contributions to this Chronicle reflect the diversity of practices in healthcare provision in various jurisdictions, ranging from the concerns raised in more socialized healthcare systems, to concerns relating to vertical integration in more privatized systems.

Despite the diversity of systems throughout the world, practitioners and commentators across jurisdictions have much to learn from each other. The contributions to this Chronicle form a vital contribution to the cross-pollination of information and practices concerning enforcement in healthcare as it continues to develop over the months and years to come.

As always, thank you to our great panel of authors.

Sincerely,

CPI Team

SUMMARIES

SUMMARIES

WHAT'S NEXT?

For June 2021, we will feature Chronicles focused on issues related to (1) **Buyer Cartels**; and (2) **Interoperability**.

ANNOUNCEMENTS

CPI wants to hear from our subscribers. In 2021, 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 2021

For July 2021, we will feature Chronicles focused on issues related to (1) **Foreign Direct Investments**; and (2) **The New Madison Approach**.

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.

ON THEIR SILVER ANNIVERSARY, IT'S TIME TO BURNISH THE HEALTHCARE GUIDELINES

BY PETER MUCCHETTI & EVA KURBAN[1]

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In 1996, the United States Department of Justice and the Federal Trade Commission issued revised Statements of Antitrust Enforcement Policy in Health Care (the "Healthcare Guidelines").[2] These nine statements address a variety of issues concerning healthcare providers and health insurance companies. But the federal antitrust agencies have not subsequently updated these now 25-year old guidelines. Some of the statements have aged well, providing guidance that is regularly used. Other statements, however, have largely been ignored or effectively been replaced by subsequent guidance.

Updating the Healthcare Guidelines would provide valuable guidance on important healthcare and antitrust issues. We recommend that the FTC and DOJ initiate a process, similar to the one used last year to create the Vertical Merger Guidelines, that includes soliciting public input on what statements should be amended, deleted, or added. As this article discusses, adding new statements to the Healthcare Guidelines may be the most needed update. In particular, the agencies should add three new statements to address the following issues:

1. What types of steering restrictions are permissible in hospital-payer contracts;

2. How hospitals may structure discounts to payers; and

3. How competitors may collaborate to address healthcare crises, incorporating lessons from the response to the COVID-19 crisis.

The creation of new statements on these topics would have particular value because they involve tricky issues where it is often difficult to separate conduct that raises significant competition concerns from conduct that is pro-competitive or competitively neutral. Furthermore, the agencies should create "safety zones" for these new statements, as they did in many of the 1996 statements, that describe conduct that the agencies will not challenge under the antitrust laws absent extraordinary circumstances. In the three areas listed above, the agencies have significant experience, which, along with public comments, should allow the agencies to create antitrust safety zones.

I. THE 1996 HEALTHCARE GUIDELINES AND OTHER AGENCY HEALTHCARE GUIDANCE

The Healthcare Guidelines were originally released in 1993 with six statements. In 1994, the DOJ and FTC added new statements to the guidelines and expanded the antitrust safety zones for several statements. The 1996 Healthcare Guidelines later amplified policy statements concerning physician network joint ventures and multiprovider networks. But since 1996, the antitrust agencies have not further updated the Healthcare Guidelines.

Some statements have been more widely relied upon than others. For example, 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 healthcare industry.[3] Statement 7, concerning joint purchasing arrangements among healthcare providers, is regularly used as a reference for how to analyze the conduct of group purchasing organizations.[4]

Other statements do not appear to be widely used. In particular, there are almost no court cases, law review articles, or business review letters that cite to Statements 1 through 3 of the Healthcare Guidelines.[5] Furthermore, the Healthcare Guidelines were most often cited in the late 1990s and early 2000s, with relatively few references made after 2010.

Many of the statements appear to be collecting dust in part because a wide variety of other guidance from the federal antitrust agencies has been provided since August 1996, including the following:

- the 2000 Antitrust Guidelines for Collaborations Among Competitors;

- the 2004 report Improving Health Care: A Dose of Competition;

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2 Dep't of Justice & Federal Trade Comm'n, *Statements of Antitrust Enforcement Policy in Health Care, available at* https://www.justice.gov/atr/page/file/1197731/download.

3 See, e.g. Response to Greater New York Hospital Association (Jan. 16, 2013) available at https://www.justice.gov/atr/response-greater-new-york-hospital-associations-request-business-review-letter.

4 See, e.g. Response to American Optometric Association and AOAExcel GPO, LLC (Jan. 15, 2020) available at https://www.justice.gov/opa/press-release/file/1235206/download.

5 Statements 1-3 concern (1) hospital mergers; (2) hospital joint ventures involving high technology or other expensive healthcare equipment; and (3) hospital joint ventures involving specialized clinical or other expensive healthcare services.

- the 2010 Horizontal Merger Guidelines;
- the 2011 Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program;
- the 2020 Vertical Merger Guidelines;
- filings relating to the approximately 35 DOJ and 220 FTC healthcare enforcement actions since August 1996; and
- approximately 30 DOJ business review letters and 50 FTC advisory opinions relating to healthcare issued since August 1996.

These additional sources for guidance have supplanted some of the Healthcare Guidelines. For example, Statement 1, which concerns hospital mergers, has essentially been replaced by the 2010 Horizontal Merger Guidelines. Updating the Healthcare Guidelines would provide the federal antitrust agencies with the opportunity to withdraw outdated statements and synthesize antitrust guidance from subsequent materials into a modern set of guidelines.

One of the salient innovations in the Healthcare Guidelines was the inclusion in most statements of antitrust safety zones describing conduct that the agencies would not challenge absent extraordinary circumstances. For example, Statement 7 creates an antitrust safety zone for group purchasing organizations that fall below certain market-share thresholds. Businesses, including non-healthcare businesses, have consulted many of the Healthcare Guidelines safety zones to understand how the federal antitrust agencies would analyze business conduct and to determine how to structure their operations to minimize antitrust concerns.

II. THE VALUE IN HOLDING HEALTHCARE HEARINGS AND PROVIDING UPDATED GUIDANCE

Hearings conducted by the DOJ and FTC concerning how to update the Healthcare Guidelines would be beneficial in at least two ways. First, the process would enable companies and other participants in the healthcare industry to identify for the federal antitrust agencies the areas that are most in need of updated antitrust guidance. Second, the hearings would allow for input from businesses, academics, government agencies, and others on difficult issues that are facing the antitrust healthcare community. Discussions should focus on the difficult questions because unsettled areas are precisely where guidance is most valuable.

At least three areas are ripe for new statements: (1) steering restrictions in hospital-payer contracts; (2) the structure of hospital discounts to payers; and (3) lessons from the COVID-19 crisis on how competitors may collaborate to address healthcare crises.

These three issues have common characteristics. First, they are not addressed in the current Healthcare Guidelines. Second, antitrust agencies have developed significant experience, and competition analysis has significantly advanced, in these areas since 1996. Third, despite these advancements, thorny antitrust questions still exist in these areas, as discussed below.

In the absence of DOJ and FTC providing guidance through healthcare statements on these and other topics, antitrust practitioners will continue to review case and other enforcement developments to navigate complex antitrust issues. But developments through enforcement actions can be fragmented, haphazard, and uncertain because they vary depending on the investigations, settlements, and litigation that the antitrust agencies can and do pursue. Issuing new statements, in contrast, provides an avenue for comprehensive consideration of issues, systematically analyzing conduct that can benefit or harm consumers, and providing more holistic guidance.

III. STEERING RESTRICTIONS

The antitrust community's understanding of the potential for harm concerning hospital steering restrictions has advanced significantly since 1996. Steering is a method used by insurers to offer consumers options to reduce their healthcare expenses, including designing health benefit plans that give patients financial incentives to choose more cost-effective hospitals and physicians. Two principal cases have laid out the antitrust concerns that can arise from a dominant hospital's use of restrictions that prevent steering: *Atrium Health* and *Sutter Health*.[6]

In *Atrium*, the DOJ and the State of North Carolina alleged that Atrium, the largest hospital system in the Charlotte area, used its market power to restrict health insurers from encouraging consumers to choose healthcare providers that offered better overall value. The litigation was resolved in 2019 when the court entered a consent decree that enjoined Atrium from using certain steering restrictions.

In *Sutter*, the California Attorney General joined a lawsuit filed by private plaintiffs in California state court, challenging Sutter's use of anti-steering provisions and other allegedly anticompetitive contracting practices. On the eve of trial, in October 2019, the parties reached a settlement agreement. In addition to a $575 million monetary settlement, the settlement includes wide-ranging injunctive relief through behavioral remedies.

Sutter's use of anti-steering provisions in its contracts with insurers formed a significant part of the foundation of the antitrust claims against it. Sutter's contracts allegedly prohibited or disincentivized insurers from offering incentives to patients to use lower-cost or higher-quality competitors through steering or tiered plan benefit designs. The Sutter settlement recognizes the positive competitive effects that steering can have in providing lower costs and greater choices for consumers and prohibits Sutter from directly or indirectly interfering with many steering or tiering arrangements.[7]

The steering restrictions at issue in *Atrium* and *Sutter* were both evaluated under the rule of reason because some steering restrictions can be pro-competitive or competitively neutral. For this reason, the consent decrees in both cases permitted the defendants to continue to use certain steering restrictions. For example, the *Atrium* decree provides that if Atrium is the most prominently featured provider in a narrow-network plan or hospital-insurer cobranded plan, Atrium may restrict an insurer from steering away from Atrium in that plan. As the DOJ recognized, this type of restriction may help narrow networks and co-branded plans be more effective by allowing insurers to steer patients to a hospital in a narrow network.[8]

Similarly, the proposed *Sutter* decree allows an individual Sutter provider to offer lower prices for networks or products that feature that provider, including co-branded products.[9] The decree also allows Sutter to negotiate and enforce contract terms that provide that an insurer may not unilaterally change the participation status of a Sutter provider in an existing commercial product during the contract term.[10] This provision allows Sutter to restrict one way in which insurers could steer away from a particular Sutter provider.

A healthcare statement on steering restrictions: Healthcare systems and insurers today face a difficult analysis when trying to determine what steering restrictions are permissible or problematic because of competition concerns. Holding hearings to study this issue would allow these businesses and other industry participants to discuss their concerns and vet this issue. Additionally, the inclusion of permitted conduct in the *Atrium* and *Sutter* decrees indicates that a healthcare statement on steering restrictions can include an antitrust safety zone for permitted steering restrictions. As in the *Atrium* matter, the proposed safety zone should permit steering restrictions that are reasonably necessary for creating competition based on narrow network or co-branded plans. Along with defining a safety zone, the antitrust agencies should consider articulating additional safeguards that hospitals could implement to make any steering restriction less likely to harm competition, including having the hospital-insurer contract explicitly state that the insurer remains free to create other plans that exclude the hospital.

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6 See Final Judgment, *United States v. Charlotte-Mecklenburg Hospital Authority*, No. 3:16-cv-00311-RJC-DCK (W.D.N.C. Apr. 24, 2019), ECF No. 99, available at https://www.justice.gov/atr/case-document/file/1157461/download; Notice of Motion and Motion for Preliminary Approval of Settlement, *UFCW & Employers Benefit Trust v. Sutter Health* and *People of the State of California ex rel. Xavier Becerra v. Sutter Health*, Case No. CGC 14-538451 (Cal. App. Dep't Super. Ct. Feb. 25, 2020), available at https://oag.ca.gov/system/files/attachments/press-docs/2019-12-19%20-%20Notice%20of%20Motion%20and%20Motion%20for%20Preliminary%20Settlement%20Approval%20with%20Exhibits%20-%20REDACTED.pdf.

7 See Notice of Motion and Motion for Preliminary Approval of Settlement at 16, *UFCW & Employers Benefit Trust v. Sutter Health* and *People of the State of California ex rel. Xavier Becerra v. Sutter Health*.

8 Competitive Impact Statement at 14, *United States v. Charlotte-Mecklenburg Hospital Authority*, No. 3:16-cv-00311-RJC-DCK (W.D.N.C. Dec. 04, 2018), ECF No. 89, available at https://www.justice.gov/atr/case-document/file/1117111/download.

9 See [Proposed] Final Judgment and Order Pursuant to Stipulation at 15, *UFCW & Employers Benefit Trust v. Sutter Health* and *People of the State of California ex rel. Xavier Becerra v. Sutter Health*.

10 *Id.* at 14.

IV. VOLUME AND LOYALTY DISCOUNTS

Antitrust law recognizes that discounts, including discounts for higher volume, often benefit consumers. Lower prices, after all, is one of the main benefits that competition produces. But economists agree that loyalty discounts or "non-linear pricing" (pricing that does not charge a constant price per unit sold), when used by companies with market power, may foreclose competition and substantially lessen competition.[11] One situation where discounts may be anticompetitive is where the discount results in the price of units sold being below an appropriate measure of cost.

For example, in *United Regional*, the Justice Department challenged a hospital's use of a discounting mechanism that it alleged resulted in below cost pricing.[12] According to the DOJ, United Regional, the largest hospital in Wichita Falls, Texas, offered insurers contracts with substantially larger discounts if United Regional was the only local hospital in the insurer's network. The DOJ explained that the discounts violated the antitrust laws in part because they failed an appropriate "price-cost" test.[13] The DOJ used this test to compare the entire discount offered in United Regional's contracts to the contestable volume and determined that the resulting price was below any plausible measure of United Regional's incremental costs. This pricing mechanism effectively prevented equally or more efficient hospitals from attracting additional consumers.

A healthcare statement on pricing discounts: Over the past 25 years, antitrust scholarship and case law have progressed significantly in understanding when pricing discounts are potentially harmful or pro-competitive/competitively neutral.[14] Building on these developments, advice from the antitrust agencies concerning pricing programs would be beneficial for several reasons. First, identifying pricing programs most likely to generate antitrust concerns would likely deter businesses from pursuing those types of pricing strategies. Second, creating an antitrust safety zone would encourage healthcare companies to engage in the more conservative pricing programs identified in the safe harbor. For example, the agencies could explain the parameters under which linear discounts are not likely to be challenged. Third, additional guidance would enable companies to better understand at the time that they are offering a discount, rather than years later when the conduct might be challenged, whether the discount likely would be considered to be anticompetitive.

V. COMPETITOR COLLABORATIONS DURING A HEALTHCARE CRISIS

The devasting impact of COVID-19 has presented a tremendous challenge to the United States and the world. Early into this crisis, the antitrust agencies, other government actors, and healthcare companies realized that they would need to work together to more effectively address its challenges.[15] In March 2020, the Justice Department and the FTC responded by announcing, that to help enable competitors to provide needed goods and services, the agencies would respond to all COVID-19-related business review and advisory opinion requests within seven days of receiving all necessary information. The DOJ received four healthcare related requests, to which it quickly responded by issuing positive business review letters.[16]

A healthcare statement concerning competitor collaborations to address a healthcare crisis: With the experience of how competitors and government agencies can work together to better address a catastrophic emergency, the DOJ and FTC should draw out what lessons have been learned and create guidance in a new healthcare statement for reacting to future healthcare crises. This statement should define and discuss what conduct is permissible to respond to a national emergency under existing antitrust laws, the National Cooperative Research and Production Act, the Defense Production Act, and the Pandemic and All-Hazards Preparedness Act.

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11 See, e.g. Willard K. Tom et al., *Anticompetitive Aspects of Market-Share Discounts and Other Incentives to Exclusive Dealing*, 67 Antitrust L.J. 615, 627 (2000).

12 Competitive Impact Statement, *United States v. United Regional Health Care System*, Civ. No. 7:11-cv-00030 (N.D. Tex. Feb. 25, 2011), ECF No. 4, available at https://www.justice.gov/atr/case-document/file/514151/download.

13 *Id.* at 13-16.

14 See, e.g. *Cascade Health Solutions v. PeaceHealth*, 515 F.3d 883 (9th Cir. 2008).

15 Dep't of Justice & Federal Trade Comm'n, *Joint Antitrust Statement Regarding COVID-19* (Mar. 2020) available at https://www.ftc.gov/system/files/documents/public_statements/1569593/statement_on_coronavirus_ftc-doj-3-24-20.pdf (stating that the spread of COVID-19 "will require unprecedented cooperation between federal, state, and local governments and among private businesses to protect Americans' health and safety").

16 See Response to Baxalta US Inc., Emergent BioSolutions Inc., Grifols Therapeutics LLC, and CSL Plasma Inc., (Jan. 12, 2021); Response to Eli Lilly & Co., AbCellera Biologics, Amgen, AstraZeneca, Genentech, and GSK (Jul. 23, 2020); Response to AmerisourceBergen Corp. (Apr. 20, 2020); Response to McKesson Corp., Owens & Minor, Inc., Cardinal Health, Inc., Medline Indus., Ind., and Henry Schein, Inc. (Apr. 4, 2020); all available at https://www.justice.gov/atr/business-review-letters-and-request-letters.

VI. A PROCESS WORTH UNDERTAKING

For many years, the Justice Department's 1984 Non-Horizontal Merger Guidelines Statements were largely ignored because legal and economic developments had made the statements a relic. Last year's Vertical Merger Guidelines surely were a tremendous improvement over the 1984 Statements. Updating the Healthcare Guidelines through critical examination and thoughtful revision would likely create similar significant improvements. As healthcare is fundamental to the well-being of all Americans, the potential for greater competition, innovation, and consumer welfare would make the process well worth the effort.

STACKING THE BLOCKS: VERTICAL INTEGRATION AND ANTITRUST IN THE HEALTHCARE INDUSTRY

BY CORY CAPPS, NITIN DUA, TETYANA SHVYDKO & ZENON ZABINSKI[1]


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In a well-functioning market, firms seek to profit by producing, as efficiently as possible, goods or services that customers value. This often entails firms pursuing not just technological but also organizational innovation, including pursuit of the most effective extent of vertical integration. Through the choices of end-customers, market competition will then select organizational forms that deliver the greatest value to customers. This may result in a single organizational form or may sustain a variety of organizational forms that compete with one another. For example, Apple's integrated iPhone and iOS compete in a paired fashion against the Android operating system and a variety of mobile device manufacturers. By the same token, within healthcare, Kaiser is a vertically integrated health insurer-provider organization that competes with the non-integrated offerings of insurers that largely rely on arms-length contractual agreements with providers. The efficacy of market competition at selecting organizational forms that deliver value to customers depends on at least two conditions. First, there must be sufficient competition throughout the value chain to spur firms to compete vigorously. Second, firms' paths to greater profitability must coincide with delivering greater value to customers. The first condition highlights the role for antitrust policy. The second highlights the need for an institutional and regulatory environment that aligns firm incentives with consumer welfare.

For many decades, the U.S. healthcare industry mostly consisted of a diversity of unintegrated physicians, hospitals, and insurers. Over the last decade or so, vertical consolidations involving insurers as well as providers have brought greater attention to the effects of vertical integration on the cost and quality of healthcare. The 2020 Department of Justice ("DOJ") and Federal Trade Commission ("FTC") *Vertical Merger Guidelines* ("VMG") provide a framework for assessing potential antitrust concerns that is generally applicable across industries and types of vertical transactions. Antitrust analysis of mergers, whether horizontal, vertical, or both, must take into account the specific details of the industry and the regulatory framework that governs the incentives of industry participants. The healthcare industry, for example, has a number of features that complicate antitrust analysis. Because of insurance, most healthcare end-customers do not pay the full prices of the healthcare services they receive. Most end-customers also do not possess the information required to choose the care they need and instead rely on their physician as an agent. These features create incentives that vary throughout the supply chain, from hospitals on one end, to payers on the other, with physicians in the middle. Because the healthcare value chain has more than two levels, a vertical merger can take many forms — including different pairwise mergers of entities at distinct levels of the value chain or an already partially integrated entity moving into a new level of the value chain. Mergers yielding different vertical configurations may generate distinct competitive effects and efficiencies.

In this article, we discuss different forms of vertical integration among insurers, hospitals, and physicians and the different antitrust considerations and analyses they are likely to raise. We focus on recent examples of vertical integration that have drawn scrutiny from antitrust enforcement agencies and other interested parties: hospital-physician integration, insurer-physician integration, and full vertical integration of all three. We summarize potential efficiencies and concerns associated with each type of integration and relevant empirical research. While outside the scope of this article, similar considerations arise in integration among other branches of the healthcare industry, such as among insurers, pharmacy benefit managers, and pharmacies (e.g. the recent mergers between Aetna and CVS and between Cigna and Express Scripts).

