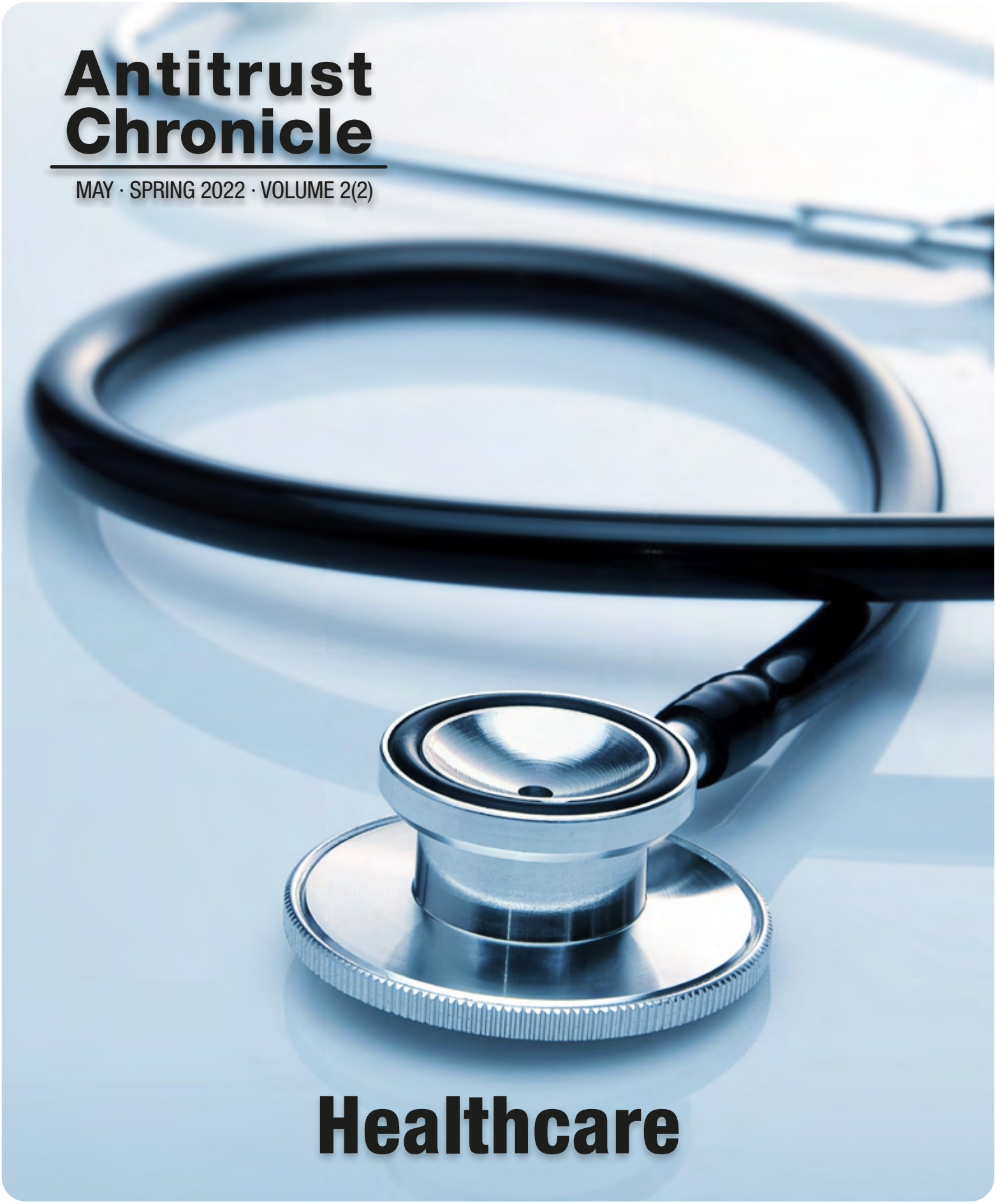
Antitrust Chronicle

MAY · SPRING 2022 · VOLUME 2(2)



Healthcare

CPI COMPETITION POLICY™ INTERNATIONAL

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LETTER FROM THE EDITOR

Dear Readers,

More than any sector, healthcare has come under particular scrutiny in recent years. The reasons are almost too obvious to state. The pandemic; soaring costs; difficulties in the supply chain for key medicines – all have propelled healthcare to the headlines on both sides of the Atlantic, and beyond.

The vagaries of medical research; the difficulties inherent to insurance; and the intrinsic risks based on investment into medical research all feed into this concern.

As Andrew Stivers, Emily Walden & Subramaniam Ramanarayanan illustrate, healthcare antitrust practitioners are grappling with the increasingly prominent value of patient data in competition. This data can be examined using traditional antitrust concepts. However, other stakeholders have raised more skeptical questions about consumers' interests in mergers, particularly from a privacy perspective. Specifically, these relate to four key concerns: price discrimination, data security, intrinsic value and autonomy.