I. HOSPITAL-PHYSICIAN INTEGRATION

Hospital acquisitions of physician practices have grown steadily over the last two decades. As of 2018, 44 percent of physicians were employed by hospitals (up from 26 percent in 2012) and 31 percent of physician practices were owned by hospitals (up from 14 percent from in 2012).[2] In response to this and other market trends, in January 2021, the FTC announced that it had required six insurers to submit claims data spanning 2015–2020 so the agency could study the effects of healthcare provider consolidation.[3] The study aims to develop evidence on the effects of consolidation among healthcare providers — physicians, hospitals, and outpatient facilities — on the "proper functioning of healthcare markets." The FTC will review horizontal mergers among physician practices and among facilities, as well as vertical mergers between physician practices and healthcare facilities.[4] This is especially notable because, while there have been many hospital acquisitions of physician practices in recent years, few have been challenged or even investigated by the FTC. Most such acquisitions fall below the HSR thresholds for mandatory reporting, which likely explains this lack of systematic antitrust enforcement in this area.[5] One partial exception is *St. Luke's-Saltzer*, which the FTC successfully challenged retroactively, *on horizontal grounds*, due to overlap between the parties' adult primary care physician ("PCP") practices. St. Luke's main rival, St. Alphonsus Medical Center, challenged that same merger under a vertical theory of harm by which the acquired PCPs would have had an increased incentive to refer patients to the acquiring hospital system, thereby foreclosing rival hospitals such as St. Alphonsus from patient referrals. The FTC did not join in the vertical portion of the complaint, and the court concluded that it did not need to consider vertical issues to order a divestiture.[6]

Physician integration with hospital systems has the potential to generate benefits. It may promote greater care coordination. For example, integration of electronic health records between physicians and hospitals could facilitate more efficient exchange of patient clinical data. More generally, when one level of the value chain can benefit from coordination with other levels of the value chain, especially if tacit knowledge is important and complete contracts cannot be written, combining entities within a single firm through vertical integration may outperform arms-length interactions.[7] Finally, since physician and hospital services are complements, rather than substitutes, economic theory predicts that a firm selling both would have an incentive to lower prices.

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2 Physicians Advocacy Institute, "Updated Physician Practice Acquisition Study: National and Regional Changes in Physician Employment 2012–2018," Feb. 2019, http://www.physiciansadvocacyinstitute.org/Portals/0/assets/docs/021919-Avalere-PAI-Physician-Employment-Trends-Study-2018-Update.pdf?ver=2019-02-19-162735-117. See also Michael F. Furukawa et al., "Consolidation of Providers into Health Systems Increased Substantially, 2016–18," *Health Affairs* 39, no. 8 (2020): 1321–1325, https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.00017; David M. Cutler & Fiona Scott Morton, "Hospitals, Market Share, and Consolidation," *JAMA* 310, no. 18 (2013), https://scholar.harvard.edu/files/cutler/files/jsc130008_hospitals_market_share_and_consolidation.pdf.

3 FTC, "FTC to Study the Impact of Physician Group and Healthcare Facility Mergers," Jan. 14, 2021, https://www.ftc.gov/news-events/press-releases/2021/01/ftc-study-impact-physician-group-healthcare-facility-mergers.

4 *Id.* For a discussion of the vertical linkage between hospitals and physicians, see Thomas Greaney and Douglass Ross, "Navigating Through the Fog of Vertical Merger Law: A Guide to Counselling Hospital-Physician Consolidation under the Clayton Act," *Washington Law Review* 91, no. 1 (2016): 206–207, https://digitalcommons.law.uw.edu/cgi/viewcontent.cgi?article=4947&context=wlr.

5 Cory Capps, David Dranove & Chris Ody, "Physician Practice Consolidation Driven by Small Acquisitions, so Antitrust Agencies Have Few Tools to Intervene," *Health Affairs* 36, no. 9 (2017): 1556–1563. The FTC has investigated hospital acquisitions of physician groups, but those have been horizontal merger investigations that came about because a hospital system with an existing physician group had acquired or was seeking to acquire one or more competing physician practices — that is, these were horizontal cases and the vertical aspect was largely incidental.

See FTC, "FTC Bureau of Competition Director Issues Statement on Providence Health & Services' Abandonment of Its Plan to Acquire Spokane Cardiology and Heart Clinics Northwest," Press release, Apr. 8, 2011, https://www.ftc.gov/news-events/press-releases/2011/04/ftc-bureau-competition-director-issues-statement-providence; FTC, "FTC Order Will Restore Competition for Adult Cardiology Services in Reno, Nevada," Press release, Aug. 6, 2012, https://www.ftc.gov/news-events/press-releases/2012/08/ftc-order-will-restore-competition-adult-cardiology-services-reno; FTC, "Healthcare Provider in St. Cloud, MN Settles FTC Charges That Its Acquisition of Rival Provider Would Likely Lessen Competition for Certain Physician Services," Press release, Oct. 6, 2016, https://www.ftc.gov/news-events/press-releases/2016/10/healthcare-provider-st-cloud-mn-settles-ftc-charges-its; FTC, "After Healthcare System Sanford Health Abandons Acquisition of North Dakota Healthcare Provider Mid Dakota Clinic, FTC Dismisses Case from Administrative Trial Process," Press release, July 9, 2019, https://www.ftc.gov/news-events/press-releases/2019/07/after-healthcare-system-sanford-health-abandons-acquisition-north.

6 *Saint Alphonsus Med. Ctr.-Nampa Inc. v. St. Luke's Health Sys.*, Findings of Fact and Conclusions of Law, No. 1:12-CV-00560-BLW (D. Idaho, filed Jan. 24, 2014), https://www.ftc.gov/system/files/documents/cases/140124stlukesfindings.pdf, 49–50.

7 Oliver Williamson, "The Vertical Integration of Production: Market Failure Considerations," *American Economic Review Papers & Proceedings* 61, no. 2 (1971): 112–123. Williamson argued that "In more numerous respects than are commonly appreciated, the substitution of internal organization for market exchange is attractive less on account of technological economies associated with production but because of what may be referred to broadly as 'transactional failures' in the operation of markets for intermediate good."

Economic research to date, however, indicates that integration between hospitals and physician groups more commonly results in higher prices and spending for hospital and physician services.[8] Capps, Dranove & Ody (2018) find evidence of post-acquisition price increases, about half of which are attributable to exploitation of payment rules that reimburse services performed in a hospital setting at higher rates than when the same or similar services are provided outside the hospital, such as in a physician office.[9] Carlin, Feldman & Dowd (2016) study the acquisition of three multispecialty clinic systems in Minnesota and find similar results.[10] Neprash et al. (2015) find that regions with greater increases in hospital-physician integration experienced significantly greater increases in outpatient prices and spending.[11] Robinson & Miller (2014) find that hospital ownership of physician groups is associated with significantly higher total expenditures per patient compared with physician-owned organizations, and that the increase is larger for hospital systems than local hospitals.[12]

Hospital-physician integration could lead to higher prices and spending through several mechanisms. First, as discussed above, systems may be able to exploit site-of-service payment rules to bill services at a higher rate.[13] An open question is whether obtaining greater revenue by exploiting payment rules constitutes an exercise of market power. Consider a hospital acquisition of a physician practice that allows the new entity to bill some of the practice's services at the hospital's higher rates. In the first instance, this may simply reflect the new entity taking advantage of a contractual loophole. But if the increase persists into new, renegotiated contracts, then it more likely reflects an exercise of market power.[14] Even if changes in prices due to site-of-service rules do not reflect market power, they could potentially be counted against any efficiencies claimed by the parties.

Second, hospital systems may be able to negotiate higher prices for physician services than the practices are able to themselves. The acquiring hospital systems may possess greater bargaining skill than the physician groups.[15] Alternatively, if a hospital with market power were setting prices below the profit-maximizing level (e.g. to avoid regulatory oversight, bad publicity, or challenges to its nonprofit status), it could leverage that pre-existing market power to raise the prices of acquired physician groups through tying.[16] It is not clear, however, that either mechanism would constitute an antitrust violation, even if the result is higher prices to consumers, since the cause is not lessened competition among firms.

While the joint pricing of complements promotes lower prices in general, Peters (2014) identifies a mechanism through which tying negotiations for physician and hospital services could raise prices.[17] He shows that upstream suppliers that are not substitutes for one another (e.g., a hospital and physician group) can enhance their bargaining leverage with downstream firms (e.g., insurers) by bargaining jointly if they are able

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8 See also, Jaime S. King & Erin C. Fuse Brown, "The Double-Edged Sword of Health Care Integration: Consolidation and Cost Control," *Indiana Law Journal*. 92, no. 1 (2016): 55–112, https://www.repository.law.indiana.edu/cgi/viewcontent.cgi?article=11232&context=ilj.

9 Cory Capps, David Dranove & Christopher Ody, "The Effect of Hospital Acquisitions of Physician Practices on Prices and Spending," *Journal of Health Economics* 59 (2018): 139–152.

10 Caroline S. Carlin, Roger Feldman & Bryan Dowd, "The Impact of Hospital Acquisition of Physician Practices on Referral Patterns," *Health Economics* 25 (2016): 439–454.

11 Hannah T. Neprash et al., "Association of Financial Integration between Physicians and Hospitals with Commercial Health Care Prices," *JAMA Internal Medicine* 175, no. 12 (2015): 1932–1939, https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2463591.

12 James C. Robinson & Kelly Miller, "Total Expenditures per Patient in Hospital-Owned and Physician-Owned Physician Organizations in California," *JAMA* 312, no. 16 (2014): 1663–1669, https://jamanetwork.com/journals/jama/fullarticle/1917439.

13 Greaney & Ross, *supra* note 4, 227–237.

14 In the *St. Luke's/Saltzer* matter, the parties' business documents projected that St. Luke's would be able to increase revenue by billing certain ancillary services as "hospital-based" rather than "Saltzer-based." The FTC's expert testified that St. Luke's increased market power over physician services would "give St. Luke's the ability to make these higher rates [from facility-based billing] 'stick' in future contract negotiations." Findings of Fact and Conclusions of Law, https://www.ftc.gov/system/files/documents/cases/140124stlukesfindings.pdf, ¶¶ 121–129.

Although the district court agreed, the Ninth Circuit did not, because "the district court made no finding about St. Luke's market power in the ancillary services [i.e., the services subject to hospital-based billing] market." Opinion, *Saint Alphonsus Med. Ctr.-Nampa Inc. v. St. Luke's Health Sys., Ltd.*, 778 F.3d 775 (9th Cir. 2015), https://www.ftc.gov/system/files/documents/cases/150210stlukeopinion.pdf, 19–20. This appears to misapprehend the FTC's point, which was that increased market power in a *physician services market* (not an ancillary services market) could allow the combined entity to increase the effective price of ancillary services through hospital-based billing. From an economic perspective, focusing on changes in the total amount of payments for a given volume of services is more logical than focusing on the specific payment mechanism.

15 Matthew S. Lewis & Kevin E. Pflum, "Hospital Systems and Bargaining Power Evidence from Out-of-Network Market Acquisitions," *RAND Journal of Economics* 48, no. 3 (2017): 579–610.

16 Gregory Vistnes & Yianis Sarafidis, "Cross-Market Hospital Mergers: A Holistic Approach," *Antitrust Law Journal* 79, no. 1 (2013): 253–293, n. 69.

17 Craig Peters, "Bargaining Power and the Effects of Joint Negotiation," (2014), https://www.justice.gov/sites/default/files/atr/legacy/2014/09/26/308877.pdf. See also, Esther Gal-Or, "The Profitability of Vertical Mergers between Hospitals and Physician Practices," *Journal of Health Economics* 18 (1999): 623–654.

to recapture some lost volume through other downstream intermediaries (e.g., other commercial insurers) in the event of a disagreement.[18] The logic is as follows. When an insurer reaches an agreement with one provider, that raises the value of the insurer's network and attracts additional enrollment. This increases the value to other providers in the same geography of being in that insurer's network, since it gives them access to more enrollees. Joint bargaining by providers, even if they are not themselves substitutes for patients, internalizes this effect, allowing the joint entity to obtain higher prices in negotiations. While this is not a strictly vertical effect, since the merging upstream suppliers need not be vertically related, it would constitute an enhancement of bargaining leverage by the merging parties that could result in price increases.[19]

Finally, prices and spending may increase, or decrease, due to potential changes in physician referral patterns. The acquired physician group may internalize the acquiring hospital systems' profits and increase referrals to it.[20] This can lead to higher spending if the hospital system is more expensive than its rivals or if utilization of hospital services increases. This may also lead to greater market power for the acquiring hospital through foreclosure effects.[21] In particular, physician referrals and services are inputs into hospital services, and the acquiring hospital may weaken competition if the acquired physician practice denies either referrals or services to rival hospitals. Such foreclosure could be harmful even if the acquiring hospital does not have higher prices or lower quality services compared to alternatives.[22]

18 Peters also cites anecdotal evidence that industry participants believe that hospitals and physicians bargaining together could enhance their market power: "Based on interviews with representatives of hospitals, physician groups, health plans, and other health industry participants, Berenson et al. (2010) conclude that 'one clear goal of an alliance between hospitals and physicians is to improve negotiating clout for both.' Similarly, Berenson et al. (2012) report that 'Respondents from health plans and provider organizations agreed that hospitals negotiating on behalf of their employed physicians are able to obtain higher prices for physician services than can be achieved by independent physician practices. Some plan respondents reported that having a large employed physician contingent also increased hospital leverage over rates for hospital services.'" *Id.* 2.

19 In this sense, this constitutes a "cross-market" effect across apparently distinct product markets rather than geographic markets, as is more commonly considered in mergers among hospitals with non-overlapping service areas. Vistnes & Sarafidis, *supra* note 16; Leemore Dafny, Kate Ho, & Robin S. 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.

20 Baker, Bundorf, & Kessler (2014) found empirical evidence that hospital acquisition of physician groups affects patient referral patterns. Specifically, the acquired group's patients are more likely to choose the acquiring hospital for inpatient services after the merger, including when the hospital is high-cost or low-quality. Laurence C. Baker, M. Kate Bundorf & Daniel P. Kessler, "Vertical Integration: Hospital Ownership of Physician Practices Is Associated with Higher Prices and Spending," *Health Affairs* 33 (2014): 756–763.

21 Recent enforcement actions by the DOJ and FTC have focused on theories of vertical harm through foreclosure-type effects. Complaint, *United States v. AT&T Inc., DirectTV Group Holdings, LLC, and Time Warner Inc.*, No. 1:17-cv02511 (D.D.C. Nov. 20, 2017), https://www.justice.gov/atr/case-document/file/1012916/download; Complaint, *In re UnitedHealth Group Incorporated et al.*, FTC Docket No. C-4677 (Jun. 19, 2019), https://www.ftc.gov/system/files/documents/cases/181_0057_c4677_united_davita_complaint_6-19-19.pdf; Complaint, *In re Illumina, Inc., a corporation and GRAIL, Inc., a corporation*, FTC Docket No. 9401 (Mar. 13, 2021), https://www.ftc.gov/system/files/documents/cases/redacted_administrative_part_3_complaint_redacted.pdf.

22 Martin Gaynor, "Is Vertical Integration Anticompetitive? Definitely Maybe (But That's Not Final)," (2005), http://www.andrew.cmu.edu/user/mgaynor/Assets/Gaynor%20JHE%20VI%20Editorial%201.pdf. "Since physicians and hospitals complement [each] other in producing health care treatments, it is possible that integration could have a foreclosure effect. Integration could foreclose rival hospitals from access to doctor services, or it could foreclose rival physician practices from hospital services. This can increase market power."

This was, essentially, the private plaintiffs' theory of harm in the FTC's challenge to the *St. Luke's/Saltzer* transaction. See Greaney & Ross, *supra* note 4, 210–211.

II. INSURER-PHYSICIAN INTEGRATION

There are other forms of vertical integration beyond just hospitals and physicians, such as joint ownership of pharmacies and insurers or of insurers and physician groups, either with or without hospitals. Examples of the latter include Kaiser, Geisinger, and efforts by traditional insurers to acquire physician groups. In the latter category, UnitedHealth Group (through its Optum subsidiary) has led the trend nationally, but insurers like Centene, Humana, and Anthem have also recently acquired or entered joint ventures with physician groups.[23] Insurer-physician integration itself is not new to the US healthcare system, and examples go back at least to the 1980s when insurers like Aetna, Cigna, and Humana employed physicians as part of their HMO offerings.[24] These entities did not survive over the long term, and most insurers eventually divested their physician practices. Recent instances of insurer-physician vertical integration may, at least in part, be spurred by a strategic need of insurers to defend against hospital-physician integration or to offer a more insurer-centric care delivery model.

Public records of antitrust investigations of insurer-physician vertical integration are limited, but at least one recent FTC case included a vertical theory of harm. In 2019, the FTC, citing both horizontal and vertical concerns, challenged UnitedHealth's $4.3 billion acquisition of DaVita Medical Group and required divestiture in Nevada.[25] In addition, the Colorado Attorney General challenged that same transaction in Colorado Springs on solely vertical grounds and ultimately obtained a set of conduct restrictions but no divestiture.[26] Two FTC commissioners, Rohit Chopra and Rebecca Slaughter, endorsed the vertical theory of harm but opted out of challenging the transaction in Colorado because of the state Attorney General's action.[27]

While federal and state action related to the United Health-DaVita merger sheds some light on how antitrust agencies evaluate competitive effects in insurer-physician transactions, empirical literature examining the impact of such transactions on competition and consumer welfare is scant. This limits confidence in predicting market outcomes from insurer-physician integration. Economic theory and past industry experience, however, do identify some potential competitive concerns and potential benefits.

When insurers and physicians are integrated, incentives differ from those at issue in hospital-physician integration. In the largely fee-for-service model that still predominates, hospitals and physicians generally face similar incentives: for both, greater service volume generally implies greater revenues and profits. Insurers, however, benefit from lowering healthcare costs and spending on healthcare services received by enrollees: reductions in healthcare spending will increase insurer profits and can lower enrollee costs, including premiums.[28] Because physicians serve as agents of end-consumers and guide their utilization of healthcare services, acquisition of primary care practices by insurers has significant potential to shift incentives towards reducing healthcare spending. A value-based payment system has long been advanced as a solution to perennially increasing national healthcare costs, though fee-for-service payment remains predominant.[29] Acquiring physician practices outright

23 Shelby Livingston, "Reigniting the Physicians Arms Race, Insurers Are Buying Practices," *Modern Healthcare*, June 2, 2018, https://www.modernhealthcare.com/article/20180602/NEWS/180609985/reigniting-the-physicians-arms-race-insurers-are-buying-practices; Anna W. Mathews, "Physicians, Hospitals Meet Their New Competitor: Insurer-Owned Clinics," *Wall Street Journal*, Feb. 23, 2020; Paige Minemyer, "Humana, Private Equity Firm Team Up to Open Medicare-centric Primary Care Clinics," *Fierce Healthcare*, Feb. 3, 2020, https://www.fiercehealthcare.com/payer/humana-private-equity-firm-team-up-to-open-medicare-centric-primary-care-clinics; Shelby Livingston, "Blue Shield of Calif. Company Altais to Acquire Large Physician Group," *Modern Healthcare*, Apr. 10, 2020, https://www.modernhealthcare.com/mergers-acquisitions/blue-shield-calif-company-altais-acquire-large-physician-group.

24 Lawton R. Burns, Jeff C. Goldsmith & Aditi Sen, "Horizontal and Vertical Integration of Physicians: A Tale of Two Tails," *Advances in Health Care Management* 15 (2013): 39–117, https://www.semanticscholar.org/paper/Horizontal-and-vertical-integration-of-physicians%3A-Burns-Goldsmith/b547ed1ba669bb64ab6956513ab43f074c5c2b7e.

25 FTC, "FTC Imposes Conditions on UnitedHealth Group's Proposed Acquisition of DaVita Medical Group," Press release, June 19, 2019, https://www.ftc.gov/news-events/press-releases/2019/06/ftc-imposes-conditions-unitedhealth-groups-proposed-acquisition.

26 Complaint, *State of Colorado ex rel. Philip J. Weiser, Attorney General v UnitedHealth Group Inc. and DaVita Inc.* (D. Colorado El Paso Cty., filed June 19, 2019), https://coag.gov/app/uploads/2019/06/2019-06-19-08-00-13-United-DaVita-Complaint-final.pdf; Consent Judgment, *State of Colorado ex rel. Philip J. Weiser, Attorney General v UnitedHealth Group Inc. and DaVita Inc.* (D. Colorado El Paso Cty, filed June 19. 2019), https://coag.gov/app/uploads/2019/06/2019-06-19-08-04-30-UHC-DaVita-CO-consent-judgment-final.pdf.

27 "We believe the evidence uncovered by Commission staff demonstrates that the vertical merger of United's health insurance and [DaVita Medical Group]'s healthcare services businesses would likely result in actionable harm to competition in Colorado. We were prepared to challenge the transaction in court, given the likelihood of harm. . . . Fortunately, the Attorney General of Colorado has taken action in an effort to address some of the harmful effects of the merger in a separate action." Statement of Commissioners Rohit Chopra & Rebecca Slaughter in the Matter of UnitedHealth Group and DaVita, Commission File No. 181-0057, June 19, 2019, https://www.ftc.gov/system/files/documents/public_statements/1529359/1810057uniteddavitachopraslaughterstatement.pdf.

28 For an insurer, lower spending on healthcare services acts as a decrease in marginal costs and can increase profit margins holding premiums fixed or result in greater customer volume for the insurer (and savings to customers) if some of the reduced spending is passed through in the form of lower premiums.

29 "In 2020, as in 2018, almost all physicians (97%) relied on FFS and/or salary for their compensation and 36% also drew compensation from value-based payments." Mark J. Bethke et al., "Equipping Physicians for Value-Based Care: What Needs to Change in Care Models, Compensation, and Decision-Making Tools?" Deloitte Insights, Oct. 14, 2020, https://www2.deloitte.com/us/en/insights/industry/health-care/physicians-guide-value-based-care-trends.html.

may provide an insurer with the control and ability to implement value-based care more easily than can be achieved via contracts and looser forms of affiliation.

Vertical integration with physicians can, in theory, make it easier for insurers and physicians to efficiently coordinate, determine mutually agreeable financial incentives that reward physicians for improving overall health outcomes, and steer enrollees to lower-cost providers. In principle, more elaborate contracts between non-integrated insurers and physicians could achieve similar outcomes. But in practice these goals, which were promoted by the 2010 Affordable Care Act, have largely remained elusive, though there is some evidence of progress.[30] One likely impediment is the challenge of writing complex, complete contracts that reliably define quality of care and allow for measurement of quality in a way that is transparent and that both providers and insurers agree is appropriate.[31] Insurer-physician integration is one potential solution to this problem.

Insurer-physician integration, however, is not free of the competitive concerns associated with vertical mergers more generally. An insurer that acquires a physician group could have the incentive and ability to disadvantage rival insurers by either terminating the group's contracts with those rivals or seeking higher prices for the group's services.[32] The FTC cited this concern in its complaint in the United-DaVita merger.[33] Because this incentive rests upon, among other factors, the integrated insurer gaining enrollees when its integrated physician group terminates its contract with a rival insurer, this class of concern is more likely to be salient for PCPs who, in contrast to most specialists, often have ongoing relationships with their patients. That is, a patient is more likely, though not at all certain, to change her insurer to retain access to her PCP, whom she sees regularly, than to retain access to a specialist she does not.[34]

Several factors act in the opposite direction of this strategic incentive. Terminating rival insurers would reduce the physician group's volume and profits (some patients covered by a rival insurer may change insurers to stay with their physician group, but others may not, reducing the payoff to the vertically integrated insurer). Favoring an owned physician group could imperil an insurer's relationship with non-owned physician groups that the insurer may need in order to offer an attractive product. Rival insurers may respond with their own strategic moves, such as acquiring, partnering with, or promoting rival provider organizations. In addition, the vertically integrated insurer-provider will have an economic incentive to lower insurance premiums because integration makes gaining additional enrollees (e.g., by lowering premiums) more profitable: each additional enrollee brings both an insurer-level and a provider-level profit margin, whereas without integration the insurer gains only the

30 U.S. Department of Health and Human Services, Office of the Inspector General, "Medicare Shared Savings Program Accountable Care Organizations Have Shown Potential for Reducing Spending and Improving Quality," Report in Brief, Aug. 2017, https://oig.hhs.gov/oei/reports/oei-02-15-00450.pdf; Michael E. Chernew, Patrick H. Conway & Austin B. Frakt,"Transforming Medicare's Payment Systems: Progress Shaped by the ACA," *Health Affairs* 39, no. 3 (2020): 413–420.

31 Under a volume-based fee-for-service system, a primary concern is that providers will render too great a volume of services, including low-value healthcare services — because that is what fee for service encourages. See, e.g. MedPAC, "Medicare Coverage Policy and Ase of Low-Value Care," Report to the Congress, June 2018, Ch. 10.

Conversely, if providers were compensated solely on the basis of low healthcare spending (e.g. a simple capitation payment), the concern would instead be that providers render too low a volume of services, imperiling the delivery of high-value healthcare services. This explains why value-based payment methods commonly embed a set of quality and performance standards for providers. But this necessarily increases the complexity and uncertainty of contracts with payers and providers. As one example, under the Medicare ACO program, CMS has adopted a relatively complicated system that requires providers to meet certain quality metrics to receive shared savings. CMS, "Medicare Shared Savings Program: Quality Measurement Methodology and Resources," May 2019, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/quality-measurement-methodology-and-resources.pdf.

32 Economic literature refers to the former as input foreclosure and the latter as raising rivals cost. William Rogerson, "A Vertical Merger in the Video Programming and Distribution Industry: Comcast-NBCU," in *The Antitrust Revolution*, 6th ed., ed. John Kwoka & Lawrence White, (Oxford: Oxford University Press, 2014), 534–575.

This is not the only possible effect, as rivals may respond strategically. For example, when the Pennsylvania insurer Highmark vertically integrated by acquiring a Pittsburgh hospital system, the leading hospital system in the area, UPMC (which also operated a health plan), responded by announcing that its providers would no longer provide in-network care to Highmark enrollees. That led to years of contentious negotiations between the two integrated entities and the state, culminating in the state filing a lawsuit against UPMC. Commonwealth of Pennsylvania, Office of Attorney General, "Restoring Fairness in Western Pennsylvania," n.d., https://www.attorneygeneral.gov/upmc/.

33 FTC, *supra* note 25 ("The proposed acquisition positions UnitedHealth Group to raise the costs of its [Managed care provider organization] MCPO services to rival Medicare Advantage insurers, or even withhold such services from these rivals.").

34 The strength of patient-physician relationships spans a range. Some women may also have loyalty to their OB/GYNs, and some patients may have relationships with cardiologists or orthopedists. In contrast, for most patients, relationships with surgeons or hospital-based physicians are likely to be minimal. This illustrates the point that evaluating vertical incentives, as with merger review in general, is case specific.

insurer-level profit margin.[35] Both incentives — to disadvantage rivals and to lower downstream prices — can co-exist in the same merger, and determining which is greater is case-specific and can be complicated.[36]

Other potential competitive concerns from vertical integration include a greater chance of coordination among sellers (e.g. if integration gives firms better insight into each other's costs and strategies), a decrease in the probability of new entry (e.g. if an integrated seller can withhold an important input from would-be entrants), and possible reduction in innovation.[37] These are general concerns that are not specific to vertical integration in the healthcare industry.

Perhaps due to the relative recency of such transactions, empirical research on healthcare outcomes associated with insurer-physician integration is lacking. One recent survey of empirical studies of vertical integration in various industries includes a summary of studies of vertical combinations in the healthcare and pharmaceutical industries. Consistent with the theoretical ambiguity described above, the empirical evidence is mixed: "Like studies of other industries, these articles report a variety of effects, ranging from increased patient spending to no change in health outcomes to improved drug development."[38] The FTC's recent retrospective initiative would likely yield data sufficient to also study insurer-physician combinations, although the agency did not highlight this topic among its stated goals.[39]

35 An equivalent way to characterize this incentive is that vertical integration removes the provider group's profit margin from the costs that the insurer considers when setting premiums. Generally, for a seller, the received price can be subdivided into marginal cost and incremental profit margin: $p = c + m$. When the insurer pays p to a provider group, the provider's profit margin m is a cost to that insurer. But if the insurer owns the physician group, m is not a cost but simply a shift of funds from one division to another. For this reason, economists commonly refer to this beneficial pricing incentive from vertical integration as elimination of double marginalization ("EDM") — the two margins, insurer and provider, become a single margin due to the elimination of the provider margin. The marginal cost term, c, includes, in addition to other costs, the opportunity cost to the provider group of supplying its services. The full extent to which an integrated insurer reduces premiums due to EDM also depends on the size of this opportunity cost after integration. If the additional enrollees whom the integrated insurer gains by reducing premiums come from rival insurers that rely on the provider group's services, then the integrated provider group incurs an opportunity cost in the form of a lost margin on sales to rivals. This post-integration opportunity cost will tend to reduce the size of EDM due to the vertical integration.

36 The net effect, under specific assumptions, will depend on a number of parameters, including, at least, upstream and downstream segment shares and incremental margins, diversion ratios among insurers, and consumer loyalty to physicians. William P. Rogerson, "Comment on the U.S. Department of Justice and the Federal Trade Commission Draft Vertical Merger Guidelines," Feb. 26, 2020, https://www.ftc.gov/system/files/attachments/798-draft-vertical-merger-guidelines/rogerson_verticalguidelines1_2.pdf. See also, Testimony of Cory S. Capps before the Senate Judiciary Committee, "Your Doctor/Pharmacist/Insurer Will See You Now: Competitive Implications of Vertical Consolidation in the Healthcare Industry," June 12, 2019, https://www.judiciary.senate.gov/imo/media/doc/Capps%20Testimony.pdf. Analysis of vertical merger incentives also needs to account for, among other things, potential strategic responses by rivals, which do not enter in the baseline calculations in Rogerson and similar approaches.

37 U.S. Department of Justice and Federal Trade Commission, "Vertical Merger Guidelines," June 30, 2020, https://www.ftc.gov/system/files/documents/reports/us-department-justice-federal-trade-commission-vertical-merger-guidelines/vertical_merger_guidelines_6-30-20.pdf ("VMG").

38 Marissa Beck & Fiona M. Scott Morton, "Evaluating the Evidence on Vertical Mergers," Dec. 31, 2020, SSRN https://ssrn.com/abstract=3554073. The authors caution against extrapolation of these results to other vertical transactions due to the "special structure" of the healthcare industry. See also, Margaret E. Slade, "Vertical Mergers: A Survey of Ex Post Evidence and Ex Ante Evaluation Methods," *Review of Industrial Organization* (2020), https://doi.org/10.1007/s11151-020-09795-7.

39 FTC, *supra* note 3.

III. HOSPITAL-INSURER-PHYSICIAN INTEGRATION

Stacking the major blocks of healthcare delivery — hospitals, physicians, and health plans — together in a single entity creates what we refer to as an Integrated Delivery Network ("IDN").[40] While there are successful and well-known examples of long-standing IDNs, such as Kaiser, Group Health of Puget Sound (now part of Kaiser), and Geisinger, even they have struggled to expand beyond their historical footprints. For example, Kaiser has tried to replicate its success in areas outside of California, such as the District of Columbia, Colorado, and Georgia, but has not achieved comparable market acceptance or growth.[41]

As we will describe, IDNs have significant theoretical benefits but with caveats. First, efforts to create IDNs may raise antitrust questions, particularly in the face of increased enforcement based on vertical theories of harm. Second, the empirical literature on the performance of IDNs does not so far find evidence that they consistently achieve their theoretical benefits. Even so, healthcare policy-makers continue to promote value-based finance and delivery models, such as accountable care organizations ("ACOs"), as a superior alternative to volume-based payment (i.e., fee-for-service).[42] Antitrust enforcers will have to evaluate such ventures on a case-by-case basis.

In theory, hospital-physician-insurer integration could realize any benefits of physician-insurer integration, any benefits of hospital-physician integration, and potentially more. For end consumers, IDNs can offer centralized functions under a single roof with more coordinated care and reduced administrative burden. Moreover, IDNs may allow for greater efficiency in healthcare delivery, better alignment of financial incentives, and greater ability to shift from fee-for-service models to value-based payment models. Against this, however, end consumers who enroll in an IDN-owned health plan will typically have a restricted choice of PCPs, specialists, and clinical facilities, either because of requirements to use IDN providers for most care or because of higher cost-sharing for selecting external providers.

It is natural for an IDN to orient around its own entities, and many do so; for instance, Kaiser physicians do not contract with non-Kaiser health plans and Geisinger Health Plan prefers but does not require that its enrollees receive routine care from Geisinger physicians. For an IDN, favoring its own entities will also mean disfavoring rival entities, which can be suspect under the VMG.[43] One effect of the VMG, whether intended or not, could be to slow the ability of IDNs to grow via acquisitions, particularly for IDNs that an antitrust agency deems to have market power at one or more levels of the value chain that they could leverage to disadvantage rivals.

Another potential competitive concern under the VMG is that IDN growth could increase entry barriers by requiring potential entrants to succeed at two or more levels in the value chain.[44] For example, an IDN that includes the leading provider system in a geography could have an incentive to prevent a rival insurer from entering and could make strategic use of its leading system to make entry more difficult. The would-be rival insurer may then need to enter at both the provider and insurer levels of the supply chain. That would be costlier and riskier, and therefore less likely to occur, all else equal. Hospital-physician integration without an insurance arm could raise similar concerns, but likely to a lesser extent.

While the theoretical benefits and potential antitrust issues surrounding IDNs are relatively clear, empirical literature that can inform antitrust policy is less developed. Part of the explanation seems to be a lack of robust public data on IDN performance, especially outside of Medicare

40 In the health services literature, different researchers may refer to hospital-physician, hospital-insurer, and hospital-insurer-physician entities as IDNs. In more recent usage, which we follow here, the term more commonly references integrated systems that include hospital, physician, and health insurance components.

41 Katherine Ho, "Barriers to Entry of a Vertically Integrated Health Insurer: An Analysis of Welfare and Entry Costs," *Journal of Economics and Management Strategy* 18, no. 2 (2009): 487–545. Likewise, Geisinger remains concentrated in central Pennsylvania; Group Health remains concentrated in the greater Seattle Area; and Dean Clinic remains concentrated in Wisconsin.

42 An ACO brings together doctors, hospitals, and other providers in order to bear financial risk for the cost and quality of care for a population of patients. The ACO can bear risk by also including a health plan (i.e. by being an IDN) or by accepting global capitation or some lesser form of two-sided risk. Either way, an ACO can bring providers together through outright vertical integration, meaning joint ownership; or an ACO can bring otherwise independent providers together through contractual agreements. See, e.g. CMS, "ACO Providers and Suppliers," n.d., https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/for-providers (showing ACO models including "ACO professionals in group practice arrangements," "Partnerships or joint venture arrangements between hospitals and ACO professionals," and "Hospitals employing ACO professionals").

43 VMG, § 4 ("A vertical merger may diminish competition between one merging firm and rivals that trade with, or could trade with, the other merging firm" and "A vertical merger may diminish competition by allowing the merged firm to profitably use its control of the related product to weaken or remove the competitive constraint from one or more of its actual or potential rivals in the relevant market.").

44 VMG, § 4, "Example 4: Creating the need for two-level entry."

ACOs.[45] The literature that does exist paints a mixed picture that, so far, provides a less-than-optimistic view of IDNs' ability to systematically deliver on the promise of cost-effective, high-quality healthcare.

In a 2015 report commissioned by the National Academy of Social Insurance ("NASI"), Jeff Goldsmith and colleagues surveyed the existing literature on IDNs and conducted case studies of 15 "nationally prominent IDNs that are dominant actors in their respective metropolitan and regional hospital markets."[46] Of the fifteen, eight operate health plans, two bear substantial two-sided risk, three are exploring establishing a health plan, and two are not bearing significant risk (thus, 10 to 13 of the studied systems are IDNs as we use the term).[47]

Bearing more risk should, all else equal, strengthen an IDN's incentive to control healthcare costs, and the scale and sophistication of IDNs should give them greater ability to manage care to achieve that goal.[48] However, the authors reach a pessimistic conclusion: "Despite more than 30 years of public policy advocacy on behalf of IDN formation, there is scant evidence in the literature either of measurable societal benefits from IDNs or of any comparative advantage accruing to providers themselves from forming IDNs. We have similarly found no such evidence in our analysis of 15 IDNs."[49]

The authors base that conclusion on several findings. Risk bearing and profitability are not related for IDNs.[50] Based on the flagship hospitals in each of the IDNs, bearing greater risk was also not associated with lower case mix-adjusted costs of care for Medicare patients.[51] Among IDNs that bear risk, flagship hospitals were on average 21 percent more expensive than their most comparable in-market competitor.[52] And flagship hospitals within IDNs performed no differently than their competitors with respect to quality and safety scores, consumer satisfaction, or Leapfrog ratings.[53]

Overall, the NASI survey provides no basis to presume that horizontal or vertical expansions by IDNs, or mergers and acquisitions that move a healthcare system closer towards being an IDN, will increase efficiency.[54] Instead, merging parties will have to substantiate their claims of benefits. But this is no different than the status quo in which merging parties bear the burden of establishing efficiency claims.[55]

Although researchers generally do not have access to detailed data on the structure and performance of IDNs, past performance could prove relevant in merger analyses.[56] Most IDNs and even aspiring IDNs are large systems that became so through a combination of organic growth and acquisitions. That growth is likely to have created a track record that, for many transactions, can be used to test an agency's theories

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45 CMS does make Medicare ACO performance publicly available. See, e.g. CMS, "Medicare Shared Savings Program: Publicly Available ACO Data and ACO Performance Data Sources Maintained by CMS," updated January 2021, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/MSSP-ACO-data.pdf.

46 Jeff Goldsmith et al., "Integrated Delivery Networks: In Search of Benefits and Market Effects," National Academy of Social Insurance, February 2015, https://www.nasi.org/sites/default/files/research/Integrated_Delivery_Networks_In_Search_of_Benefits_and_Market_Effects.pdf.

47 Examples of the 15 studied systems include Advocate Health Care in Chicago, Geisinger Health System in Central Pennsylvania, Intermountain Healthcare in Utah and Idaho, Penn Medicine in Philadelphia, and UPMC in Western Pennsylvania. They do not examine Kaiser. *Id.* 17–19, 23.

48 They authors describe the theoretical case for IDNs as follows: "Under claimed societal benefits, the principal ones are providing better coordinated care leading to improved quality and lower cost. These improvements are said to derive from eliminating duplicative tests and reducing unnecessary care, as well as coordinating care across the continuum . . . Joining these activities with the assumption of insurance risk, IDNs are believed to be able to pare down the volume incentives inherent in fee-for-service medicine . . ." *Id.* 1–2, 7–16.

49 *Id.* 3.

50 *Id.* 23–24.

51 *Id.* 24, 33.

52 *Id.* 24, 33. Among the smaller group of IDNs that do not bear risk, flagship hospitals were on average 10 percent less expensive than the comparator in-market hospital.

53 *Id.* 25.

54 The NASI survey is somewhat dated, but we have not identified any more recent research that would reverse the basic conclusions. There are some positive findings, however. For example, one study finds that Medicare Advantage ("MA") contracts for plans offered by health systems have higher quality ratings than unintegrated MA plan offerings. However, that difference was heavily, though not entirely, driven by Kaiser, and the quality advantage for integrated MA plans shrank over the study period. Garret Johnson, Zoe Lyon & Austin Frakt, "Provider-Offered Medicare Advantage Plans: Recent Growth and Care Quality," *Health Affairs* 36, no. 3 (2017): 539–547.

55 The VMG state that the FTC and DOJ will evaluate efficiency claims in vertical mergers by "using the approach set forth in Section 10 ['Efficiencies'] of the Horizontal Merger Guidelines." VMG, § 6. The ensuing discussion is focused almost entirely on EDM.

56 The authors of the NASI study had to rely on financial disclosures pursuant to IDNs issuing bonds and tax filings. They did not have access to unit-level structure or performance data; for example, they knew whether an IDN bears risk but could not determine how, if at all, that risk was passed on to the IDN's component hospitals and physicians.

of harm as well as parties' efficiency claims. For example, for a hospital system seeking to acquire a physician group, past acquisitions by that same system would provide direct evidence on the likelihood of competitive harms as well as efficiencies.[57] Likewise, in an investigation of an insurer acquiring hospitals or physician groups, the agencies and courts are likely to give significant weight to the insurer's track record in similar past acquisitions, where available.[58]

IV. CONCLUSION

Over last several decades, the major building blocks in the healthcare finance and delivery system — hospitals, physicians, and insurers — have come together in various vertically integrated organizational structures, including hospital-physician, insurer-physician, and hospital-physician-insurer combinations. To varying degrees and possibly in combination, these stacks can reflect attempts to increase efficiency and improve value to customers, to exploit regulatory rules that favor one organizational form over another, or to leverage market power to disadvantage actual or potential rivals. The challenge for antitrust enforcers will be to discern which of these apply, and how strongly, to the specific mergers that come before them. The implication is that vertical merger analysis will proceed on a case-by-case basis, consistent with the VMG.[59]

Recent public statements and merger challenges by the FTC and DOJ, and the issuance of the VMG themselves, show that both agencies are now focused on vertical theories of harm and are less likely to presume that vertical mergers are beneficial.[60] When it comes to hospitals, physicians, and insurers specifically, the FTC's vertical enforcement track record is still limited. To date, the FTC has not challenged a hospital system's acquisition of a physician group under a vertical theory of harm, but it has cited a vertical theory of harm in challenging a health insurer's acquisition of a physician group. Given the small number of enforcement actions, it is unclear whether this simply reflects the mix of transactions before the FTC or differences in the FTC's assumptions and expectations regarding these two categories of vertical healthcare mergers.

Either way, the FTC's future enforcement priorities and theories of harm will likely be guided by conclusions from its retrospective study of horizontal and vertical mergers involving physician groups and healthcare facilities.[61] The last similar retrospective investigation by the FTC, a series of retrospective studies of hospital mergers in the early 2000s, led to the FTC's successful challenge of the Evanston-Highland Park consummated transaction and subsequent revitalization of its prospective hospital merger enforcement agenda.[62]

57 For example, in the *St. Luke's/Saltzer* litigation, the parties claimed a number of efficiencies from adding the Saltzer physicians to St. Luke's. Findings of Fact and Conclusions of Law, https://www.ftc.gov/system/files/documents/cases/140124stlukesfindings.pdf, ¶ 147 *et seq*. The FTC's economic expert used claims data produced in discovery to evaluate the effects of St. Luke's past acquisitions of physician groups and found "no evidence of systematic reductions in healthcare costs." Demonstratives for the testimony of Professor David Dranove, https://www.ftc.gov/system/files/documents/cases/131002stlukedemodranove.pdf, 49–51.

58 DOJ and FTC, *Horizontal Merger Guidelines*, Aug. 19, 2010, § 2.1.2 ("The Agencies look for historical events, or 'natural experiments,' that are informative regarding the competitive effects of the merger.").

59 "To determine whether the merger may substantially lessen competition, the Agencies would analyze the specific facts and circumstances, including in particular the relative magnitude of these offsetting incentives." VMG, § 4(a), "Example 2: Input foreclosure and raising rivals' costs."