Amanda Wait & Antonia Mordino draw out the conclusions deriving from Alvaro Bedoya's confirmation; and how this has restored a Democratic majority on the Federal Trade Commission. Under a Democratic majority, FTC Chair Khan would have the ability to continue to test novel theories of harm in various antitrust matters. Interestingly, Commissioner Bedoya's background in privacy and technology could potentially broaden the scope of both merger and non-merger investigations.

Michael Carrier addresses how the intersection of patent law and antitrust presents several challenges for courts, particularly in the pharmaceutical industry. What should courts do when drug companies engage in conduct that may be allowed under patent law but threatens significant anticompetitive effects? The article focuses on patent settlements, analyzing four mistakes U.S. courts have made: 1) resurrecting the "scope of the patent" test, 2) bestowing immunity on patent licenses, 3) imposing high causation standards for patent invalidity, and 4) resuscitating a "risk aversion" defense.

Ken Field & Steven Tenn address the issue of hospital merger cases. Typically, such cases are won or lost on geographic market definition. The U.S. Third Circuit's recent finding that it is appropriate to define geographic markets based on patient location will likely incentivize the FTC to define such geographic markets more frequently in future hospital merger litigations.The article considers the implications of defining a geographic market based on patient location and highlights a key shortcoming of this approach. Virtually any candidate geographic market based on patient location likely passes the Merger Guidelines' Hypothetical Monopolist Test, and any such conclusion is possibly meaningless from the point of view of antitrust analysis. As a result, the FTC's reliance on patient-based markets could erode courts' willingness to endorse the Merger Guidelines' approach to such issue.

Peter Herrick, Lisl Dunlop & Matthew Hayden address the consequences of AAG Jonathan Kanter's recent pronouncement that the Government will "fight for American workers including in connection with illegal mergers that substantially lessen competition for laborers." This formulation, which once may have been outside the mainstream, is now widely shared among enforcers and policymakers alike. The U.S. antitrust agencies have now stated their intent to focus on labor markets, including in merger reviews. However, courts' limited past consideration of labor market issues results in there being no clear guidance. Some economic studies purport to link concentration in labor markets with lower wages. However, these studies are not without flaws. The piece provides valuable insight in how such inquiries might continue into the future.

David A. Balto examines the U.S. FTC's allegedly lax approach to Pharmacy Benefit Managers ("PBMs"), the middlemen in prescription drug markets. This has allegedly led to significant concentration, higher prices, and other potentially abusive practices. As the article outlines, the FTC is considering conducting a study of PBM practices under Section 6(b) of the FTC Act. This study could provide the public with greater insight into PBMs' drug pricing practices, contracts with drug manufacturers, and contracts with independent pharmacies.

Finally, Dina Older Aguilar, Andrew Sfekas, Arthur Corea-Smith & Shannon Wu note that mergers that expand healthcare systems are increasingly under scrutiny. Academic studies have found evidence of price increases following mergers combining hospitals that are too distant to serve as close substitutes for most patients — so called "cross-market" mergers. The models used in such studies note mechanisms under which a cross-market merger could potentially affect the set of options available to insurers in constructing provider networks. As a result, in order to assess the likely impact of an individual merger, the specific features of the proposed merger and competitive environment should be compared to the proposed theoretical mechanisms under which cross-market mergers may impact prices.

In sum, the set of articles in this Chronicle set out a broad cross-section of the issues that will arise (and have already arisen) in the interaction between healthcare and antitrust in the foreseeable future.

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

Sincerely,

CPI Team

SUMMARIES

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NOVEL PRIVACY CONCERNS IN HEALTHCARE ANTITRUST

By Andrew Stivers, Emily Walden & Subramaniam Ramanarayanan

Healthcare antitrust practitioners are grappling with the increased value and prominence of patient data in competition. In many respects, this data can be examined using traditional antitrust concepts. However, antitrust authorities and other stakeholders have also raised questions about consumers' interests in mergers, or other competition practices from a privacy perspective. Privacy advocates have identified a range of possible welfare effects stemming from the commercial collection and use of personal data. Four of these – price discrimination, data security, intrinsic value and autonomy – seem likely to also be applied in some form to antitrust with varying degrees of overlap with traditional consumer welfare analysis. We examine these issues in the context of healthcare, but the analysis is likely to apply similarly to other areas of antitrust.

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PBMS: THE MIDDLEMEN WHO DRIVE UP DRUG COSTS

By David A. Balto

Ensuring effective competition in healthcare markets is a critical priority for antitrust enforcers. Traditionally enforcement has focused on manufacturers and providers but far too little attention has been given to intermediaries such as Pharmacy Benefit Managers ("PBMs"). A lack of attention and enforcement has permitted a highly concentrated PBM market to evolve in which PBMs prevent transparency and exploit conflicts of interest to raise costs and deny necessary low-cost drugs and services to consumers. This article outlines how these problems have arisen and how the FTC can conduct a comprehensive study to spotlight the market failures and need for enforcement and regulation.

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PHARMACEUTICAL SETTLEMENTS AND JUDICIAL ERROR

By Michael A. Carrier

The intersection of patent and antitrust law presents challenges for courts. Some of the most complex issues have arisen in the pharmaceutical industry. What should courts do when drug companies engage in conduct that may be allowed under patent law but threatens significant anticompetitive effects? The question arises in multiple settings. In this article, I focus on patent settlements, analyzing four mistakes courts have made: (1) resurrecting the "scope of the patent" test, (2) bestowing immunity on patent licenses, (3) imposing high causation standards for patent invalidity, and (4) resuscitating a "risk aversion" defense. Courts are continuing to make these errors, as shown by the patent-immunity mistake underlying the D.C. district court's March 2022 decision in *FTC v. Endo Pharmaceuticals*.

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NEW FTC COMMISSIONER'S POTENTIAL IMPACT ON HEALTHCARE ANTITRUST REVIEW

By Amanda Wait & Antonia Mordino

Alvaro Bedoya's confirmation has restored a Democratic majority on the Federal Trade Commission. Under a Democratic majority, FTC Chair Khan has the ability to continue to further test novel theories of harm in both merger and non-merger matters generally and in healthcare in particular. Additionally, Commissioner Bedoya's background in privacy and technology could further broaden the scope of both merger and non-merger investigations. We consider the potential scope of these novel theories of harm as applied to healthcare transactions and conduct.

SUMMARIES

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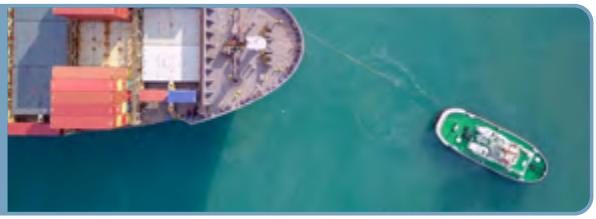

PATIENTS v. HOSPITALS: WHY DEFINE MARKETS AT ALL IF EVERY MARKET SATISFIES THE SSNIP TEST?

By Ken Field & Steven Tenn

Hospital merger cases are won or lost on geographic market definition. The Third Circuit's recent finding that it is appropriate to define geographic markets based on patient location will likely incentivize the FTC to define such geographic markets more frequently in future hospital merger litigations. We consider the implications of defining a geographic market based on patient location and highlight a key shortcoming of this approach: since virtually any candidate geographic market based on patient location likely passes the Merger Guidelines' Hypothetical Monopolist Test, any such conclusion is essentially meaningless and addresses an issue largely irrelevant to whether a proposed merger is likely anticompetitive. Consequently, the FTC's reliance on patient-based markets could erode a key advantage that the FTC currently enjoys in hospital merger litigations: the courts' willingness to endorse the Merger Guidelines' presumption that mergers that sufficiently increase concentration are anticompetitive.

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LABOR MARKETS IN HEALTHCARE TRANSACTIONS: A WORK IN PROGRESS

By Peter Herrick, Lisl Dunlop & Matthew Hayden

"We will fight for American workers including in connection with illegal mergers that substantially lessen competition for laborers." So said Assistant Attorney General Jonathan Kanter recently. This sentiment, which once may have been outside the antitrust mainstream, is now widely shared among antitrust enforcers and policymakers alike. The U.S. antitrust agencies have now stated their intent to focus on labor markets, including in merger reviews. But courts' limited past consideration of labor market issues provides no clear guidance. And while some economic studies purport to link concentration in labor markets with lower wages, they are not without flaws. The antitrust agencies' shift puts labor competition in play for mergers across all industries, and healthcare is no exception. Agency staff have demonstrated a willingness to investigate and challenge even small or "under the radar" healthcare transactions, and the combination of a highly specialized workforce and past "no poach" conduct means healthcare will remain in their crosshairs. This paper analyzes how the agencies have approached labor market issues, the challenges they face in the future, and the potential steps merging healthcare parties can take to head off a potential fight with agency staff.