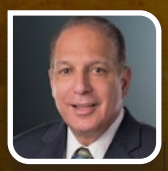
60 "While the agencies more often encounter problematic horizontal mergers than problematic vertical mergers, vertical mergers are not invariably innocuous." *Id.* § 1.

61 FTC, *supra* note 3.

62 "While it is not possible to measure the impact of the hospital retrospective program on subsequent enforcement precisely, it is suggestive that the FTC was able to obtain thirteen federal injunctions in hospital cases from 2008 to 2018, compared with only two from 1997 to 2007." FTC, "Overview of the Merger Retrospective Program in the Bureau of Economics," n.d., https://www.ftc.gov/policy/studies/merger-retrospectives/overview.

A STEP FORWARD OR BACKWARD: THE COURT'S APPLICATION OF GEOGRAPHIC MARKET DEFINITION PRINCIPLES IN *FTC ET AL. v. THOMAS JEFFERSON UNIVERSITY AND ALBERT EINSTEIN HEALTHCARE*

BY DAVID EISENSTADT & JAMES LANGENFELD[1]



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I. INTRODUCTION

On February 27, 2020 the Government (the Federal Trade Commission and the Pennsylvania Office of Attorney General) challenged the proposed merger of Thomas Jefferson University ("TJU") and Albert Einstein Healthcare Network ("AEHN") (the "merging parties") as a violation of Section 7 of the Clayton Act.[2] On the same date, the Government filed a motion for Preliminary Injunction ("PI") with the District Court for the Eastern District of Pennsylvania to temporarily enjoin the merger pending a full-trial on the merits. Six days of PI hearings occurred during October 2020. On December 8, 2020 the Court denied the Government's motion, finding Plaintiffs had failed to meet their evidentiary burden that they would likely prevail on the merits of their market definition claims during a full trial on the merits. Two weeks later, an Emergency Motion filed by the Government to the 3rd Circuit for a temporary injunction was denied without comment. On January 6, 2021, the FTC voted to remove the matter from Adjudication, including withdrawal of its Part 3 Administrative Complaint.

The FTC lost this challenge in large part because it failed to convince the Court of the two alleged relevant geographic markets for inpatient general acute care ("GAC") despite apparent agreement between the two sides economists about plausibility of the hypothetical monopolist(s) ("HM") market definition test constructed with the use of statistical and other analysis. Both alleged markets were rejected on grounds the Government had failed to reconcile statistical evidence of "diversion ratios"[3] constructed from patients' hospital usage patterns with the abilities of commercial health plans to resist and defeat a price increase by contracting with facilities located outside either market. This disconnect caused the Court to question whether the purported HM in each of the two markets would have the ability to successfully leverage its ownership or control of the composite hospitals to profitably impose at least a small, but significant non-transitory increase in price ("SSNIP") at the merging party hospital around which the HM was constructed.

The Opinion raises questions that may well be the subject of market definition in future merger litigations. Specifically, what exactly is commercial reality, how does it fit into market definition, and in what way does commercial reality relate to quantitative market definition analysis performed by economic experts?

II. FTC'S APPROACH TO MARKET DEFINITION

The Government's market definition allegations were both similar to and different from those advanced in other recent hospital merger litigations. As with previous challenges, the proposed merger allegedly would reduce competition in the inpatient GAC market. However, for the first time the Government also alleged harm in an inpatient rehabilitation facility ("IRF") market. As an additional wrinkle, in an apparent effort to comport more closely with the 2010 Horizontal Merger Guidelines ("HMGs"), the Government alleged separate GAC geographic markets around the merging parties' individual hospitals allegedly most susceptible to a post-transaction price increase.[4] Diversion ratio analysis, strategic documents, and payer testimony indicated that Jefferson was a closer competitor to Einstein (i.e. prevented Einstein from unilaterally raising price profitably) than vice-versa. Given this, the Government deemed the different Einstein hospitals were more susceptible to a post-transaction price increase and it constructed individual geographic markets around each.[5]

The HM around each Einstein hospital included (1) the Jefferson hospital with the highest diversion percentage from that Einstein facility; (2) any non-merging-party hospital for which the diversion percentage from that Einstein hospital equaled or exceeded the diversion percentage to the Jefferson hospital identified in step (1); (3) any non-merging-party hospital with a drive-time from the Einstein hospital that was shorter

2 Collectively, the two sets of litigants are referred to as "the parties." TJU owned eleven GAC hospitals in the Philadelphia metropolitan area (Southeastern PA and Southeast NJ), three of which were alleged to be significant and direct competitors to two Einstein GAC hospitals, Einstein Medical Center Philadelphia ("EMCP") and Einstein Medical Center Montgomery ("EMCM"). The three Jefferson facilities were Jefferson-Abington and Jefferson-Frankford, alleged to be direct competitors to EMCP, and Jefferson-Abington and Jefferson Abington-Lansdale, alleged to be direct competitors to EMCM. The parties also owned directly competing inpatient rehabilitation facilities ("IRF"), most notably the MossRehab facility owned by and located at Einstein Medical Center Elkins Park ("EMCEP") and Jefferson Magee. MossRehab at EMCEP allegedly significantly competed with Jefferson-Magee, a freestanding IRF in Philadelphia as well as Jefferson-Abington's IRF unit. MossRehab had additionally located IRF beds at EMCP, and at Jefferson-Frankford and Jefferson-Bucks, two Jefferson-owned hospitals that had contracted with MossRehab prior to their acquisition by Jefferson in 2016. EMCEP also provided GAC services.

3 Section 6.1 of the 2010 Department of Justice-FTC Horizontal Merger Guidelines defines a diversion ratio as "the fraction of unit sales lost by the first product due to an increase in its price that would be diverted to the second product." In practice, diversion ratios between two products are computed with information of triggering events other than a price increase such as a quality decline/increase or closure/unavailability of the first product.

4 HMG's §4.1. In recent prior litigated hospital mergers involving multi-hospital systems situated in highly urban areas a single geographic market was defined for affected facilities of the two merging parties. See, for example, *FTC v. Advocate Health Care Network*, 841 F.3d 460,475 (7th Cir. 2016).

5 In its Complaint for a PI, the Government cites to Einstein facility-to-Jefferson diversion ratios and vice versa. The diversion percentages from EMCP or EMCM to Jefferson were at least several times larger than the diversion percentages from Jefferson-Abington or Jefferson-Abington-Lansdale to Einstein. In the alleged IRF market, the Government's diversion ratio analysis indicated that Jefferson was roughly twice the competitive constraint on Einstein Moss-Rehab than vice-versa.

than the drive-time to any non-merging-party hospital included in step (2); and (4) the aggregate diversion percentage from the Einstein hospital to all the hospitals identified in steps (1) – (3) had to be large enough for the imposition of a profitable SSNIP at the Einstein hospital.[6] The criteria employed in steps (2) and (3) necessarily excluded some hospitals from the market simply because they were deemed to be worse substitutes to the target Einstein hospital than the Jefferson hospital that accounted for the largest percentage diversion.

The Government respectively labeled the separate HMs around EMCP, EMCM and EMCEP as the North Philadelphia, Montgomery area, and Philadelphia area markets. The North Philadelphia market centered around EMCP included eleven GAC hospitals, two Einstein facilities (EMCP and EMCEP), two Jefferson hospitals (Jefferson-Abington and Jefferson-Frankford), two Temple University facilities, individual hospitals owned by Prime and Tower Health, and three individual specialty facilities, one pediatric and two that specialized in cancer treatment. In that market, the Government alleged that consummation of the merger would cause the Herfindahl Hirschman Index ("HHI") to increase by 1,200 points to 4,500.

The Montgomery area market included nine hospitals, EMCM, two Jefferson (Abington and Abington-Lansdale) facilities, two Tower hospitals, two Prime hospitals, and two others. In this market, the Government alleged an HHI increase of 700 points to 3,500. The Philadelphia area ("IRF") market centered around EMCEP included two Einstein facilities, three Jefferson, an IRF facility owned by the University of Pennsylvania, and another non-party IRF situated at Trinity's Nazareth Hospital. In this alleged market, the HHI was projected to rise by 2,500 points to 5,900.

In all three markets, the alleged post-merger HHI and increase therein exceeded the standards set forth in the HMGs for a merger to likely enhance market power – a post-merger HHI of 2,500 or greater and an HHI increase of at least 200 points.[7]

Both parties' economic experts agreed that the HMs for each of the two GAC markets would be able to profitably impose a SSNIP at the Einstein facility around which the market was constructed.[8]

III. ANALYSIS OF THE COURT'S OPINION

At first read, the District Court's decision about geographic market definition appears to be on more solid footing than several prior District Court hospital merger opinions that denied the Government's Motion for a Preliminary Injunction. The portions of expert and fact witness testimony that pertained to market definition were discussed in greater detail, with the Court making specific findings about the credibility of different fact-witness testimony, all of which suggests its decision would have been difficult to reverse on factual grounds as "clearly erroneous." Further, both parties conceded the importance of reconciling expert and fact-witness testimony with the Court finding that the Government failed do this.

In particular, the alleged markets were rejected on grounds the Government failed to reconcile with commercial realities its statistical evidence of diversion ratios and the construction of each HM.[9] The nature of the evidentiary inconsistencies varied between the two alleged product markets. The GAC geographic markets were rejected because health plan payers that provided "supporting" geographic market definition testimony failed to confirm the alleged market boundaries to the Court's satisfaction. In rejecting each GAC market, the Court seemed to emphasize that United, Cigna, and IBC, in that order, were insufficiently versed with the contours of either market to validate their existence. In addition, the Court found the veracity of one health plan witness that offered supporting market definition testimony on behalf of the Government was likely influenced by economic concerns unrelated to market definition.

6 A SSNIP is typically considered to be a profitable price increase of at least 5 percent imposed by the HM at the hospital location of the merging party around which the market is "centered" (although the HMGs formally apply the test to include a SSNIP at one or more of the merging firms' locations that comprise the HM; HMGs §4.2.1). If the candidate HM does not satisfy the SSNIP test, of the non-merging-party hospitals *not* part of the putative HM, the one that functions as the next best substitute to the hospital around which the market is defined is added and so on. Assuming linear demand, a contribution margin of 50 percent, and application of a generalized upward pricing pressure ("GUPPI") formula which measures first-order price effects of a horizontal merger, an aggregate diversion ratio from the target hospital of 20 percent would be sufficient for a SSNIP of 5 percent (=20 percent x 50 percent x 0.5). The Government alleged that the aggregate diversion percentage in each alleged market was at least several times larger than that necessary for the threshold 5 percent SSNIP, arguably providing statistical confirmation each HM had been properly constructed.

7 HMGs §5.3.

8 The Court did not describe other areas of agreement or disagreements between the parties' experts on the mechanics used to construct each GAC HM.

9 The Court also criticized the Government's economic expert for failing to reconcile the two. In response, the Government claimed the reconciliation process had in fact been performed. In conducting this task, the Government's expert relied in part upon the content of declarations and deposition testimony rendered by payer representatives. However, the Court placed greater weight on live-payer testimony, which apparently was more equivocal, leading the Court to conclude the expert had insufficient basis to claim payer testimony supported his findings.

The Court was particularly critical of the live market definition testimony that was offered by two health insurers, Independent Blue Cross ("IBC") and Cigna. In rejecting IBC's concerns, the Court noted IBC could not identify how dependent its enrollees were on the merging parties' hospitals in the Montgomery area market for obstetrics, notwithstanding the same witness testified a contract with the merging parties' hospitals in this market, for this service, was important. But the Court went beyond the weakness of IBC's market definition testimony. It enumerated several other confounding problems including IBC's status as a health plan competitor to the merging parties, its prior contracting behavior with Einstein and Jefferson, its position as the Philadelphia area's leading health plan, and its professed goal to offer networks with greatest range of provider choice.

Cigna's concerns were dismissed largely on grounds its witness could not easily embrace the boundaries of the Government's two GAC markets and the Government's unilateral effects theory of harm.

The Court was also disturbed by the lack of corroborating testimony from the two other leading health plans, Aetna and United, reducing the weight which it assigned to the testimonies of the other two. Specifically, Aetna had no concerns about the transaction. United did not appear as a hearing witness on behalf of the Government because its witness's deposition testimony apparently did not affirm the boundaries or the two alleged GAC markets, that it would agree to pay higher rates to the merged firm post-transaction, or that its hospital network would be unmarketable to the residents of either GAC market if Jefferson and Einstein were excluded from its hospital network. In addition, an ordinary course, United analysis mentioned certain non-party hospitals located outside either GAC market as substitutes for EMCP and/or EMCM.

The IRF market was rejected because the payer witnesses that testified lacked experience in negotiating IRF rates, the Government did not prove local access to IRFs was important to employers (it is an infrequently utilized service), or that access to an IRF network was an important factor in their selection of a health plan.

A. Commercial Realities and Market Definition

The Opinion raises at least three sets of questions that may well be the future subject of market definition in merger litigations: First, what exactly *does* commercial reality mean in the context of market definition analysis, and how should commercial realities overlay with a statistical analysis of market definition performed by the plaintiff's expert? Second, should supporting testimony rendered by a complaining buyer (i.e. a health plan or third-party payer) be rejected or discounted when the merging parties are direct competitors to the buyer? Third, does the Government's theory market definition (or unilateral effects) require payers' unanimous endorsement.[10]

To an economist, the questions about commercial reality that are pertinent to geographic market definition are pretty straightforward. They are: do buyers (e.g. health plans) agree that access to locations under the control of the putative HM are necessary for the commercial success of a product sold to customers (employers) with significant concentrations of members (employees and/or dependents) that reside in the affected area (e.g. North Philadelphia)? Second and relatedly, does common control of the locations which comprise the HM make the merging-party-hospital around which the market is centered vulnerable to a profitable price increase of at least a SSNIP? If not, as a practical matter, what additional locations should be added to the proposed HM for the assumed price increase at the target-party hospital to be profitable?

The Court does not cite to health plan-witness testimony demonstrating that either GAC HM contained too few competing firms or locations to profitably impose at least a SSNIP at the pertinent Einstein facility. The Court also did not cite payer testimony which explained how an attempted SSNIP by the HM at either target Einstein hospital would be easily defeated, i.e. how the payer would substitute to hospitals not included in the HM to defeat the proposed price increase. The Court also cited no testimony that revealed a GAC hospital network which excluded the facility locations hypothetically owned by either HM could be as effectively marketed as a network that included them.

In rejecting each GAC HM, the commercial realities that the Court *did* mention seem to pertain more to each merging party's competitors and not the adequacy or lack thereof of the proposed HM at issue. For example, the Court mentioned a United internal analysis that listed a number of alternative providers to EMCP or EMCM that were not part of the either GAC HM. What the Court did not address is whether these outside hospitals could be substituted for each relevant Einstein facility if either was hypothetically under the control of the (non-Einstein) hospitals that comprised each respective HM. When the HM can successfully condition participation of all facilities under its ownership on the inclusion of each Einstein hospital, substitution away from the Einstein hospital at issue would be impossible because it would mean losing access to all of the facilities under the HM's control. Finally, while the Court observed United never explicitly recognized the legitimacy of either GAC market, its witness representative apparently never offered testimony that disproved their existence.[11]

10 Since the issue of "complaining buyers" that compete with the merging parties in the buyer's market is also pertinent to purchaser concerns about unilateral effects, this issue is addressed below in sub-section D.

11 This point is relevant because buyers may not be sufficiently facile with how a proposed HM is constructed to form an accurate business judgment about its legitimacy.

Some of the Court's grounds for rejecting IBC's testimony relate to the lack of pre-merger unilateral market power possessed by each merging party. These comments fail to shed light on the ability of each HM to profitably impose at least a SSNIP at the target-Einstein hospital or the merged firm's ability to raise price after the merger. For example, the Opinion states that IBC leveraged each merging party pre-merger by threatening to exclude it from one or more of its product networks. While this certainly suggests neither party possessed unilateral monopoly power or "must have" status, it does not demonstrate profitable price increases of at least a SSNIP by each HM at the relevant Einstein hospital would be unprofitable.[12]

The Court also referenced the contemplated marketing of a network by IBC's parent that excluded both Jefferson facilities and two Main Line hospitals (Paoli and Bryn Mawr) as evidence that a merged Jefferson-Einstein would gain no unilateral market power. At best, the analogy is relevant only to unilateral market power or the lack thereof that would result from other combinations with Jefferson. No discussion is provided about how the combined GAC share of Jefferson-Main Line in their relevant area compares to the combined share of Jefferson-Einstein in either of the two alleged GAC markets. At a minimum, appropriately applying the outcome in the former geography to the latter demands this type of comparison. Relatedly, the comment also does not address the legitimacy of either proposed GAC HM and its ability to impose at least a SSNIP at the targeted-Einstein hospital around which the market was centered.

The Court cited other dynamics to underscore its suspicions about IBC's true motive for testifying that it was vulnerable to a post-merger price increase. In this regard, the Opinion references two specific "market" facts: IBC's status as a dominant buyer and its desire to offer broad networks.[13] The first fact is used to suggest IBC would be protected against merger-related hospital input price increases because as a buyer it has more bargaining leverage than Jefferson-Einstein would possess as a seller. The second fact implies that even if IBC were susceptible to a post-merger price increase, it could simply exclude the merged firm from its different product networks and avoid adverse impact.

IBC's apparent position as a dominant buyer does not establish it would be immune from a post-merger price increase. What matters is the change in the relative bargaining positions of IBC and Jefferson and Einstein that results from their merger. Further, IBC's choice to differentiate its products by offering greater provider choice allows it to sell larger networks (all else equal), potentially at a higher price. From IBC's perspective, a merger that induces it to shrink its hospital provider network to avoid paying higher prices to Jefferson-Einstein is the equivalent to a quality-adjusted price increase for its products.

The Opinion characterizes Cigna's witness as being both contradictory and uncertain about exact market boundaries. Its witness testified EMCM, Jefferson-Abington, and Jefferson-Abington Lansdale would alone constitute a valid HM (in which case the Government's Montgomery Area HM would more than satisfy a SSNIP test), but he was less certain about the boundaries of the North Philadelphia market centered around EMCP. On the other hand, Cigna apparently offered no testimony that indicated it would easily defeat an attempted SSNIP at EMCP or EMCM by either GAC HM by selling a network that included only outside hospitals.

The Court determined Cigna's sale of health plan services to large employers throughout the Philadelphia area provided probative evidence of hospital geographic market boundaries. The employed work forces of these employers reside throughout the five-county Philadelphia PA area, prompting Cigna to contract with a large number of health systems situated therein to satisfy that wide-area demand. From this observation, the Court's seemed to conclude the entire metropolitan area is a more appropriate geographic market for hospital services than either one of the two alleged GAC markets.

Cigna's strategy to offer a hospital network of which contains multiple hospitals and different hospital-access points underscores the different contexts which are used to define markets. From a business and marketing perspective, Cigna's need to offer a hospital network that spans a wide geography is attributable to the spatial heterogeneity of the employees of its different employer-client accounts. That business imperative does not mean all hospitals in Cigna's network are equally good substitutes. In fact, Cigna's need to offer a large panel of hospitals actually demonstrates the opposite; otherwise, employers would be content to purchase a network with many fewer hospital-access points. By contrast, antitrust market definition focuses on the hospital substitution patterns of a defined enrollee/inpatient population, and considers whether employers with, say, a significant concentration of employees residing in the North Philadelphia area would readily switch to a hospital network that excludes the facilities that comprise the putative (North Philadelphia) HM if it attempted to implement a SSNIP at the relevant Einstein hospital.

12 Along those same lines, the Court made reference to Jefferson documents that identify hospitals *other* than Einstein facilities as closer competitors, a not surprising fact given local perceptions of the two merging parties and the nature of hospital competition in the Philadelphia area. This fact *is* pertinent to Einstein's apparent lesser ability to constrain Jefferson pre-merger, it does not necessarily speak to payers' abilities to use outside hospitals as leverage to successfully discipline either HM if it attempted to impose at least a SSNIP at the relevant Einstein hospital.

13 The Court also referenced IBC's apparent dislike of all hospital mergers.

B. Commercial Realities and Likely Competitive (Adverse Unilateral) Effects

Unilateral effects relate to the merged firm's ability to profitably raise price at one or more facilities under its ownership.[14] Since the Court's denial of the Government's Motion seems at least partly based on a lack of showing of adverse unilateral effects, we discuss those commercial realities that would run counter to the Government's theory of unilateral harm and then discuss several of the Court's references to this issue.