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EVOLVING ANTITRUST ANALYSIS OF HOSPITAL MERGERS: HOW DIFFERENCES BETWEEN PATIENT AND INSURER PERSPECTIVES COULD CREATE "CROSS-MARKET" EFFECTS

By Dina Older Aguilar, Andrew Sfekas, Arthur Corea-Smith & Shannon Wu

Mergers that expand healthcare systems, even when they combine providers that are unlikely to compete for inpatient discharges, are increasingly under scrutiny. Empirical academic studies have found some evidence of price increases following mergers combining hospitals that are too distant to serve as close substitutes for most patients — i.e. "cross-market" mergers. Economic models can generate such effects by positing scenarios in which provider-insurer negotiations are impacted, without combining hospital systems that are close substitutes for patients. These include mechanisms by which a cross-market merger would affect the set of options available to insurers in constructing provider networks, and mechanisms under which cross-market mergers would affect insurer/provider bargaining without altering the set of possible provider networks. To assess the likely impact of an individual merger, the specific features of the proposed merger and competitive environment should be compared to the proposed theoretical mechanisms under which cross-market mergers may impact prices.

WHAT'S NEXT?

For June 2022, we will feature an Antitrust Chronicle focused on issues related to (1) **FDI** ; and (2) **Intermediaries**.

ANNOUNCEMENTS

CPI wants to hear from our subscribers. In 2022, 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.

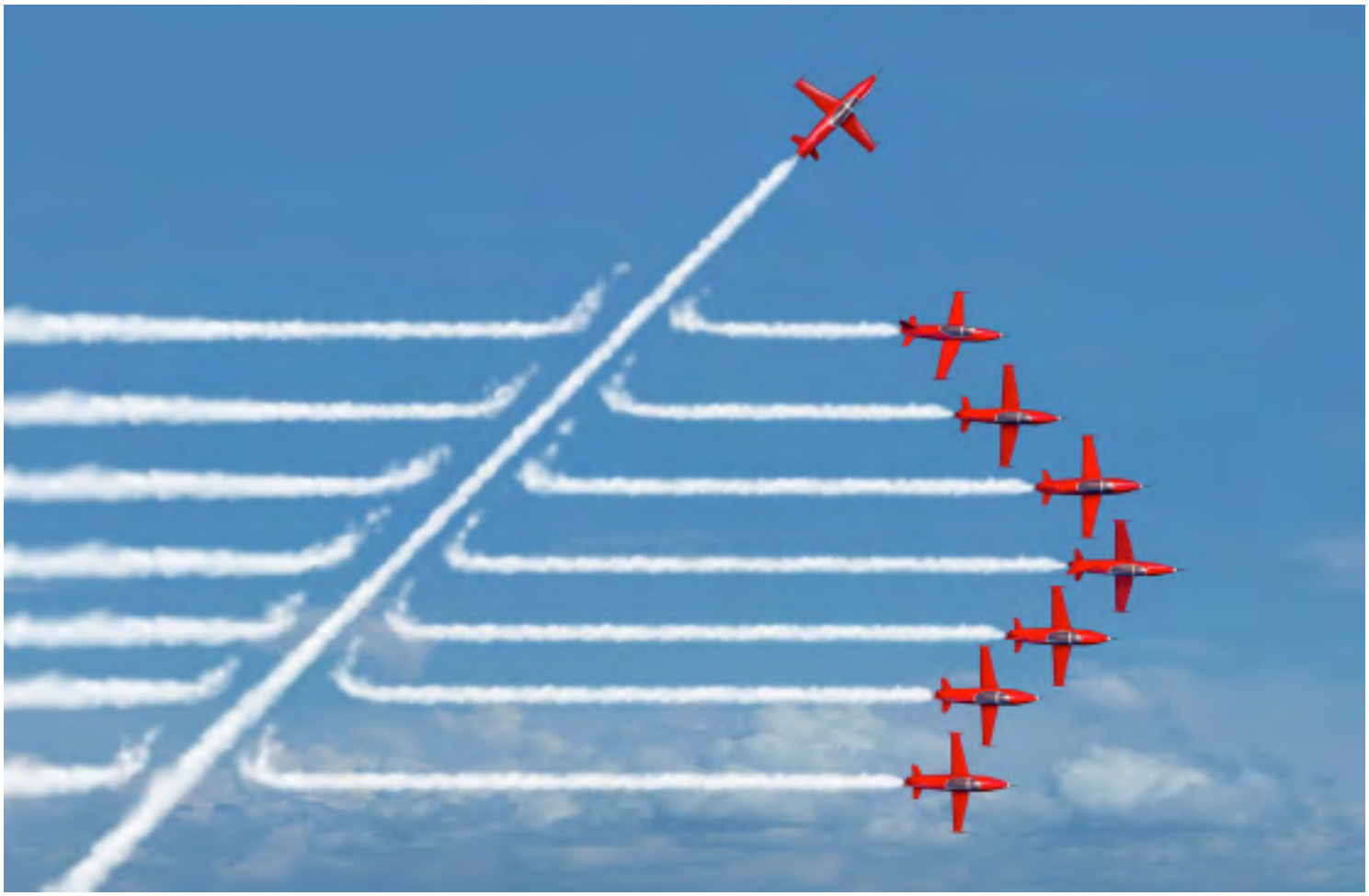
CPI ANTITRUST CHRONICLES July 2022

For July 2022, we will feature an Antitrust Chronicle focused on issues related to (1) **Values & Harms**; and (2) **LeadershIP**.

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.



NOVEL PRIVACY CONCERNS IN HEALTHCARE ANTITRUST

BY ANDREW STIVERS, EMILY WALDEN & SUBRAMANIAM RAMANARAYANAN[1]



1 Andrew Stivers and Emily Walden are Associate Directors in NERA's Antitrust and Competition Practice. Subramaniam Ramanarayanan is Chair of NERA's Healthcare Antitrust Practice and a Managing Director.

Personal health information that flows from patients and potential patients to providers and payers is an essential input to patient care and adjudication of payment. Those flows are also increasingly useful as inputs for improving the underlying technology and efficiency of healthcare delivery and as inputs for marketing and competition in the healthcare sector (finding and competing for customers). Because of its increased importance in both quality of service and in competition, antitrust regulators have been scrutinizing how proposed mergers and unilateral practices might affect that data landscape.

On one hand, this may simply mean ensuring that traditional antitrust analysis is applied to a firm's control of data assets and incentives for their use. Antitrust authorities have been signaling their heightened interest in digital markets and non-price attributes.[2] They have also been pushing to expand the scope of antitrust enforcement. That trend, with the concurrent rise in concern about privacy, and regulatory scrutiny of consumer data flows in general, have created some debate and confusion about how antitrust should be applied to patient data.[3]

As part of that debate, researchers have examined the specific privacy implications. For example, Price and Cohen lay out some of the challenges to privacy in the context of "medical big data."[4] Savage, Gaynor and Adler-Milstein examine how privacy and competition interact and may interfere with each other in the context of data security.[5] However, how antitrust intersects with consumer privacy interests, as foundational to the increasing range of global regulations and declarations of consumer rights over their data, has not been clearly articulated. This paper identifies four areas **– price discrimination, data security, intrinsic value and autonomy –** where competition and market structure may affect those interests that are novel to antitrust, and distinct from the traditional analysis of firm assets as applied to data.

I. FLOW OF HEALTHCARE DATA IN THE U.S.

Healthcare provision in the U.S. typically generates two overlapping but distinct streams of data relating to patients and their care. Electronic medical records ("EMR") are generated with a focus on clinical decision-making and practices. Business and claims data, often referred to by the underlying electronic data interchange ("EDI"), are generated with a focus on utilization management, payment administration and coverage.

An EMR is a digitized version of a patient's medical chart populated by the patient's provider, but often administered by a third-party vendor. That data includes "key administrative clinical data relevant to that person's care under a particular provider, including demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports."[6] These data are often accessible to the patient and providers via an online portal. Estimates suggest that 90 percent of providers have an EMR system.[7]

One of the key potential benefits of EMR use is improvement in clinical care quality, which may take place through a number of mechanisms, including decision support, information management, and care coordination.[8] EMRs enable providers to use decision support algorithms to prevent errors and follow care guidelines. For example, EMRs can allow a provider to check for drug allergies or interactions. EMRs may also facilitate information management, which can help providers monitor and diagnose patients with complex conditions. EMRs may improve coordination of care across providers and care settings, which can reduce errors, reduce duplication, and enable decision making. Empirical research suggests that EMRs may be successful at improving clinical care quality. Literature reviews have found that over half of empirical studies from 2007 to 2013 found a positive relationship between EMRs and quality of care compared to only about ten percent that found a negative relationship.[9]

2 FTC Virtual Press Conference for Merger Guidelines RFI Joint Announcement, Jan. 18 2022. https://www.ftc.gov/media/80865.

3 See, for a discussion: Douglas, Erika M. "The New Antitrust/Data Privacy Law Interface." Yale LJF 130 (2020): 647.

4 Price, W. Nicholson & I. Glenn Cohen. "Privacy in the age of medical big data." Nature Medicine 25, no. 1 (2019): 37-43.

5 Savage, Lucia, Martin Gaynor & Julia Adler-Milstein. "Digital health data and information sharing: A new frontier for health care competition." Antitrust LJ 82 (2018): 593.

6 https://www.cms.gov/Medicare/E-Health/EHealthRecords.

7 CDC National Center for Health Statistics, "2019 National Electronic Health Records Survey public use file national weighted estimates" https://www.cdc.gov/nchs/fastats/electronic-medical-records.htm.