Commercial realities that would indicate a *lack* of unilateral effects include credible testimony that buyers would be able to "as effectively" sell a hospital network to those commercial customers whose employees exhibit significant usage of the targeted Einstein facilities if (1) the hospital locations owned by the merged firm which are part of the HM were *excluded* from the payer's network; (2) non-merging party hospitals that are part of the HM were *included*; and (3) additional non-merging party hospitals *not* part of the HM ("outside hospitals") were also included. Such evidence would demonstrate a payer could form a substitute hospital network without inclusion of the relevant merging parties' facilities, which in terms of both enrollment and price, would be as commercially attractive as a network including those merged firm's facilities.[15]

This fact pattern cannot be demonstrated simply by evidence the same buyer offered or contemplated offer of a network that excluded the relevant locations of *both* merging parties. Although this narrower network might well be commercially salable, it could also be inferior to one that included the merging parties' locations, would have to be sold at a discount to be attractive, and even then, might be purchased by only a subset of the customers that previously bought a network which included them. The *key* issue is whether these same customers would agree to pay a higher price for network that includes both merging parties' relevant hospitals than one that excludes them.[16]

Although the Court certainly recognized the significance of these questions to unilateral effects issues, the testimony referenced in the Opinion does not provide needed answers.[17] In rejecting IBC and/or Cigna testimony, the Court made three observations: (1) health plans only need to contract with one of the two merging hospitals or systems; (2) health plan products that excluded the hospitals of both systems were either sold or contemplated for sale; (3) Jefferson (TJUH, Abington and Abington-Lansdale) were not particularly competitively constrained by Einstein, and were more constrained by the two University of Pennsylvania hospitals located in Philadelphia.[18]

Of these three observations, only the second is likely to be somewhat relevant to unilateral effects, but without more does not demonstrate the equivalence of a network which included both merging parties and one that excluded them. The Court's first observation, that a successful network could consist of one but not the other merging firm is not on-point to whether a network could be equally successful if both were excluded. The third issue pertains to the apparent asymmetry of unilateral effects, not their absence.

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14 While some case law precedent supports issuance of a preliminary injunction only with likely proof of a relevant market and the showing of a significant concentration increase therein, internal Agency review criteria and evidence presented by the Government in recent litigated hospital merger go beyond this threshold. The market definition process contained in the HMGs is used by the FTC and DOJ as an *initial* screen to identify mergers likely to raise competitive concerns. The second step of the internal review process is a more detailed consideration of competitive effects, including the extent to which the merged firm would gain unilateral market power manifesting in a price increase or quality decrease at one or more of its locations.

The threshold price increase which would justify a concern about unilateral effects is less than a SSNIP, although to be sure, many antitrust practitioners suspect both federal antitrust agencies exercise prosecutorial discretion and will challenge only proposed mergers likely to raise price by at least 5 percent at one or more locations owned by the merged entity. In the absence of offsetting efficiencies (of which in Jefferson-Einstein there either were none offered as an affirmative defense or they were disregarded for purpose of the PI) the threshold for a tolerable merger-related price increase is less than one-tenth of one percent (specifically, 5%/7,500: x/200; x = 0.06 percent(7,500 is the change in HHI of a merger to monopoly in a highly concentrated market with an HHI of 2500; 200 is the threshold change in the HHI for a presumptively anticompetitive merger under the HMGs).

15 Consider a proposed HM containing five hospitals A, B, C, D and E, where hospitals A and B are respectively owned by each merging party. The relevant thought experiment is whether a network containing C, D, E, and other non-merging hospitals F, G, and H that is deemed to be the next-best-alternative network to A-E would be as commercially successful if it sold at the same price. If so, an equally attractive network can be constructed without the inclusion of A and B. The greater the number of "equivalent" (in terms of enrollment) networks to A-E that can be constructed by excluding the merging parties' hospitals and sold for the same price as A-E, the less likely the merger creates any unilateral market power. Said differently, to achieve the same level of enrollment, if network C-H referenced above must be sold at a 20 percent discount relative to A-E, then F, G and H combined are not equivalent substitutes for A and B.

In addition, assume that two networks are also available pre-merger [A, C-H] and [B, C-H]. Each would achieve same enrollment as network A-E provided each was discounted by 10 percent relative to the price of a potential A-E network. A merger of A and B, coupled with its practice of all or nothing contracting post-merger, and normalizing the price of the [A, B, C, D, E] network to "one," would cause network prices to increase by 11 percent (=1.0/0.9 - 1).

16 An alternative way to frame the issue is to ask how much less enrollment (if any) would be realized by a network which excluded the merging parties' relevant hospitals and was sold at the same price as one which included them?

17 The Court recognized that, unlike other geographies with embedded natural experiments that measure measurement or assessment of these different issues, none of the episodic historical hospital-payer contracting behavior in the Philadelphia area provided any meaningful guidance.

18 A Bucks County hospital owned by Trinity (St. Mary's) and a Montgomery County hospital owned by Holy Redeemer.

Yet, the Court relied on these facts to conclude there would be adequate hospital competition in the Philadelphia area after the merger. Although the Court's factual findings fairly demonstrate that the addition of Einstein to Jefferson would not create an absolute GAC monopoly in any market, this high threshold is not the test for showing likely adverse unilateral effects.[19]

C. Commercial Realities and the IRF Market

It is unclear whether the opposing experts agreed about the composition of the IRF HM. The merging parties contended the Government's product market inappropriately excluded high-end nursing home facilities that provided rehabilitation care that was comparable to the services offered by the IRF facilities that were part of the HM. On the other hand, it appears that no disagreement existed about the identity of the HM constructed using diversion ratios between different IRFs, or that with a diversion percentage from EMCEP of 18.5 percent, Jefferson-Magee was its most important IRF competitor.[20] Less apparent is whether evidence was presented that demonstrated IRF diversion ratios from EMCEP to nursing homes were even larger justifying their inclusion in the relevant market under step (3) of the HM build-up.[21]

In the alleged IRF market, the Court implied IRF services were rarely used by employees or their dependents, suggesting that employers would be satisfied with networks that included some IRF facilities located anywhere, including rehabilitation hospitals situated outside the locations of the alleged HM. While reference to a market with "thin" demand is germane to measuring potential consumer dollar harm from a proposed transaction, a "size of market" test by itself has no impact on the accuracy or mechanics of product or geographic market definition.[22]

The Opinion referenced no specific payer testimony that when IRF services were required, employers with significant employee concentrations in the Philadelphia area would be indifferent to an IRF network that included the locations of the IRF HM, one consisting of different facilities. There was also was apparently no testimony that commercial customers would be indifferent to an IRF network that excluded the merging parties' IRF facilities, and one that included the non-merging party facilities that were part of the HM plus "outside" (not part of the HM) IRF facilities.

D. Dual-Role Complaining Buyers and Lack of Buyer Unanimity

More nuanced considerations apply to the Court's several observations about the mixed-motives of complaining buyers that compete with the merging firms ("dual-role" purchasers or buyers), and the weight that should be assigned to complaining purchaser testimony when (all) buyers' opinions about the transaction differ.

1. Dual Role Buyers

Dual role purchasers that also compete directly with the merging parties might object to a proposed merger either in their position as would-be disadvantaged buyers or disgruntled competitors. In Jefferson-Einstein, the Court noted that IBC's opposition to all hospital mergers, its significant prior objections to (a) UPMC's attempted acquisition of Einstein, (b) Jefferson's proposed Accountable Care Organization with Main Line Health, and (c) Jefferson's co-ownership with Einstein of a Medicare/Medicaid Advantage Plan that competed with IBC, warranted the classification of disgruntled competitor.[23]

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19 The Court found the Government offered no employer testimony that it would be difficult to market a health plan to employees which excluded Jefferson and Einstein. This demonstrates the difficulty of identifying knowledgeable employers to opine about unilateral effects when a proposed merger creates "some" additional bargaining leverage, but not nearly enough to confer monopoly power or "must have" status on the merged firm.

While interesting, the Court's reference to an employer located in a geography outside either proposed GAC market (the lower Merion School District in Montgomery County) which indicated it would be "fine" with a health plan that excluded Jefferson and Einstein seems a bit forced. More pertinent would have been evidence of employers with significant (by percentage) usage of EMCM or EMCP by their employees that would have been indifferent to a health plan that excluded both Einstein and Jefferson. The Court did not cite to such evidence.

20 Of additional note is the reference in the Complaint to MossRehab as an important IRF competitor to Jefferson.

21 It is also unclear whether formal measurement of rehabilitation diversion percentages from EMCEP to nursing homes was possible given available patient-origin data.

22 In its Emergency Appeal to the 3rd Circuit, the Government asserted that the infrequency with which IRF services are demanded did not justify its dismissal by the Court as a relevant product.

23 In a two-step process, Jefferson would acquire Einstein's ownership share in Health Plan Partners Inc. as part of their proposed merger and then purchase the remaining 50 percent interest which is owned by Temple University.

All of the above could or would have created health plan competition to IBC. UPMC, a health system based in Western Pennsylvania owns no Philadelphia-area hospitals but does operate a health plan which is the most significant competitor to Highmark Blue Cross-Blue Shield (aka Blue Cross-Blue Shield of Western Pennsylvania). Plausibly, IBC feared that UPMC would use its acquisition of Einstein as a toe-hold for its health plan entry in the Philadelphia area. The Court fairly concluded that IBC considers Jefferson a potential competitive threat as an insurer, an eventuality which becomes more likely as Jefferson adds additional owned-facility access points to its current southeast PA-NJ health system.

Ultimately, the Court afforded little weight to IBC's views about the merger because of Jefferson's stance as a health plan competitor. Interestingly, neither the testimonies of United nor Cigna were discredited on grounds Jefferson would emerge as a stronger health plan competitor to them. This suggests the Court did not conclude all complaining health plans objected out of concern the merged firm would offer greater competition to them. It is also unclear what specific conclusions the Court drew from Aetna's lack of any opposition.[24]

The Court's dismissal of IBC's testimony creates an interesting juxtaposition: whether the strong views of complaining "dual-role" buyers are inherently *so* suspect that their complaints about a proposed hospital merger should be discounted. Accordingly, in future litigations the Government will likely need to flesh out in greater detail the underlying incentives of complaining dual-role health buyers. In that regard, we can think of at least two potential evidence tie-breakers: one simple, yet potentially unreliable, and one quantitatively more precise, but also more difficult to construct.

For some time, economists have noted that the customers who purchase from dual-role complaining purchasers are in a superior position to objectively comment on whether the merger would harm competition.[25] In this instance, those customers would be employers that purchase health plan coverage from IBC, especially ones which self-insure and incur the full-pass-through expense of higher hospital claim costs that result from a merger which creates additional negotiating leverage for the merged firm *vis-à-vis* health plans. Knowledgeable, credible employers that perceive a greater benefit from more health plan competition would support the merger, while those that anticipate higher claims costs because of the merger would oppose it. As far as we can discern, no evidence was offered by employer-customers of IBC which speaks to whether they believed that on balance the proposed transaction would be to their financial benefit or detriment.

The obvious problem with this simple test is employer-customers often do not have first-hand knowledge of merged firm's position as a would-be health plan competitor. Further, because they purchase (i.e. "rent") access to hospital networks, often with the assistance of third-party benefit firms, they do not negotiate directly with the merging hospitals and are not intimately familiar with the mechanics of hospital-health plan negotiations. Simply, identifying knowledgeable employers, especially those with significant employee usage of the merging parties' hospitals that are part of a proposed HM can be a challenge.

The second test would formally compare the profit loss to the health plan from higher hospital input costs (due to the merger) with its profit decrement from more aggressive health plan competition that would be offered by the merged firm. This type of calculation could be performed either by experts or business analysts employed by the complaining health plan. A result that indicates a larger anticipated profit-loss from higher input costs would add credibility to a complaining payer's position that its opposition was rooted in anticipation of higher input prices.

2. Lack of Uniformity of Opinion Among Buyers

This has always been a thorny antitrust issue, with critics suggesting that *product* markets should be defined up-front to include only those purchasers likely to be harmed by the horizontal hospital market power created by the proposed merger.[26] In this case, the relevant product market would have included less than all the commercial volume of all four major health plans, or at least their volume minus Aetna since Aetna did not apparently object to the transaction. The advantage to this approach is it limits the Court's ability to pit the testimony of complaining purchasers against that of non-complaining ones. It also allows the Government to more adequately explain why only some buyers are likely to be adversely affected.

24 When hospitals vertically integrate into the health plan market, their entry often manifests as one or more joint ventures with incumbent health plans. In that regard, the partnering health plans may choose not to oppose the proposed merger. While we have no idea whether this scenario applies to Aetna's lack of stated opposition, in other markets Aetna has been known to joint venture with hospital systems to create managed care products which would compete against with offered by the Blue Cross-Blue Shield plan that operates in the same area.

25 David T. Scheffman & Richard S. Higgins, Vertical Mergers: Theory and Policy, George Mason Law Review, 2004, pp. 967-977, e.g. 975.

26 This is discussed in the HMGs §4.1.4 *Product Market Definition with Targeted Customers*.

This approach also suffers from limitations. First, the HMGs note that either for reasons of convenience or data reliability antitrust markets are often defined for *groups* of customers. Second, health plans likely to be harmed by a proposed transaction may choose to not complain for a number of reasons. As such, limiting market definition to only known-complaining buyers is likely to understate the real magnitude of consumer harm.

Preserving the *status quo* of defining hospital product markets according to large groups of customers (e.g. all commercial health plans), not all of which either object to the transaction or testify, leaves the Court in the delicate position of weighing different customer reactions. Perhaps the Court's ruling in *Jefferson-Einstein* will induce the Government in future litigations to at least better explain to the Court *why* its product market definition is legitimate even though only some customers complain out of fear higher hospital prices.

IV. CONCLUSION

In sum, the details and logic of the Court's reasoning provide a less-than satisfactory economic basis for its ultimate determination that the Government failed to prove a market. In the Court's view, purchaser fact-witnesses must "bless" the market boundaries that were established by the Government through quantitative means. Although implementation of this guiding principle has merit and serves as a check on an expert's quantitative findings, the Opinion also references many multiple "facts" that are irrelevant to proof of an antitrust market *or* demonstration of likely adverse unilateral effects.[27]

Witness testimony and documents referenced by the Court as part of its basis for rejecting the findings of the Government's economic expert on market definition includes (1) conflating facts relevant to unilateral effects with principles of market definition; (2) confusing pre-merger contracting behavior with the purported lack of unilateral effects; (3) failure to consider the potential anticompetitive effects of mergers which occur in product markets populated by buyers (health plans) selling differentiated products (networks); (4) not accounting for the different contexts and purposes (business, antitrust, regulatory, etc.) for which markets are defined; and (5) applying a *de minimis* threshold of commerce to the process of market definition.[28]

On the other hand, The Court's overriding and legitimate observation that fact-testimony should accurately overlay expert statistical analysis, and its admonition that a failure to reconcile the two exposes the Government to judicial determination it did not meet its burden of proof, justifiably highlights the need for thoroughness in the market definition process.

27 It is also possible of course that the Court's misapplication of these different facts to market definition or unilateral effects reflects its confusion resulting from the Government's failure to carefully explain how different fact-witness statements or testimony were relevant or irrelevant to these different issues.

28 This last point was raised by the Government in its Emergency Appeal to the 3rd Circuit.

PHYSICIAN GROUPS – THE NEXT ENFORCEMENT FRONTIER FOR HEALTHCARE PROVIDER MERGERS?

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I. INTRODUCTION

Nearly 20 years ago, the Federal Trade Commission ("FTC") set out to revitalize its hospital merger enforcement program. After the FTC and the U.S. Department of Justice ("DOJ") lost a series of hospital merger litigations in the 1990's, the FTC invested in its hospital merger enforcement program by starting a new group within its Bureau of Competition, the Merger Litigation Task Force (now known as Mergers IV).[2] Together with the FTC's Bureau of Economics, they undertook a series of merger retrospectives to assess the competitive impact of consummated hospital mergers as a step towards developing a new future for the FTC's hospital merger enforcement program.[3]

Two of the authors of this article were directly involved in those merger retrospectives – one as a lawyer representing a healthcare system in a consummated hospital acquisition, the other as an FTC economist. We saw first-hand how the FTC's merger retrospectives changed the way FTC staff thought about hospital mergers.[4] This, in turn, led to further changes as lawyers and economists retained by the merging parties in subsequent hospital mergers adjusted to the FTC's new approach to these transactions.

The FTC's approach to healthcare provider mergers may be on the cusp of its next evolution, with the agency looking for new issues to explore and new challenges to overcome. We believe this "next frontier" is likely to focus significantly on transactions involving physician groups. The FTC has been less active in physician group mergers compared to hospital mergers, with the agency taking enforcement action in only a handful of physician merger matters to date (see Section II). The agency's interest in physician mergers may be rising, however, given the FTC's recent announcement that it will be undertaking a retrospective study of physician group consolidations from the prior five years.[5,6]

In anticipation of greater FTC interest in physician group mergers going forward, we provide our perspective on key issues in the antitrust evaluation of such transactions. We consider how physician group mergers raise issues that are distinct from those in other healthcare provider mergers, and how the FTC's approach to these transactions may be impacted by their forthcoming physician merger retrospectives.

II. PHYSICIAN MERGER ENFORCEMENT BACKGROUND

To date, the FTC has challenged five acquisitions involving physician groups. The first came in 2012 when the FTC challenged Renown Health's ("Renown's") consummated acquisition of Reno Heart Physicians ("RHP"), a physician group specializing in cardiology in the Reno, Nevada area.[7] The FTC alleged that the transaction resulted in Renown employing 97 percent of cardiologists in the Reno area at the time the transaction was consummated. The consent agreement in this matter required that Renown release up to 10 cardiologists from non-compete clauses, allowing them to join competing practices.

Since that time the FTC has challenged three additional transactions in which a hospital system attempted to acquire a physician group. In 2013, the FTC and State of Idaho challenged St. Luke's Health System's ("St. Luke's") consummated acquisition of Saltzer Medical Group ("Saltzer"), respectively a hospital system and physician group offering services in Nampa, Idaho.[8] The plaintiffs alleged that the transaction would lead to anticompetitive effects related to primary care physician services. The district court ruling sided with the plaintiffs and the ruling was upheld in the subsequent appeal. St. Luke's was required to divest Saltzer.

2 See https://www.ftc.gov/news-events/press-releases/2002/08/federal-trade-commission-announces-formation-merger-litigation.

3 The public portions of the FTC's hospital merger retrospectives were published in 2011 in a series of articles in a special issue of the International Journal of the Economics of Business.

4 For an introduction to the types of models commonly used to evaluate hospital (and physician) mergers, see Steven Tenn (2019), "Introduction to the Economic Analysis of Hospital Mergers," in the Winter Newsletter of the Economics Committee of the American Bar Association's Section of Antitrust Law.

5 See https://www.ftc.gov/news-events/press-releases/2021/01/ftc-study-impact-physician-group-healthcare-facility-mergers. The FTC will also use this study to assess consummated healthcare facility transactions.

6 The DOJ and FTC revised their Vertical Merger Guidelines in 2020. While these guidelines do not particularly focus on physician group acquisitions, vertical integration is becoming increasingly prevalent in healthcare. Transactions that combine physician groups with other service providers, such as hospitals and health plans, potentially raise vertical merger issues (see Section IV). The revised Vertical Merger Guidelines are available at https://www.ftc.gov/system/files/documents/reports/us-department-justice-federal-trade-commission-vertical-merger-guidelines/vertical_merger_guidelines_6-30-20.pdf.

7 Materials related to this case are available at https://www.ftc.gov/enforcement/cases-proceedings/1110101/renown-health-matter.

8 Materials related to this case are available at https://www.ftc.gov/enforcement/cases-proceedings/121-0069/st-lukes-health-system-ltd-saltzer-medical-group-pa.

In 2016, the FTC challenged CentraCare Health's ("CentraCare's") proposed acquisition of St. Cloud Medical Group ("SCMG"), respectively a hospital system and physician group offering services in the St. Cloud, Minnesota area. The FTC alleged that the transaction would cause anticompetitive effects related to the provision of adult primary care, pediatric, and OB/GYN services.[9] However, the FTC concluded that SCMG satisfied the requirements for being a failing firm. Similar to *Renown-RHP*, the consent agreement in this matter required that CentraCare release a limited number of physicians from non-compete clauses, allowing them to join competing practices.

In 2017, the FTC and State of North Dakota challenged Sanford Health's proposed acquisition of Mid Dakota Clinic, respectively a hospital system and physician-owned professional corporation offering services in the Bismarck, North Dakota area.[10] The FTC alleged that the transaction would cause anticompetitive effects related to the provision of adult primary care, pediatric, OB/GYN, and general surgery services. The district court ruling sided with the plaintiffs and the ruling was upheld in the subsequent appeal. The parties abandoned the transaction.

In the most recent case to date, in 2019 the FTC challenged UnitedHealth Group's ("UnitedHealth's") proposed acquisition of DaVita Medical Group.[11] The FTC's complaint alleged that both firms offered Managed Care Provider Organization services in the Las Vegas, Nevada area through their respective physician groups. The complaint also raised vertical concerns related to UnitedHealth's Medicare Advantage plans. The consent agreement in this matter required the divestiture of HealthCare Partners of Nevada, DaVita Medical Group's healthcare provider organization in the Las Vegas area.

III. HORIZONTAL MERGER ISSUES

Physician group transactions potentially raise horizontal merger concerns for the FTC when they result in significantly competing physician groups being combined under common ownership (or other contractual relationships in which physician groups effectively operate as a single unit). Examples of this include when one physician group acquires another, or when a hospital system that already employs physicians acquires a physician practice with which it significantly competes.

The horizontal concern potentially raised by physician group mergers is that the merging parties may impose a significant competitive constraint on each other pre-merger and the removal of that constraint post-merger may allegedly result in anticompetitive effects such as higher prices or lower quality services. For this reason, the key issues when assessing a proposed physician merger are similar to those that arise in other types of healthcare provider transactions, including hospital mergers. Nonetheless, as discussed below, certain factors make physician mergers "special" and raise unique questions when undertaking antitrust assessments of such transactions.