8 Atasoy, Hilal, Brad N. Greenwood & Jeffrey Scott McCullough. "The digitization of patient care: a review of the effects of electronic health records on health care quality and utilization." Annual review of public health 40 (2019): 487-500.

9 Buntin MB, BurkeMF, Hoaglin MC & Blumenthal D. 2011. The benefits of health information technology: a review of the recent literature shows predominantly positive results. Health Aff. 30:464–71; Jones SS, Rudin RS, & Perry T, Shekelle PG. 2014. Health information technology: an updated systematic review with a focus on meaningful use. Ann. Intern.Med. 160:48–54.

EMR use can also improve clinical care efficiency and convenience. For example, providers can also use EMRs to send automated reminders to patients to get vaccinations or manage chronic conditions. EMR systems that track test results can also help providers avoid duplication of lab work and imaging. EMRs also provide convenience for patients by allowing them to access their medical records electronically rather than having to request paper records from their providers.

Because of all these potential benefits, government agencies have invested heavily in attempting to lower barriers to the flow of patient information to providers through subsidies and requirements for EMR adoption. The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") provides a framework for establishing a protected space within which providers, payers and claims processors have relatively few regulatory limits on patient health information flows for treatment, administrative, and quality improvement purposes. This is consistent with an underlying presumption that patients are best served with very little privacy with respect to their providers', payers', and related processors' access to protected health information ("PHI") within the EMRs. Similar rules apply to the flow of EDI data to the extent it contains PHI.

EDI data in the context of health care refers to data relating to insurance coverage, claim adjudication, and payment. As its name implies, EDI data containing information on healthcare utilization and payment requests flows from providers through clearinghouses to the various payers - often to multiple firms as adjudication of payment is resolved. As a business focused system, the most direct potential benefit to consumers of EDI is in greater efficiency adjudicating and processing payments. Like EMR, claims and payment data can be used to develop automated decision tools, which in turn can analyze incoming data for inaccuracies, incompleteness, or fraud. An ability to cross-reference EDI data with EMR may allow more complete coding of patient conditions, which in turn may lower the cost of providing service to ACA or Medicare patients. De-identified data can be aggregated and used in-house or sold for business intelligence purposes.

Due to the personal and confidential nature of PHI contained in both EMR and EDI data, breaches are a significant risk of health information systems. This PHI is protected under HIPAA and the Health Information Technology for Economic and Clinical Health ("HITECH") Act. HIPAA requires that PHI is protected with administrative, physical, and technical safeguards, while the HITECH Act prescribes a protocol for dealing with data breaches.[10]

II. TRADITIONAL ANTITRUST CONCERNS (INTERSECTING WITH CONSUMER DATA, BUT NOT "PRIVACY" CONCERNS PER SE)

The most well-articulated data-related antitrust concerns revolve around whether a firm has either exclusive control over certain kinds of essential data or has the scope and scale of access that yields uniquely valuable insights from such data.[11] A related concern may be that a firm serving as a third-party platform with access to rivals' EMR or EDI data could take unfair advantage of that access and utilize it for its own benefit.

As the research has shown, simple knowledge of data possession does not imply that one can draw any conclusions about anticompetitive effects. This is so for many reasons relating to the nature of the data and the context of its use, including contractual and regulatory controls. For example, the data at issue may not be unique, and similar (or identical) information may be available through other sources. This implies that even if a firm is trying to prevent access to its own flows or stores of essential data, rivals may not necessarily be harmed. As an example, if the essential data issue pertains to access to providers' information on healthcare claims, similar data may be accessed through the purchase of all-payor claims datasets made available by various states. Some essential pieces of information, like pricing or reimbursement of services, may also be publicly available through efforts such as CMS' price transparency initiative.[12]

In the context of access to data, unilateral conduct could raise concerns if such conduct were to adversely impact competition by a vertically integrated firm's refusal to provide essential data (or derivative downstream products) to rivals, or if the firm were to provide lower quality data inputs to rivals. In such cases, the incentive of the firm to engage in such conduct would be evaluated by the extent to which the data that rivals are being foreclosed from (or paying higher prices for) are unique, and not available from other sources such that these rivals would rather pay a higher price (or accept lower quality data) rather than switch vendors (which would result in a loss of revenues to the integrated firm). In

10 Kruse, Clemens Scott, Brenna Smith, Hannah Vanderlinden & Alexandra Nealand. "Security techniques for the electronic health records." Journal of medical systems 41, no. 8 (2017): 1-9.

11 See for example: Sokol, D. Daniel & Roisin E. Comerford. "Does antitrust have a role to play in regulating big data?." Cambridge Handbook of Antitrust, Intellectual Property and High Tech, Roger D. Blair & D. Daniel Sokol editors, Cambridge University Press, (2017); Tucker, Catherine. "Digital data, platforms and the usual [antitrust] suspects: Network effects, switching costs, essential facility." Review of industrial Organization 54, no. 4 (2019): 683-694; Hagiu, Andrei & Julian Wright. "When data creates competitive advantage." Harvard business review 98, no. 1 (2020): 94-101; Competition and Markets Authority, "Online platforms and digital advertising market study" (2020);

12 https://www.cms.gov/hospital-price-transparency.

addition, the incentives for the firm also depend on the extent to which these data may be truly integral to determining the quality of the services offered by rivals. It is important to recognize that there may be important scale-related benefits that may flow from the possession of larger amounts of data. Such greater volumes of data allow for richer analysis and the ability to draw more informative conclusions.

The above potential issues are relatively new in terms of their importance to antitrust analysis because of the massively shifted economies of data collection, storage and processing in recent years and have generated significant attention from researchers and regulators in applying the lessons of well-understood antitrust concerns. However, none of these raise novel issues specific to "privacy."

III. IMPLICATIONS FOR PRIVACY

In part because of the close, and highly regulated, relationship between healthcare provision and patient health information flows, there seems to be little widespread competition for privacy attributes in the healthcare space. However, there is also limited consumer-driven competition for privacy attributes in many other sectors – particularly online – where personally related data flows are necessary to transact. The retention and use of that data beyond the transaction are often opaque and feedback effects to the consumer are often diffuse.[13] Combined with preference heterogeneity and seeming indifference for many consumers, this means that privacy attributes often lack salience, demand may be unresponsive to changes in privacy-relevant attributes, and thus incentives to compete in this area are muted, at best.[14]

That said, shocks to consumer/patient beliefs about PHI data flows could plausibly lead to demand effects (including how willing patients are to provide their information), and as a result, firms may have incentives to conceal changes to the PHI data flows that risk triggering such demand effects. Similarly, and perhaps more importantly, shocks to consumer/patient beliefs could lead to regulatory backlash, which in turn could significantly restrict the existing data flows. Much of the recent change in privacy and data security practices across the market have been driven by nascent regulation.

If consumers are generally unresponsive to privacy attributes so that firms are not generally competing on those attributes without regulatory nudges, where does that leave us in the context of antitrust practice?

The antitrust policymakers at the state, federal and global levels have signaled their interest in reforming antitrust practice, with a particular interest in the aggregation of very large datasets and control of significant data flows as potentially anticompetitive tools. In addition, these policymakers have indicated an interest in broadening the scope of antitrust practice to deal with social issues beyond those directly implicated by the market. The form of that scope increase will take is as yet unknown but may include both changes to the antitrust framework itself and attempts to leverage antitrust regulatory gatekeeping as a way to influence company practices in other areas.

Either way, privacy is likely to be important to this debate, and here we focus on the following question:

> *What are potential/alleged privacy harms in healthcare that policymakers may try to alleviate – or already have rules in place to address – but that mergers or acquisitions might exacerbate?*

Privacy interests – or preferences, as economists conceptualize them – are idiosyncratic and context specific. People may experience concrete feedback effects or simply have strong preferences about how personal health information flows to, and is controlled and used by, payers, providers, and processors. To the extent that these interests are related to competitive or anti-competitive effects, they are generally understood to be captured by consumer welfare changes stemming from price or non-price attributes.

At least some consumers appear to have demand-relevant incentives and preferences for privacy-related attributes of the products and services that they purchase. We discuss four of the major potential concerns that could raise the cost of healthcare consumption. These are: future bargaining/discrimination concerns stemming from current PHI collection; data security concerns that unauthorized parties may gain access to PHI; intrinsic concerns relating to preferences about how PHI flows or is used independent of feedback effects; and autonomy/social concerns that are more diffuse in effect and may also be attenuated from immediate market choices.[15] To the extent that these concerns are salient, they may shift patient's valuation of health care because the flow of PHI is bundled closely with that consumption.

13 Jin, G.Z. & Stivers, A., 2017. Protecting consumers in privacy and data security: A perspective of information economics. Available at SSRN 3006172.

14 Acquisti, A., Taylor, C. & Wagman, L., 2016. The economics of privacy. Journal of economic Literature, 54(2), pp.442-92.

15 Others have offered more granular taxonomies, see, for example Citron & Solove "Privacy Harms" for an exhaustive list of the possible ways data flows could harm.

As noted, any actual effect on demand is likely to be both a function of idiosyncratic preferences and variable due to patient circumstances, knowledge, and beliefs about how PHI flows through the healthcare system. While, as noted above, aggregate demand effects in general may not be measurable, privacy advocates have argued that underlying consumer/patient interest in these flows are nonetheless strong enough to warrant significant interventions. Below, we examine each area of concern more closely.