A. Physician Mobility – Implications for Entry and Repositioning

A unique aspect of physician group mergers is that the primary "asset" involved is the professional services offered by the practice.[12] While physician group acquisitions may involve some tangible assets, such as office space and medical equipment, antitrust analyses generally focus on the physicians involved since they are the key driver of a physician practice. This is an important difference with hospital mergers where a key asset is building infrastructure, which may be very expensive to expand, reposition, or, more drastically, move to a different location. Individual physicians, on the other hand, are potentially quite mobile and can be added (or subtracted) from physician groups in increments of less than a single full-time worker by using part-time employees.

Physician mobility may reduce barriers to entry or repositioning, due to the ability of other physician groups to attract additional physicians from other geographies. This is important because, absent significant barriers to entry, even a merger that significantly lessens competition in the short run may have little long run impact, potentially making FTC enforcement action unnecessary for an otherwise challenging transaction.[13]

9 Materials related to this case are available at https://www.ftc.gov/enforcement/cases-proceedings/161-0096/centracare-health-system.

10 Materials related to this case are available at https://www.ftc.gov/enforcement/cases-proceedings/171-0019/sanford-healthsanford-bismarckmid-dakota-clinic.

11 Materials related to this case are available at https://www.ftc.gov/enforcement/cases-proceedings/181-0057/unitedhealth-groupdavita-matter.

12 Physician group acquisitions often involve non-compete agreements that prevent the merging parties' physicians from practicing in a competing physician group in the same geographic area for some time period. Non-compete agreements are an area of interest for the FTC, which recently held a public workshop on the topic. See https://www.ftc.gov/news-events/events-calendar/non-competes-workplace-examining-antitrust-consumer-protection-issues.

13 See Section 9 of the DOJ and FTC's 2010 Horizontal Merger Guidelines, available at https://www.ftc.gov/sites/default/files/attachments/merger-review/100819hmg.pdf.

As discussed earlier in Section II, the FTC has challenged relatively few physician group transactions. The transactions the agency has challenged often allege very high combined shares for the merging parties. One explanation is that barriers to entry in physician transactions are often viewed as being sufficiently low that they are expected to offset all but the most anticompetitive transactions, e.g. when the merging parties are the primary providers of a given physician service in an area.

Whether or not there are significant barriers to physician entry or repositioning depends on the specific facts in a given matter. It may depend, in part, on the physician specialty at issue and how physicians in that specialty typically acquire patients. For example, entry for a specialist who generally acquires new patients through encounters in a hospital's emergency room may be easier than for a primary care physician who slowly builds up a patient base through referrals by their existing patients to their friends and family. Similarly, barriers to entry may be significantly lower if entry is sponsored by a hospital or health plan that can drive patients to a new entrant.

Barriers to entry may be particularly low in transactions involving a small number of physicians. For example, in the *Renown-RHP* matter the FTC alleged that the transaction was to near monopoly of cardiologists in Reno, with the parties having a combined share of 97 percent. This case was unusual in that the transaction was consummated prior to the FTC completing its investigation of the transaction. Between the time of the transaction and when the FTC issued its complaint, some of the merging parties' cardiologists moved away from the area and additional competing cardiologists moved into the Reno area. According to the FTC's complaint, the net impact of these physician movements is that the parties' combined share fell by nearly 10 percentage points.[14] This highlights the potential difficulty faced by the FTC in challenging physician mergers even when a transaction initially results in a near monopoly.

Barriers to repositioning by physicians already practicing in a given area may also be relatively low in certain circumstances. It has become increasingly common for physicians to practice from multiple locations. This may allow a small number of physicians to provide a local presence across a relatively wide geography. Low repositioning barriers may be more likely to offset anticompetitive effects in situations where competing physician groups can easily open a new location and utilize their existing personnel to staff it.

The United States is a large country with more than one million physicians.[15] When hospitals, health plans, or competing physician groups have an incentive to sponsor entry, they can potentially draw on this large labor pool. Of course, the FTC may contend that the key issue is not whether it is theoretically possible for physicians outside the geographic area to enter, but rather whether incentives are such that entry is likely to occur and will be sufficient to offset potential anticompetitive effects in a timely manner.

We anticipate that one of the key issues that the FTC may be exploring in its forthcoming physician merger retrospectives is whether entry materialized in matters where the agency allowed transactions to proceed under the belief that entry barriers were sufficiently low that anticompetitive effects would not occur. If the results from the FTC's retrospectives suggest that entry barriers in those cases were significantly higher than expected, then we may see the FTC looking more closely at a wider range of physician group transactions in the future.

B. Merger Remedies

In two physician group matters, *Renown-RHP* and *CentraCare-SCMG*, the FTC accepted a remedy in which the merging parties agreed to remove non-compete agreements for a certain number of their physicians, allowing them to join competing practices. This remedy is non-traditional since there may be little economic incentive for physicians to leave the combined firm if a given transaction is allegedly anticompetitive and would, in theory, allow those physicians to receive higher reimbursement from health plans post-merger if they remained employed with the merging parties.

The FTC's willingness to engage in such a remedy potentially highlights a key difference between the behavior of firms and the behavior of individual people. Typically, antitrust agencies and economists assume that firms (generally) pursue profit maximization and will take actions which promote that interest. In contrast, physicians are people who may base their employment decisions on both economic factors, such as their reimbursement rates from health plans, and non-economic factors that impact their quality of life. For example, a physician who has historically practiced at one hospital may not want to be employed by a competing hospital that would expect them to primarily practice there, even if this would result in meaningful economic benefits. In the *Renown-RHP* matter, for example, the release of non-competes as a remedy appeared to be successful. Initially there were two significant cardiology practices in the Reno area and both were acquired by the same hospital system. Following the FTC's remedy and the release of non-competes for certain cardiologists, there were three significant competing cardiology

14 FTC complaint in *Renown-RHP* at 4, available at https://www.ftc.gov/sites/default/files/documents/cases/2012/08/120806renownhealthcmpt.pdf.

15 See https://www.kff.org/other/state-indicator/total-active-physicians.

practices in the Reno area (more than the two that existed pre-merger).[16]

Another potential reason why the FTC has been more willing to accept non-standard remedies in physician matters is that blocking an allegedly anticompetitive transaction may result in undesirable outcomes. Specifically, if two physician groups are prohibited from merging, individual physicians may gradually switch employment from one practice to the other until a significant portion of the two practices are effectively combined. As a practical matter, it may be difficult for the FTC to investigate changes in physician concentration driven by the employment decisions of individual physicians. Moreover, regulating the ability of a given physician group to hire or fire employees is a behavioral remedy, which the FTC has sparingly relied upon. Going forward, it is an open question whether the FTC will show greater willingness to investigate, and potentially seek enforcement action, in situations involving the employment decisions of individual physicians.

IV. VERTICAL MERGER ISSUES

In addition to the potential horizontal concerns resulting from mergers of physician groups discussed in the previous section, vertical implications may also arise from physician group transactions. Below, we discuss key theories the FTC may consider when physician groups are acquired by either hospitals or health plans.

A. Foreclosure of Rival Hospitals Through Physician Referrals

Competition for physician referrals is non-price based since anti-kickback statutes prevent direct payment for physician referrals.[17] For example, a primary care physician may refer to specialists with good reputations. Similarly, a physician may admit patients to a hospital that is conveniently located near to their office.

The FTC may consider whether a physician group acquisition by a hospital system may impact physician referrals by altering the incentives of the acquired physician group. For example, the acquiring system may provide guidelines or otherwise encourage referrals to affiliated physicians and may encourage patients be admitted to hospitals owned by the system. Alternatively, primary care physicians may prefer to refer patients to affiliated specialists because doing so may offer greater ease in coordinating care or other clinical benefits. As such, it may be difficult for the FTC to demonstrate that any change in referral patterns were the result of a change in competitive incentives rather than other factors.

In the *St. Luke's-Saltzer* litigation, for example, the FTC and State of Idaho argued that the market power in adult primary care services that St. Luke's would gain subsequent to acquiring Saltzer would result in foreclosure in general acute care hospital services and orthopedic surgery services.[18] The plaintiffs alleged that St. Luke's could foreclose rival hospital systems from the provision of these services by redirecting referrals by Saltzer primary care physicians away from rival hospital systems to St. Luke's. In making this argument the plaintiffs referred to both documentary evidence, such as documents indicating an expectation that post-merger Saltzer primary care physicians would shift referral patterns to St. Luke's affiliated providers of these services, and data showing similar patterns at physician group practices previously acquired by St. Luke's.

In the *St. Luke's-Saltzer* litigation, the physician referral concern was seemingly an "add on" issue that was secondary to the core concern that the horizontal overlap between St. Luke's and Saltzer in primary care physician services would result in anticompetitive effects post-merger. Since any physician group acquisition may potentially impact referral patterns, it remains to be seen whether the FTC will bring a complaint in a situation without meaningful horizontal consolidation and where a vertical physician referral concern is the primary competitive issue.

We anticipate that the FTC may explore in its forthcoming physician merger retrospectives how physician referral patterns change after a physician group is acquired by a hospital, and more importantly, whether those changes had clear pro- or anticompetitive effects. If the retrospective results are mixed, then it may be the case that this will largely remain a supplemental theory of harm in transactions where the particular facts warrant and there is also significant horizontal consolidation in physician services.

16 Following the release of non-competes, a number of cardiologists left Renown and joined practices affiliated with two other hospitals in the area, Saint Mary's Cardiology and Northern Nevada Medical Group. See https://www.saintmarysreno.com/news/2012/december/saint-marys-cardiology-welcome-five-additional-c and https://thisisreno.com/2012/12/northern-nevada-medical-group-announces-three-new-cardiologists.

17 See, e.g. the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), available at https://www.law.cornell.edu/uscode/text/42/1320a-7b.

18 Plaintiff's Pretrial Memorandum in *St. Luke's-Saltzer* at 26-33, available at https://www.ftc.gov/system/files/documents/cases/130910stlukepretrialmemo.pdf.

B. Foreclosure of Rival Hospitals to Access to Physicians

Hospital services are often rendered in conjunction with related physician services. For example, a hospital that offers inpatient cardiology services needs cardiologists to admit and treat their patients at that hospital. For this reason, the FTC may examine whether physician acquisitions by hospital systems can potentially foreclose rival hospitals with respect to hospital and other non-physician services.

Using the *Renown-RHP* transaction as an example, the question may arise whether the employment of nearly all cardiologists in Reno might allow Renown to prevent other hospitals from competing in inpatient cardiology services so long as Renown's cardiologists only practiced at Renown's hospitals.

A key issue in assessing this type of competitive concern is whether entry barriers are sufficiently low to offset any anticompetitive effects. As discussed earlier, entry barriers are likely lower in situations where a hospital system (or other entity) has a strong incentive to sponsor entry. For example, a hospital system may be willing to use a high salary to recruit physicians to the area if the alternative is that the hospital would be limited in its ability to offer profitable hospital services.

C. Foreclosure of Rival Health Plans

Vertical issues may also arise when physician groups are acquired by health plans. For example, in 2019 the FTC issued a complaint related to the acquisition of DaVita Medical Group by UnitedHealth.[19] The complaint alleged that, prior to the acquisition, UnitedHealth and DaVita Medical Group were the two largest suppliers of Managed Care Provider Organization services in the Las Vegas area to health plans offering Medicare Advantage plans. As part of these services, primary care and specialty physicians were employed or affiliated with both UnitedHealth and DaVita Medical Group. In its complaint, the FTC alleged that the merger would result in anticompetitive effects in the form of raising costs or foreclosure of UnitedHealth's rivals that offer Medicare Advantage plans in the Las Vegas area.[20]

While currently many health plans do not employ large numbers of physicians, trends toward vertical consolidation have made this more common, e.g. larger healthcare systems may both employ physicians and offer health plans. As this trend continues and given the recent update of the DOJ and FTC's Vertical Merger Guidelines, we anticipate that the FTC may look more closely at transactions in which physician groups are acquired by health plans.

V. CONCLUSION

Physician group consolidation potentially raises both horizontal issues for mergers between physician groups and vertical issues for physician group acquisitions by hospital systems and health plans. Our expectation is that the FTC's general approach to physician group mergers will continue as the healthcare industry evolves. But, the agency will likely adapt to changing industry conditions by revisiting old issues and exploring new ones, particularly as the FTC assesses the competitive impact of prior transactions and reconsiders how physician group transactions should be evaluated. In this article we have highlighted issues that we believe will be important going forward and prepare to evaluate and respond to others that may develop in the future.

19 Available at https://www.ftc.gov/system/files/documents/cases/181_0057_c4677_united_davita_complaint.pdf.

20 FTC complaint in *UnitedHealth-DaVita* at 4-5.

EU COURT OF JUSTICE RULES ON *LUNDBECK* PATENT SETTLEMENT AGREEMENTS

BY MARIE MANLEY & ANNE ROBERT[1]

1 The views expressed in this article are exclusively those of the author and do not necessarily reflect those of Sidley Austin LLP and its partners. This article has been prepared for informational purposes only and does not constitute legal advice. This information is not intended to create, and receipt of it does not constitute, a lawyer-client relationship. Readers should not act upon this without seeking advice from professional advisers.

On March 25, 2021, the Court of Justice of the European Union ("CJEU") published six judgments assessing the patent settlement agreements entered into between Lundbeck (Case C-591/16 P) and several manufacturers of generic medicines. The CJEU dismissed the parties' appeals in their entirety. It upheld the findings of the General Court ("GC") that Lundbeck and the generic manufacturers were potential competitors and that each of the agreements restricted competition "by object" in violation of Article 101(1) of the Treaty on the Functioning of the European Union (TFEU). The Court's legal analysis is largely based on its judgment from January 30, 2020 in the *Paroxetine* case (Case C-307/18). The CJEU nevertheless provides helpful clarifications specific to the Lundbeck agreements.

In one of the judgments (C-611/16 P), the CJEU establishes a novel "specific duty of care" requiring companies to properly retain evidence in the context of a sector inquiry. This obligation may have wide-ranging implications for rights of defense of companies in the pharmaceutical sector and beyond.

I. BACKGROUND

Lundbeck entered into the agreements in 2002. At that time, the compound patent for Lundbeck's antidepressant medicinal product containing the active pharmaceutical ingredient citalopram had expired, but Lundbeck still held several process patents. The latter included patents for the production of citalopram using salt purification methods by crystallization and film distillation. In 2002/2003, Lundbeck planned to launch Cipralex (escitalopram), an antidepressant meant to treat the same patients as those previously treated with citalopram.

The agreements, which covered various geographic areas with some covering the entire European Economic Area, were aimed at settling disputes between the parties. The disputes related to the possible invalidity of Lundbeck's process patents and the possible infringement of those patents by the generic manufacturers had they entered the market with their generic citalopram products. All of the agreements entailed value transfers by Lundbeck to the generic manufacturers in return for the latter's commitment not to enter the market for the duration of the agreement. Some of the agreements allowed the generic manufacturers to distribute Lundbeck's own generic citalopram.

The European Commission ("Commission") was informed about the agreements at issue in October 2003 by the Danish Competition Authority. In January 2008, the Commission initiated its inquiry into the pharmaceutical sector. It issued its decision fining Lundbeck approx. €93.8 million and the generic manufacturers a total of €52.2 million in June 2013, more than 10 years after the agreements were concluded. Lundbeck and the generic manufacturers appealed the decision but the GC upheld the Commission's findings in September 2016 (Case T-472/13 for Lundbeck). In particular, the GC agreed with the Commission that the agreements at issue "were comparable to market exclusion agreements, which are among the most serious restrictions of competition" and thereby restricted competition "by object" (para. 435 of the GC's *Lundbeck* judgment).

II. ASSESSMENT OF POTENTIAL COMPETITION

The CJEU upheld the GC's finding that the parties were potential competitors at the time the agreements were concluded. It affirmed its "test," set out in the *Paroxetine* judgment, to assess whether potential competition exists. Whether a generic manufacturer is a potential competitor depends on whether it has "real and concrete possibilities" to enter the market and compete with the companies present on that market (paras. 54 and 55 of the Lundbeck judgment). This requires in particular an assessment as to whether the generic manufacturer has a "firm intention and an inherent ability" to enter the market, and "does not meet barriers to entry that are insurmountable" (paras. 56 and 57).

The CJEU clarified that although one has to take "due account of the regulatory constraints that are characteristic of the medicine sector and of the intellectual property rights" (para. 56), the existence of a patent, which protects the manufacturing process of an active ingredient that is in the public domain will not qualify as an insurmountable barrier to entry. This is regardless of the presumption of validity attached to that patent because, according to the CJEU, that presumption "sheds no light, for the purposes of applying Articles 101 and 102 TFEU, on the outcome of any dispute in relation to the validity of that patent" (para. 58).

Regarding Lundbeck's process patents, the CJEU agreed with the GC that it was not for the Commission to provide definite proof that the citalopram the generic manufacturers intended to market did not infringe Lundbeck's process patents. The fact that Lundbeck held such patents could not preclude a finding that there was potential competition (para. 61). The CJEU added that it is not necessary to demonstrate with certainty that the generic manufacturers would have entered the market and that such entry would necessarily have been successful (para. 63).

If no insurmountable barriers to market entry exist, the existence of potential competition presupposes only that the generic manufacturer has taken "sufficient preparatory steps to enable it to enter the market concerned within a period of time capable of putting competitive pressure" on the originator manufacturer. It is, however, according to the CJEU of "no relevance whether those steps will in fact be finalized in due time or will be successful" (para. 84). The fact that a generic manufacturer does not hold a marketing authorization at the time a patent settlement agreement is concluded will not exclude it from being considered a potential competitor of the originator manufacturer (para. 83).

The CJEU further confirmed that "additional factors" can be taken into consideration to assess whether potential competition exists. This may include subjective factors (such as the originator manufacturer's perception of the risk that the generic manufacturer presents to its commercial interests), provided that the assessment is not based exclusively or principally on those factors (para. 75).

III. EVIDENCE TO ESTABLISH THE EXISTENCE OF POTENTIAL COMPETITION

The CJEU clarified a number of general principles regarding the assessment of evidence submitted by the parties. It confirmed that "any evidence prior to, contemporaneous with or even subsequent to the conclusion of the agreement at issue may be taken into consideration if it is of such a nature as to throw light on the existence or absence of a competitive relationship between the [companies] concerned at the time when that agreement was concluded" (para. 67). However, evidence unknown to the parties at the time the agreement is concluded is not capable of having influenced their conduct on the market. The CJEU concluded that it can therefore not shed light on the existence or absence of a competitive relationship between them (para. 69).

On that basis, the CJEU found that the GC was right to take evidence subsequent to the agreements at issue (i.e., documents indicating how the parties perceived the strength of Lundbeck's process patents when the agreements were concluded) into consideration. It could, however, refuse to take account of other evidence submitted by Lundbeck also subsequent to those agreements, such as the confirmation by several patent offices of the validity of one of Lundbeck's patents or the fact that Lundbeck "had been 'granted preliminary injunctions or other forms of interim relief' in more than 50% of the proceedings it had initiated in 2002 – 2003" (paras. 70 to 72). This raises the question whether the CJEU's conclusion would have been different if Lundbeck had been granted some (or all) of those injunctions before it entered into the agreements.

IV. RESTRICTION OF COMPETITION "BY OBJECT"

At the outset of its analysis as to whether or not the agreements at issue restricted competition "by object," the CJEU confirmed that the concept of a restriction "by object" must be interpreted strictly. It can be applied only to those agreements "which reveal, in themselves and having regard to the content of their provisions, their objectives, and the economic and legal context of which they form part, a sufficient degree of harm to competition for the view to be taken that it is not necessary to assess their effects" (para. 112).

The CJEU clarified that patent settlement agreements relating to disputes over a process patent for the manufacture of an active ingredient that is in the public domain, which have the effect of delaying the market entry of generic medicines in exchange for monetary or non-monetary transfers of value "cannot be considered to be 'restrictions by object' in all cases for the purpose of Article 101(1) TFEU" (para. 113).

That said, the CJEU added that such agreements will restrict competition "by object" if it is "plain from the examination of the settlement agreement concerned that the transfers of value […] cannot have any explanation other than the commercial interest of [the parties] not to engage in competition on the merits" (para. 114).

This will in particular be the case if the net gain of the transfers of value from the originator manufacturer to the generic manufacturer was "sufficiently significant actually to act as an incentive" to the generic manufacturer to refrain from entering the market concerned. The net gain does, however, not necessarily have to be greater than the profits the generic manufacturer would have made if he would have been successful in the patent proceedings (para. 115).

The CJEU noted a number of facts specific to the Lundbeck agreements and that it was mainly the size of the reverse payments that had induced the generic manufacturers to accept the limitations governing their behavior (para. 117). The CJEU concluded on that basis that the GC was right to characterize the agreements as restrictions "by object" (para. 118). The CJEU explained in particular that Lundbeck had not "in any way" argued that the value transfers could be justified (para. 118). There was "no basis for Lundbeck's attempt to rely on the fact that the agreements at issue are a legitimate expression of its intellectual property rights" (para. 123). The GC had stated in that context that the companies had not demonstrated that the restrictions set out in the agreements at issue were "objectively necessary in order to protect their intellectual property rights" (para. 458 of the GC's Lundbeck judgment). The CJEU moreover found that Lundbeck had not mentioned "any pro-competitive effect associated with those agreements" in the appeal to rebut the characterization of the agreements as restrictions of competition "by object" (para. 136).

V. COUNTERFACTUAL SCENARIO AND NOVELTY OF THE INFRINGEMENT

Regarding the necessity to examine the counterfactual scenario, the CJEU found that this was not required to characterize a concerted practice as a restriction "by object" "unless the clear distinction between the concept of 'restriction by object' and the concept of 'restriction by effect' […] is to be held not to exist" (para. 140).

Moreover, according to the CJEU, for an agreement to be considered to be restrictive of competition "by object," it is "in no way necessary that the same type of agreement has already been censured by the Commission." That remains the case "even if [such an agreement occurs] in a specific context, such as that of intellectual property rights" (para. 130). The CJEU also found that it was "at the very least foreseeable" that the agreements at issue could lead to penalties (para. 161).

VI. "SPECIFIC DUTY OF CARE" TO RETAIN EVIDENCE

In one of the judgments, the CJEU assessed the parties' argument that the GC made an error of law by not properly assessing whether their rights of defense had been violated. According to the parties, the Commission had failed to inform them in a timely manner of the existence of an inquiry and of its objections regarding them. As a result, they did not have certain exculpatory evidence available to them. The CJEU found that the GC erred in law by imposing on the parties an obligation of diligence to keep any document, which might prove useful to their defense. The GC derived that duty of diligence from case law that is applicable only to the period *after* the initiation of the administrative procedure by the Commission. For the parties at issue, this would have been only as of 2010 and 2011 when the procedure against them was launched. However, the CJEU did not annul the GC's ruling on that basis but considered that a substitution of grounds had to be made (para. 149 of the CJEU's judgment in Case C-611/16 P).

The CJEU went a step further and found that the GC was entitled to impose on the parties a (novel) "specific duty of care," which required them to ensure that "information enabling details of their activities to be retrieved is retained properly in their books or records, in order, in particular, that they have in their possession the necessary evidence in the event of subsequent administrative action or judicial proceedings" (para. 151). As a result, even companies which have not yet been put on notice of an investigation "must expect that individual procedures may possibly be initiated against them in the future."

This duty of care arose because the parties were aware of the fact that the Commission had opened its sector inquiry in January 2008 and that the objective of the latter was the examination of agreements concluded between pharmaceutical companies, such as patent settlement agreements. The CJEU held that this should have led the companies to "take precautions against the loss, due to the passage of time, of evidence that might prove to be useful to them in the context of subsequent administrative procedures or judicial proceedings" (para. 152). The CJEU further noted that "sector inquiries are an instrument designed to confirm suspicions of restrictions of competition in the sector concerned by those inquiries" (para. 153).

VII. PRACTICAL IMPLICATIONS

The CJEU's judgments confirm the legal "test" to determine whether a generic manufacturer qualifies as a potential competitor of an originator manufacturer and set out the general principles to assess whether a patent settlement agreement restricts competition "by object." Although the CJEU mostly upheld the GC's findings, and concluded that Lundbeck's agreements restricted competition "by object," a number of practical takeaways for companies can be noted:

- First, the CJEU provides clarifications and guidance relating to the specific facts and agreements at issue in this case. The CJEU refers on a number of occasions to the arguments put forward by Lundbeck and the generic manufacturers before the GC and explains why those did not change the outcome in this case.

- Second, the CJEU confirms that patent settlement agreements need to be assessed on a case-by-case basis and that not all agreements, even if they entail value transfers, will automatically amount to a restriction of competition "by object." Companies have the possibility to justify any monetary or non-monetary value transfers. They may also show that their agreements have pro-competitive effects.

- Third, the CJEU is careful to refer consistently to the fact that the patents at issue were patents which protected the manufacturing process of an active ingredient that was in the public domain. This bears the question whether the assessment may be different if the patent at issue is, for example, a compound patent.

- Fourth, although the CJEU's judgments are final for Lundbeck and the generic manufacturers in this case, several other cases are still pending before the EU Courts. Each of those presents its own facts and context. Those may therefore provide further guidance to companies. This may in particular be the case for the appeals before the CJEU involving, amongst others, originator manufacturer Servier (Case C-201/19 P and Case C-176/19 P). The appeals raise a number of additional questions, including whether or not the agreements at issue restricted competition "by effect" and how the relevant product market should have been defined under Article 102 TFEU. In addition, two other companies recently filed an appeal before the GC against a Commission decision fining them for allegedly having entered into a patent settlement agreement that restricted competition "by object" and "by effect." At Member State level, the Competition Appeal Tribunal ("CAT") in the United Kingdom is expected to issue its final judgment in the Paroxetine case soon. The CAT had referred the case to the CJEU for a preliminary ruling.

- Finally, with regard to the CJEU's novel obligation on companies to adopt a "specific duty of care" when they are subject to a sector inquiry, and "properly retain" evidence that may become useful in a potential follow-on investigation, this may have implications beyond the pharmaceutical sector. It may introduce a wider obligation on companies that are subject to a sector inquiry to retain documents as evidence for potential future individual investigations. This may raise a number of practical concerns, notably if such evidence relates to agreements or conduct that occurred many years prior to an investigation (as was the case for the parties in this case) or even the sector inquiry itself. Such evidence may often no longer exist. Therefore, companies should ensure that they have appropriate document retention policies and guidance in place, which would assist them in case of an investigation in the future.

ENFORCING COMPETITION LAW IN THE ENGLISH HEALTH CARE SYSTEM

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I. INTRODUCTION

In February 2021, the UK Department of Health and Social Care published a white paper titled *Integration and innovation: working together to improve health and social care for all*.[2] The White Paper promises to reform the system of competition enforcement introduced by the Health and Social Care Act of 2012.[3] This follows a request made in the 2019 The Long Term Plan by NHS England for the legislature to "Remove the counterproductive effect that general competition rules and powers can have on the integration of NHS care."[4]

In this article we set out (i) the system in which health care is provided in England and (ii) the role of competition law within that system (iii) a high-level overview of current mechanism for enforcement of competition law in the sector and (iv) the reforms now in view. We conclude by setting out some of the challenges ahead.

II. HEALTHCARE PROVISION IN ENGLAND

The founding principles of the National Health Service in England are that it should provide comprehensive medical care, that is universally available, and free at the point of use.[5] These principles are often described as principles of solidarity or equity. The challenge has always been to harness the power of market competition in a way that is consistent with the principles of solidarity on which the NHS is founded.

The attempt to use competition as a key organising principle of the health service began in 1989 with the publication of *Working for Patients*.[6] This proposed a division between bodies that provide care and bodies that purchase care, creating an internal market. The internal market would, for the first time, establish a link between the volume of activity being performed and the amount of money a health care provider received. It was hoped that this would create incentives for providers to invest in treating an ever-greater number of people more quickly and more efficiently than had been possible in the past.

The internal market was protected by two sets of rules. A first set of rules was ere designed to ensure that NHS bodies on the provider side did not acquire any greater market power than was necessary or desirable and did not abuse any monopoly power they possessed.[7] A second set of rules was designed to ensure the purchaser selects the most efficient provider of health care services. Underpinning these two sets of rules is the central idea that disputes between an NHS purchaser and an NHS provider are internal — such disputes should not be the subject of litigation in the courts but should ultimately be resolved by the Secretary of State.[8]

As the resources devoted to health care increased the protection of the internal market was strengthened, a key publication in this regard being *The future regulation in health and social care in England*.[9] This culminated in what became the Principles and Rules for Cooperation and Competition (PRCC), which covered four areas: (1) **procurement** of NHS services; (2) anti-competitive **conduct** by providers and commissioners; (3) **mergers** between NHS organizations; and (4) false and misleading **advertising** of NHS services.[10] It was argued strongly that account should be taken of social as well as economic objectives when enforcing these rules and that political input would be required to resolve the significant conflicts that arise between the economic and social objectives.[11] As a result, enforcement of the PRCC was not through the courts and remained internal. Instead, in January 2009 the Cooperation and Competition Panel (CCP) for NHS funded services was established under section 2(1)(b)

2 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/960548/integration-and-innovation-working-together-to-improve-health-and-social-care-for-all-web-version.pdf.

3 Integrating care: next steps to building strong and effective integrated care systems across England: https://www.england.nhs.uk/publication/integrating-care-next-steps- to-building-strong-and-effective-integrated-care-systems-across-england/.

4 (Long Term Plan para. 7.14).

5 These principles are set out in section 1 of the National Health Service Act 2006.

6 Department of Health Working for Patients (HMSO, 1988/89).

7 Department of Health The Operation of the Nhs Internal Market: Local Freedoms, National Responsibilities (NHS Executive, 1994) and Diane Dawson "Regulating Competition in the Nhs: The Department of Health Guide on Mergers and Anti-Competitive Behaviour," Centre for Health Economics, University of York, UK: Discussion Paper 131 (1995), 4-5.

8 See J.V. McHale, D. Hughes & L. Griffiths "Disputes in the NHS Internal Market: Regulation and Relationships" Medical Law International (1996)2:215-227.

9 Department of Health "The Future Regulation of Health and Adult Social Care in England," Gateway Ref: 7377 (2006), and Department of Health "The Future Regulation of Health and Adult Social Care in England: Respone to Consultation," Gateway Ref: 8701 (2007), para. 1.7.

10 Department of Health "Principles and Rules for Cooperation and Competition," Gateway Ref: 14611 (2010), 3.

11 King's Fund Response to the Department of Health Consultation on the Future of Regulation of Health and Adult Social Care in England(2007), para. 12 and 23.

of the NHS Act 2006 to provide advice to the Secretary of State in relation to disputes under the PRCC.[12] The advisory role meant that the CCP was reactive only, able to rule on complaints, but unable to launch investigations on its own initiative. The CCP also did not have power to award compensation or prevent infringement by means of injunction.

III. THE HEALTH AND SOCIAL CARE ACT 2012

Three constants since 1989 are the distinction between purchasers and providers; a body of competition rules to supervise the relationship between purchasers and providers; and a system of internal enforcement. A central weakness of the enforcement model is that compliance was not assured — the CCP made recommendations that are for others to implement and the influence the PRCC and CCP actually had on behavior within the sector was limited.[13] The key innovation in the Health and Social Care Act (HSCA) 2012 was to move from internal enforcement to external enforcement. This would make it clearer that compliance was necessary and that the rules would be backed by sanctions. External enforcement was affected by (i) providing a statutory basis to support the PRCC;[14] and granting the sector regulator, at the time styled Monitor, concurrent powers with the CMA so as to enable it to enforce Chapter I and II of the Competition Act 1998 in relation to health care service providers. Further, section 79 of the Health and Social Care Act 2012 would ensure that the Competition and Markets Authority could apply the Enterprise Act 2002 (in so far as it would not otherwise apply) to control mergers involving NHS foundation trusts.[15] Finally, the Public Contracts Regulations 2015 and section 75 of the HSCA 2012 would provide a route to court adjudication over decisions to allocate resources to particular providers.

The Health and Social Care Act 2012 struggled to bring about the change in behaviour envisaged.[16] By 2014 the idea of turbo-charging 1989 with enhanced enforcement was very much on the wane.[17] Regulators of NHS trusts and foundation trusts are often the instigators of a transaction with the potential to create market power.[18] The risks of market power are viewed as being outweighed by the advantages of dealing with clinical, operational or financial challenges by enabling highly regarded management teams to take struggling organizations under their wing. Providers have struggled to understand the nature of an objection to a transaction that the regulator has proposed, supports or encourages. Further, the Competition and Markets Authority has ultimately approved all transactions proposed and so the question as to what merger review adds to the process — other than cost and delay — has been asked. On the purchasing side, the perception was of there being only one possible outcome but demonstrating this in accordance with Public Contracts Regulations 2015 and Regulations promulgated under section 75 of the HSCA 2012 was costly, complex, and always subject to the threat of legal challenge.

12 Department of Health "Principles and Rules for Cooperation and Competition," Gateway Ref: 14611 (2010), 5.

13 This is a long standing criticism: see Diane Dawson "Regulating Competition in the Nhs: The Department of Health Guide on Mergers and Anti-Competitive Behaviour," Centre for Health Economics, University of York, UK: Discussion Paper 131 (1995), 5-8, 11.

14 Department of Health "Government Response to the Nhs Future Forum Report," command 8113 (2011), paragraph 5.16.

15 Health and Social Care Bill 2011: Impact Assessments: Annex B, B119. And EA 02, s 22.

16 See Nicholas Timmins, Never Again? The story of the Health and Social Care Act 2012 (The King's Fund and the Institute for Government, 2012) and Alderwick H, Ham C. NHS in England embraces collaboration in tackling biggest crisis in its history. BMJ2016;352:i1022.doi:10.1136/bmj.i1022 pmid:26902256:

17 (Five Year Forward View).

18 (Long Term Plan para. 1.53).

IV. THE NEW SYSTEM ARCHITECTURE: ENFORCEMENT DE-EMPHASISED

The new model for the health service in England is set out in the 2019 Long Term Plan.[19] The point of departure for the new model is to accept that focusing on volume of activity is not a good way to view the productivity of a health system and can instead incentivise behavior that is not productive. The aim of reform is to develop system architecture capable of preventing people becoming sick and enabling them to live health lives rather than a system capable of treating an ever-increasing number of sick. To do so, the first key change is to incorporate providers of primary, community, mental health, and acute hospital services into provider collaboratives. The second key change is to establish integrated care systems ("ICS") as statutory bodies that will decide "how to use resources, design services and improve population health."[20] Each ICS will be responsible for securing the provision of health services to meet the needs of the population from provider collaboratives.[21] Finally, rather than unit pricing, provider collaboratives will receive blended payments, comprising a fixed element to cover all treatment or care required by a population, plus a variable element designed to incentivise particular activity or behavior.[22]

Whether the new system architecture can achieve its objective is open to debate, but the new architecture clearly requires a modification of the role that competition law plays in the allocation of health care resources.[23] The HSCA 2012 modified the three constants in place since 1989 so that while a distinction between purchasers and providers and a body of competition rules to supervise the relationship between purchasers and providers were maintained, a system of external enforcement was introduced. Ending recourse to competition might have meant restricting the ability to provide NHS-funded services to NHS bodies, so that NHS organisations would not be in competition with other types of provider (though they would remain in competition with other NHS provider bodies). Ending competition might also have meant restricting the ability of NHS-funded patients to choose the provider of their treatment or care, with the money following the patient. Neither of these approaches are taken to ending competition in the White Paper and instead the White paper states that "It has become clear that the CMA is not the right body to review NHS mergers."[24] Rather than the CMA the White Paper proposes that it be for "NHS England, as overseer of the system, to ensure that decisions can always be made in the best interests of patients."[25]

The return to internal adjudication, or at least the remove of a threat of external scrutiny, is also proposed on the purchasing side. Purchasing decisions will not be subject to procurement law and the threat of court action, but instead, a bespoke health services provider selection regime that puts pragmatism at the heart of the system will be created.[26] The Government is currently consulting on the regime. There is a concern that absent a robust procurement regime there will be waste and cronyism.[27] What that regime will look like and whether it is capable of addressing the acknowledged risks in the purchasing decision is an open question.[28]

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19 NHS. The NHS long term plan. 2019. https://www.longtermplan.nhs.uk/ See also Alderwick H, Dixon J . The NHS long term plan. BMJ2019;364:l84. doi:10.1136/bmj.l84 pmid:30617185.

20 (NHS Long Term Plan, para. 1.51).

21 (White Paper; para. 5.7; para. 3.15 and para 5.8) The White paper says that within an ICS it will be necessary "To manage conflicts of interest, any procurement decisions – including whether to procure – would be reserved to the commissioner only." (para. 7.14).

22 NHS England, NHS Improvement. Developing the payment system for 2021/22: engagement on national tariff and related contracting policies for 2021/22. 2020. https://improvement.nhs.uk/documents/6779/Developing_the_payment_system_for_2021-22.pdf.

23 The National Audit Office considers that there is not yet a robust evidence base to show that integration leads to better outcomes for patients or lower cost of health care provision: See https://www.nao.org.uk/wp-content/uploads/2017/02/Health-and-social-care-integration.pdf.

24 (White Paper para. 5.42).

25 (White Paper 5.42).

26 (White paper para. 3.15. Also para. 5.47); (Long Term Plan para. 7.14).

27 R on the application of Good Law Project Limited and others v Secretary of State for Health and Social Care. 2021 www.bailii.org/ew/cases/EWHC/Admin/2021/346.html and Iacobucci G. Covid-19: Government has spent billions on contracts with little transparency, watchdog says. *BMJ*2020;371:m4474. doi:10.1136/bmj.m4474 pmid:33208349; Martin McKee. England's PPE procurement failures must never happen again. BMJ 2020; 370:m2858 doi: https://doi.org/10.1136/bmj.m2858 (Published July 17, 2020). ; Elisabeth Mahase. NHS reorganisation must not be rushed through during pandemic, leaders warn BMJ 2021; 372:n431 doi: https://doi.org/10.1136/bmj.n431 (Published February 11, 2021).

28 https://www.england.nhs.uk/publication/nhs-provider-selection-regime-consultation-on- proposals.

V. CHALLENGES

The future of competition in the English health care system remains to be revealed in detailed legislative proposals, though some of the challenges are now clear. For example, the Long-Term Plan acknowledges "the CMA's critical investigations work in tackling abuses and anti-competitive behaviour in health-related markets such as the supply of drugs to the NHS" and suggest that this will be maintained.[29] What also of the role played by the CMA and Competition Act 1998 when NHS bodies operate in markets that are not state-funded? NHS trusts and NHS foundation trusts remain specifically empowered to engage in activity with the specific aim of generating a profit, having been granted so-called "income generation" or "wider market" powers.[30] HM Treasury has opined that the exercise of such power is always subject to competition law.[31]

The model of health care provision retains separate provider organisations that still rely on obtaining resources from purchasers of health care services.[32] Patients and ICS must still choose their provider and that choice will still have implications for resource allocation. While not be a traditional model of competition, competition law's role had been to ensure that the choices offered are fair or made on a rationale, open and transparent basis. Changing the system level rules and the oversight regime does not eliminate competition in itself. Maintaining the fundamental market features while reforming the system of enforcement may be based ultimately on an acceptance that "competition" has proven to be effective.[33] The white paper makes clear the intention to retain a plurality of health care service providers, so that an ICS may purchase health care services from NHS trusts and foundation trusts, as well as from independent, voluntary and community providers. Will those outside the NHS family be content to participate in a system that is adjudicated on by NHS family members? Within the NHS there are institutions that are too big, or too important to fail, but which draw resources away from other institutions and organisations that are capable of making better use of those resources. Does the new system architecture provide a transparent mechanism for identifying when this is occurring and a mechanism to prevent it from occurring? Patients in England will continue to enjoy the right to choose the provider of their hospital and specialist healthcare *within* the State-funded system.[34] Will patient voice matter or will the need for resources to flow to a particular institution take precedence?[35] What mechanism will be in place to prevent such "market sharing"?

What is missing from the White Paper, and what we hope will reveal itself through the legislative process, is a clear articulation of what we are trying to achieve. What is clear is that external enforcement is not desired. What is not clear, particularly since so many market features are retained, is whether the idea of competition has been abandoned.

29 (Long term Plan para. 7.14).

30 National Health Service Act 2006 s 43(3). Health and Medicines Act 1988 s 7(2); National Health Service Act 2006 Sch 4 para 20(1). National Audit Office 'Income Generation in the Nhs' REPORT BY THE COMPTROLLER AND AUDITOR GENERAL (1993),.

31 Hm Treasury "Selling into Wider Markets: A Policy Note for Public Bodies," Enterprise & Growth Unit (2002), para. 18, also Annex B, para. 16. and Hm Treasury "Managing Public Money," (2007), box A.7.6A, noting that public entities operating in wider markets "must comply with general competition law."

32 (White Paper para. 5.8, 5.11-5.12) and (NHS Long Term Plan, para. 1.51).

33 See for example Zack Cooper, Stephen Gibbons, Simon Jones, Alistair McGuire, "Does Hospital Competition Save Lives? Evidence from the English NHS Patient Choice Reforms" The Economic Journal, Volume 121, Issue 554, August 2011, Pages F228–F260, https://doi.org/10.1111/j.1468-0297.2011.02449.x and Russell Whitehouse and Pasquale Schiraldi, "Does hospital competition reduce rates of patient harm in the English NHS?" (CMA Economics working paper January 2019): https://www.gov.uk/government/publications/does-hospital-competition-reduce-rates-of-patient-harm-in-the-english-nhs.

34 Department of Health "The Handbook to the Nhs Constitution," Gateway Ref: 17278 (2012), 51. (White Paper para. 3.11. See also paras 5.35 -5.38). also (Long Term Plan para. 7.14).

35 Richard Murray. NHS reforms: politicians will be back in the driving seat BMJ 2021; 372:n481 doi: https://doi.org/10.1136/bmj.n481 (Published February 19, 2021).

RETHINKING COMPETITION IN HEALTHCARE – REFLECTIONS FROM A SMALL ISLAND

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I. INTRODUCTION

Competition reforms in healthcare are often seen as a challenge, if not outright problematic, given the range of questions posed. Is competition intended as a means to an end, or an end in itself? Is the focus on competition on price, or quality, or both? Competition *for* or *in* the market? How much competition, and who decides this? What can be learned from other sectors, or other countries? Can competition only be antithetical to an overarching aim of delivering a healthcare system based on universal access?

Some of these questions can be answered by starting with the healthcare system type. Insurance-based systems can offer greater scope for competition than taxation-funded ones. Where a private healthcare market coexists with a public healthcare system, there may be both scope for both competition *for* and *in* the market, although the focus may differ: competition on price in the former, competition on quality in the latter. The experience from other sectors may help shape the corresponding regulatory framework – for example, introducing a licensing regime, or determining the relationship between the government, competition authority and sectoral regulator.

What emerges is that competition reforms can affect all three levels of a healthcare system: the macro level (interaction between government/competition authority/sectoral regulator), the meso level (healthcare purchasers) and the micro level (healthcare providers). Yet it is the final question which arguably proves the most challenging: the tension between solidarity and competition mean it is difficult to strike a balance, and the political sensitivities which can arise in connection with marketisation should not be underestimated. This can lead to further – more nuanced – considerations such as whether general rules are enough, or "healthcare-specific" modifications are needed, and who should apply the rules, with a general distinction emerging between government or regulators.

Between approximately 1989 and approximately 2019, the taxation-funded National Health Service ("NHS") in England[2] experimented with varying degrees of competition reforms under governments across the political spectrum. This period started with the introduction of the NHS quasi-market, characterized by the separation of purchasing and providing functions proposed by Alain Enthoven,[3] which underpinned successive competition reforms culminating in the Health and Social Care Act 2012 (HSCA 2012). This proved a highly controversial piece of legislation, but serious reform has emerged only recently, with the 2019 NHS Long Term Plan, which forms the basis for current legislative proposals. These were outlined in February 2021[4] to enshrine the current policy (since approximately 2015) of developing integrated care systems (ICSs) and move decisively away from competition. There have been further developments regarding competition with responses to COVID-19 which may also affect the evolution of these proposals.

This paper reviews the treatment of the prohibition on anticompetitive agreements and merger control under the HSCA 2012 reforms since these demonstrate clearly both some of the difficulties in setting out a competition regulation framework.

II. THE "FOUR CATEGORIES" AND A SHORT HISTORY OF COMPETITION IN THE NHS

Competition in English healthcare has two broad aspects.

Firstly, the sense of competition which has emerged with the coexistence of the NHS and the smaller, supplementary private healthcare market. This might broadly be considered a type of competition *in* the market insofar as patients have the option to "go private" to receive treatment, for example to avoid lengthy waiting lists, or to receive a particular treatment. It can also be possible to combine NHS and private treatment in certain circumstances.

Secondly, the successive concerted efforts to introduce competition reforms in the NHS in England by governments across the political spectrum. These efforts have sought to replicate the wider interaction between the NHS and private healthcare in some ways via patient choice policies, but mainly can be described as competition for the market.

2 But not Wales, Scotland or Northern Ireland. It should also be noted that the NHS is subject to different oversight regimes across the four countries of the UK.

3 Alain C. Enthoven, *Reflections on the Management of the National Health Service – An American looks at incentives to efficiency in health services management in the UK*, Nuffield Trust, 04/10/1985.

4 Department of Health and Social Care (DHSC), *Integration and Innovation: working together to improve health and social care for all*. CP381. February 11, 2021.

A combination of the wider relationship between the NHS and private healthcare and the separation of purchasers and providers which has characterized successive competition reforms, mean it is possible to speak of "four categories":[5]

1. Public Purchaser and Public Provider	2. Public Purchaser and Private Provider	3. Private Purchaser and Public Provider	4. Private Purchaser and Private Provider

Broadly, categories 1 and 2 relate to the NHS, and 3 and 4 to the private healthcare sector, so could represent the aforementioned "first aspect" of competition. This includes the development of the private healthcare market by the CMA.[6]

The "second aspect" is illustrated by the HSCA 2012 framework and successive policies to encourage expansion of private sector delivery of NHS services in category 2, and to develop NHS bodies (NHS Foundation Trusts) to have greater autonomy from central government and operate in a more commercial manner, for example, by running private patient units (in category 3).

The HSCA 2012 reforms were threefold: to reduce ministerial oversight of the NHS by introducing an "arms-length" oversight body (NHS England); to enshrine in legislation NHS competition policy inherited from previous governments; and to bring competition in the NHS into line with the experience of other sectors (such as energy) by NHS Improvement and the CMA sharing concurrent powers (or being "co-competent")[7] to apply general competition law. While these may appear overly ambitious with hindsight, the controversy surrounding the enactment of the HSCA 2012[8] led to a scaling back of the original scope for the competition reforms, and ongoing concerns limited these still further with the shift to integration. Part of the controversy surrounding the HSCA 2012 framework was the explicit involvement of the CMA in overseeing the NHS (categories 1 and 2), as well as the private healthcare market (categories 3 and 4) and providing for the application of general competition rules with regard to cases of providing healthcare services for the NHS.

The current legislative proposals represent a near total volte-face, in statements such as "[t]he NHS should be **free to make decisions on how it organises itself without the involvement of the [CMA]**";[9] and "[i]t has become clear that the CMA is not the right body to review NHS mergers."[10] Although draft legislation is pending, and further detail may yet emerge, references to the underlying substantive law framework are conspicuous by their absence, and the focus on oversight has been described as "deregulation, not demarketisation."[11] As the overarching purpose of the current proposals is to enable development of Integrated Care Systems, which are defined as "…new partnerships between the organisations that meet health and care needs across an area…,"[12] it is difficult to see how competition law may cease to be relevant totally. Indeed, the focus on partnerships raise questions about the scope of both the prohibition on anticompetitive agreements and the assessment of mergers, so new legislation should offer an opportunity to examine how current policy may benefit from competition law, or where exceptions can be used effectively.

5 M Guy, *Competition Policy in Healthcare – Frontiers in Insurance-Based and Taxation-Funded Systems*, Intersentia 2019, and developed from the relationships as set out in Office of Fair Trading (OFT), *Private Healthcare Market Study*, OFT1396, and Okeoghene Odudu, "Competition Law and the National Health Service," *Competition Bulletin: CompetiStion Law Views from Blackstone Chambers*, October 8, 2012.

6 CMA, Private Healthcare Market Investigation Final Report, CMA25, May 2, 2014.

7 The term used by Albert Sánchez Graells, "Monitor and the Competition and Markets Authority," (2014) *University of Leicester School of Law Research Paper*, No. 14-32.

8 Which included a three-month pause in the passage of the legislation to address some of the concerns.

9 Above n3, paragraph 3.15. Emphasis as per the original.

10 *Ibid*. paragraph 5.42.

11 Health and Social Care Committee, *NHS Long-Term Plan: Legislative Proposals* (HC 2017-19, 15), page 16, citing written evidence by Andrew Taylor, former Director of the Cooperation and Competition Panel for NHS-funded Services.

12 NHS England, "What are integrated care systems?," https://www.england.nhs.uk/integratedcare/what-is-integrated-care/.

III. PROHIBITION ON ANTICOMPETITIVE AGREEMENTS

The HSCA 2012 reforms introduced two levels of competition oversight and rules with regard to the prohibition on anticompetitive agreements.

The first had the effect of including this within a wider "NHS-specific" prohibition on "anticompetitive behaviour,"[13] which was then made specific to providers by the licensing regime,[14] and to NHS commissioners (purchasers) by specific regulations.[15] The intention was for NHS Improvement, the regulator, to apply these specific provisions as needed, although no recourse was ultimately made.

The second was the prohibition on anticompetitive agreements contained in the UK Competition Act 1998.[16] The HSCA 2012 introduced a new oversight regime here too in that the CMA and NHS Improvement were to share "concurrent powers" in applying the prohibition,[17] consistent with the interaction between the CMA and economic regulators in other sectors. This prompted questions about the application of competition law, with the CMA being clear that its enforcement priorities lay with category 4 rather than category 2,[18] after its predecessor had issued a compliance notice to NHS providers regarding the sharing of sensitive commercial information about their private patient units[19] (category 3), consistent with the wider focus on the private healthcare market.

Given the consensus that general competition law is applicable in connection with the NHS,[20] one explanation for the lack of recourse is seen with the controversies surrounding the HSCA 2012 reforms. As noted above, the CMA or NHS Improvement could apply general UK competition law to cases involving NHS provision, consistent with the wider "concurrency" framework within the UK competition regime. However, the effect of this was subsequently amended to reserve such cases to NHS Improvement only.[21] The current proposals for legislative reform would see this power being removed from NHS Improvement as well. Consequently, there exists a situation where general UK competition law may be applicable, but it is unclear who would apply it. Whether this would pave the way for private enforcement is moot.

However, the competition landscape in healthcare may be changing – or at least be being redefined – by COVID-19. In March 2020, an "historic deal" was signed between NHS England and the Independent Healthcare Provider Network enabling the vast majority of private providers to support the NHS in the initial response phases – a move which encapsulated all of the above 4 categories.

This was given effect in law by a Public Policy Exclusion Order, a temporary mechanism for relaxing competition law with regard to specific kinds of agreement which would otherwise be deemed anticompetitive. Examples include sharing information about capacity to provide certain services, coordination on deployment of staff, sharing or loan of facilities, joint purchasing of goods, facilities or services, and division of activities, including agreement to limit or expand the scale or range of services supplied by one or more providers.[22] Although the mechanism is intended to be temporary, it is defined by reference to the "healthcare disruption period," which may be considered to be longer than the "disruption period" of other sectors also receiving such orders (such as groceries) which lasted only a few months. Various collective agreements have been notified under this Order, so cover not only the initial crisis response, but also continuity responses as non-COVID-19 services have been restarted to run alongside crisis responses.[23] While the initial crisis response included all four categories, the subsequent agreements notified under the Order appear to focus increasingly on category 2 activity as the private healthcare market (specifically category 4) re-establishes itself to continue alongside the NHS, seemingly re-affirming the long-standing coexistence of the two.

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13 Section 64(2) HSCA 2012.

14 The Choice and Competition condition of the NHS Provider Licence. https://www.gov.uk/government/publications/the-nhs-provider-licence.

15 Regulation 10 of The National Health Service (Procurement, Patient Choice and Competition) Regulations (No.2) 2013.

16 Section 2 CA 98.

17 Section 72 HSCA 2012.

18 CMA, "60-second summary: Private medical practitioners: information on competition law," December 3, 2015.

19 Office of Fair Trading (OFT), "OFT welcomes action by NHS trusts to ensure compliance with competition law," *OFT Press Release* 71/12, August 16, 2012.

20 O. Odudu, "Are State-owned healthcare providers undertakings subject to competition law?," (2011) 32(5) *European Competition Law Review* 231.

21 By Regulations 5 and 8 of the Competition Act 1998 (Concurrency) Regulations 2014.

22 Article 3(2) of the Competition Act 1998 (Health Services for Patients in England) (Coronavirus) (Public Policy Exclusion) Order 2020.

23 https://www.gov.uk/guidance/competition-law-exclusion-orders-relating-to-coronavirus-covid-19#history.

In light of the "four categories," the development of ICSs might appear to suggest an expansion of category 2 activity, if not a conflation of categories 1 and 2. However, the applicability of the prohibition on anticompetitive agreements with regard to ICSs may be in question insofar as ICSs are intended to remove "traditional divisions between hospitals and family doctors, between physical and mental health, and between NHS and council services."[24] What appears to be envisaged is collaborations between healthcare providers operating in different markets, so not competing directly. In addition, provided benefits can be demonstrated which outweigh anticompetitive effects, this may also serve to question whether arrangements may fall foul of the prohibition. However, it may be the case that there are also collaborations between providers who would typically compete, so in developing new legislation, it would be positive to provide explanations of how and why competition law may not be applicable[25] to help facilitate delivery of the reforms.

IV. MERGER CONTROL

Section 79 HSCA 2012 made provision for the UK general merger control regime to be applied to mergers involving NHS Foundation Trusts, with the other parties to the merger including NHS or private providers. Thus, NHS mergers were for the first time to be subject to at least a Phase I (and sometimes Phase II) examination of whether a merger would give rise to a substantial lessening of competition, as opposed to an "NHS-specific" version of this test. In contrast to the "antitrust" rules, questions of applicability of UK general merger control to the NHS have not arisen in the same way: the main question being whether a merger between NHS bodies represented the requisite "change in control," as different NHS bodies have lesser or greater autonomy from central government. The CMA was given sole responsibility for approving or blocking a merger, but NHS Improvement was given responsibility for identifying "relevant patient benefits," based on the general concept of "relevant customer benefits,"[26] which could offset a substantial lessening of competition. At the time the HSCA 2012 was enacted, there was a policy in place to encourage certain NHS bodies (NHS Trusts) to achieve greater autonomy and NHS Foundation Trust status, and it was anticipated that this would progress, but was discontinued around 2014.

The first hospital merger – between two NHS Foundation Trusts in Dorset – to be assessed under the HSCA 2012 regime was blocked in 2013, leading to much criticism, but was eventually approved in May 2020. Subsequent mergers were approved, with increasing reliance on the "relevant patient benefits" mechanism which was extended to cover evolving NHS policy, including the initial stages of ICS development. The effect of this has been that the majority of mergers have been approved at Phase I, and where complications were anticipated, merging parties have requested assessment under an expedited Phase II investigation, such as happened with the *Manchester Hospitals* merger in 2017. This merger also saw a significant intervention by the CMA in its acknowledgement of the changing NHS policy background to focus on integration. Although reform of the HSCA 2012 competition framework had been called for at various intervals and by various quarters since its enactment, to see the competition authority acknowledge that competition "…currently plays a limited role in the NHS and is not the basic organising principle for the provision of NHS services"[27] was striking. In approving the *Dorset Hospitals* merger in May 2020, the CMA effectively acknowledged that its role in such mergers was coming to an end in line with the NHS Long Term Plan proposals. This seems logical: what purpose is served by assessing whether a proposed merger gives rise to a substantial lessening of competition in a system which the competition authority acknowledges is not based on competition? And indeed, how can this be done?

The current legislative proposals envisage transferring authorization power from the CMA to NHS England "…to ensure that decisions can always be made in the best interests of patients."[28] It is clear, however, that this refers only to mergers involving two or more NHS Foundation Trusts, as distinct from a merger which involves, for example, an NHS Foundation Trust and a private provider. In the latter case, the CMA will still be involved,[29] which simply appears to reflect the current situation under HSCA 2012.

24 https://www.england.nhs.uk/integratedcare/what-is-integrated-care/.

25 As happened in the Netherlands in connection with recent healthcare reforms. The Netherlands Authority for Consumers and Markets (ACM), ACM Policy Rule on arrangements as part of the movement called "The right care in the right place." Case no. ACM/19/034968 Document no. ACM/UIT/524798.

26 Section 30(1)(a) EA02.

27 CMA, Central Manchester University Hospitals/University Hospital of South Manchester merger inquiry. Final Report. August 1, 2017.

28 DHSC (above n3), para 5.42.

29 *Ibid.* para 5.43.

A further notable aspect of the current legislative proposals is that a scaling-back of NHS England's powers is envisaged, with the Secretary of State for Health regaining more power of direction over day-to-day operation of the NHS. It appears that this may extend to merger assessment, in that where the minister directs a reconfiguration or a merger, this will be subject to a public interest test.[30] Whether this would take the form of the current Public Interest Intervention Notice mechanism within the UK merger control regime,[31] whereby the CMA would advise the minister on the decision, remains to be seen, but would represent a very distinctive change in direction.

V. CONCLUDING REMARKS

It is clear that the current legislative proposals represent a long-standing rethinking of competition in English healthcare. In light of the foregoing remarks about the complicated evolution of the prohibition on anticompetitive agreements and merger control within the HSCA 2012 reforms, it is not difficult to see why competition might be seen as "bureaucracy" in need of reduction. This perhaps suggests the problem lies more with the HSCA 2012 vision of competition, rather than competition law and policy in a general sense. Indeed, the HSCA 2012 experience highlights some of the pitfalls in designing legislation to enshrine a particular policy direction in healthcare, a sector with particular need for flexibility.

With the current legislative proposals, the underlying market structures of the NHS and private healthcare sector remain, although the shift towards integrated care models may suggest that the distinction between the NHS and private healthcare may ultimately outweigh the disaggregation of "four categories." In recognising the significant cultural shift away from the purchaser/provider separation, there is a need to clarify the parameters of applicability of competition law in the current environment, even if this means acknowledging where competition law is not expected to be applied.

Part of the failings of the HSCA 2012 reforms might be attributed to the attempt to map competition mechanisms (such as concurrent oversight powers and a licensing regime) onto the NHS in the erroneous belief that competition would simply work in the same way as in other sectors. This belief was erroneous because it failed to engage with the complexity of the tension between solidarity and competition and the associated political sensitivities attached to the core principles of the NHS, which favor solidarity.

Starting from the configuration of the healthcare sector – the interaction between the NHS and smaller, supplementary private healthcare market – would have been a more logical approach. More recently there has been some evidence of more nuance, and recognition that competition can work in different ways in healthcare. Notably, a distinction was drawn in the 2019 NHS Long Term Plan between the HSCA 2012 reforms, and the CMA's activity concerning pharmaceutical companies found to have charged the NHS excessive prices for certain drugs has been held up as a positive example of competition. This vision would see the NHS effectively cast in the role of consumer in need of protection against anticompetitive conduct, which could be extended beyond the realm of pharmaceutical regulation, to healthcare provision.

A shift towards integration enables a rethink of the scope for competition in healthcare reform. This is welcome, particularly at a time when benefits of collaboration between NHS and private providers have been in evidence in responding to COVID-19.

30 In response to Q142. Health and Social Care Committee Oral evidence: Department's White Paper on Health and Social Care, HC 1274, Tuesday, March 16, 2021. https://committees.parliament.uk/oralevidence/1881/pdf/.

31 Section 42(2) Enterprise Act 2002.

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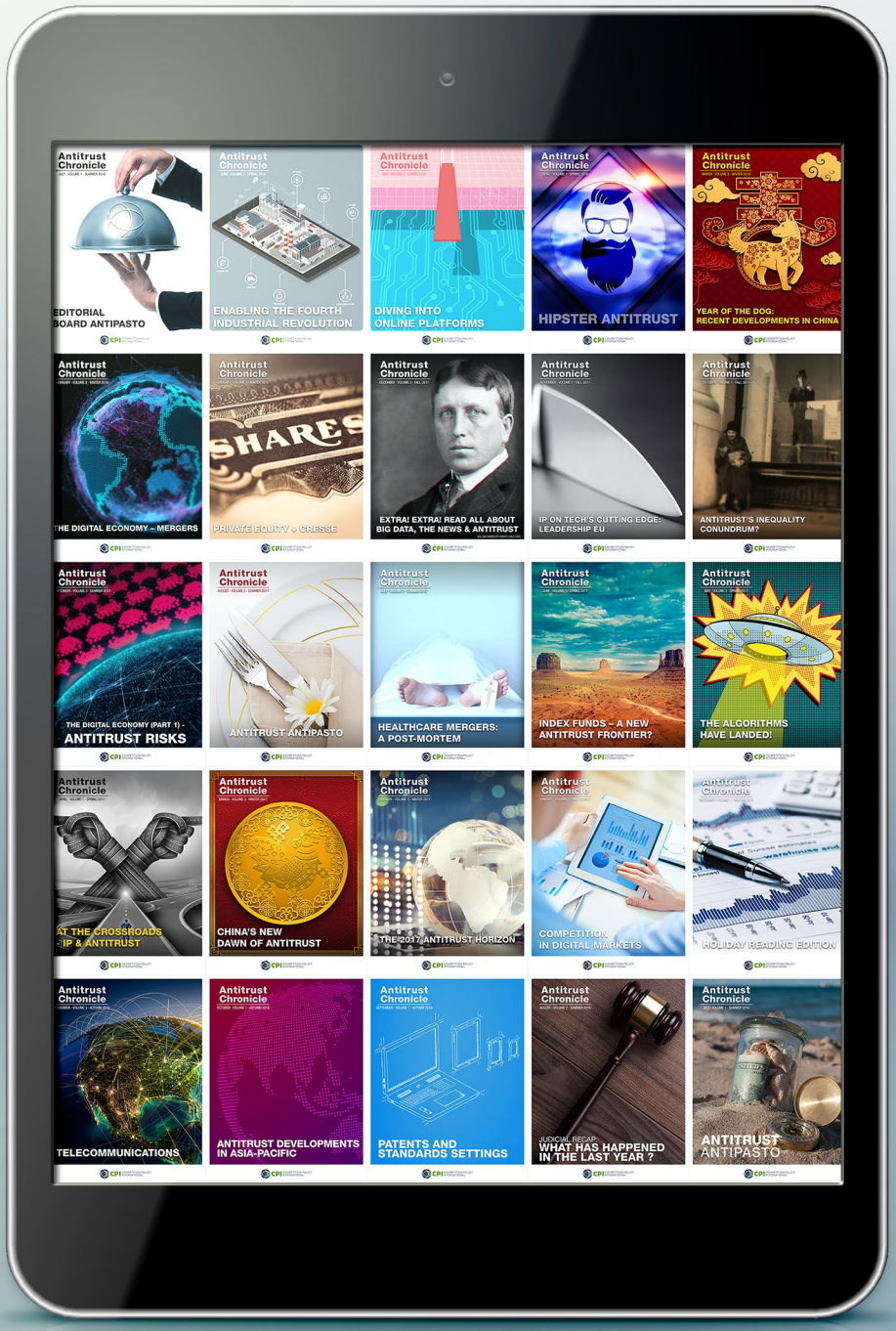


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