1. Bargaining/Discrimination Concerns

One concern is that market actors with access to PHI could use it to differentially worsen patient bargaining positions or deny them access to coverage or care. In a health care setting, this could come at the point of insurance plan offerings or at the point of care decisions, delivery, and payment. Conceptually, a payer may have incentives to exclude riskier individuals or cohorts from coverage to reduce their costs. More information – less privacy – about potential members could allow a payer to identify riskier membership pools, and avoid, or soften, competition for those pools, which would tend to reduce availability and increase price for the affected population.

A merger could enhance a healthcare firm's bargaining position or ability to deny patients coverage through access to the other merging party's PHI (as each firm necessarily has access to PHI about its own customers). To some extent this issue is already covered under existing antitrust theories. First, most effects on consumers will be mediated through price, availability, and quality of care, which are well-understood effects of mergers in health care. Second, health data flows and discriminatory practices are both subject to significant existing regulatory control in health care. A potential new issue is whether patient fears of future bargaining effects would materially affect their willingness to seek care or share information with healthcare providers. If so, patient outcomes may be worse following the merger. We discuss each of these issues below.

In practice, the regulatory infrastructure in healthcare insurance is sensitive to the potential incentives to discriminate against sicker and more costly individuals or cohorts. For example, Medicare Advantage ("MA") and Affordable Care Act ("ACA") plans are subject to risk adjustment payments that are designed to reduce the incentives for discrimination in membership pools. Payers serving less risky populations in a geographic area pay in, and payers with more risky populations get pay outs. These risk adjustments are based on diagnostic coding that provide a proxy for the expected cost of providing health care to the payers' plan members.

For MA enrollees, the relevant diagnoses come from the previous year and CMS keeps a complete history of a beneficiary's diagnoses. This complete history is available to any payer serving that beneficiary, meaning that a MA enrollee's risk adjustment score will follow them if they change plans. A payer's ability to completely code for risk of an MA enrollee is in part a function of its technology for scanning claims and medical records for uncoded diagnoses. For ACA plans, risk adjustment is based on the current year's diagnoses, and an insurer will not necessarily have access to claims from prior insurers. That means that both available technology and increased access to pre-enrollment medical records and claims could influence the desire of a payer to insure a patient in the first place.

For both ACA and MA markets, the risk adjustment system means that payers have incentives to encourage complete coding to maximize their likelihood of payment from, rather than into, the risk adjustment system. In both markets more complete coding and thus increased risk adjustment subsidy for a population would allow more aggressive pricing. These incentives to completely code are especially acute for ACA plans, because risk adjustment payments are zero sum.

The existing regulatory framework to control such effects outside the antitrust apparatus likely means that greater access to data stemming from acquisitions may have ambiguous effects on price, quality, and coverage, holding market power concerns constant. To the extent that prices or quality of care are implicated in some way by increased access to patient data, the welfare effects of any such changes would typically be considered as part of a standard merger analysis. That is, they may arguably be privacy related in that they stem from use of PHI, but they are not different from price or quality effects that arise from other factors in the merger analysis.

Finally, one area that may deserve more study is whether the intensity of PHI data flows are affected. That is, whether consumers, in anticipation of future discrimination, significantly reduce the amount of information they provide through their healthcare service.[16]

2. Data Security Concerns/Personal Risk

In addition to concerns about how "authorized" users of PHI may use that data against patients' interests, concentrated repositories of PHI may create greater risk of data breaches and unauthorized use. The persistence and proliferation of PHI may increase the likelihood of a data breach by non-market actors that negatively affects patients. The business of providing coverage and care and adjudicating payment involves significant collection, sharing and use of PHI, whether from EMRs or claims data. Data security is never certain, and breaches across all types of players

16 Conitzer, Vincent, Curtis R. Taylor & Liad Wagman. "Hide and seek: Costly consumer privacy in a market with repeat purchases." Marketing Science 31, no. 2 (2012): 277-292.

in this sector have demonstrated the vulnerability. In addition to the risks associated with breached personally identified data generally – from SSNs, CCNs, and other identifying information that could be used for ID theft – breached PHI may increase risk of injury through embarrassment or negative social, employment, or other ill effects.

The effect of a merger or acquisition that increases access to patient data is generally ambiguous even if the merger is otherwise found to increase market power. First, as discussed above, data security is not necessarily a driver of competition. Second, a firm's own interest in protecting its assets – which would increase if data were a significant factor in a merger – may actually increase investment in data protection. Consolidation of processing may reduce threat surfaces for attack. On the other hand, such consolidation, and the potentially greater intensity of collection, may also create the perception of a richer target, and therefore increase incentives to attack. Finally, regulatory pressure (including indirectly through data partners' concerns about regulatory liability) may drive data security practices independent of competition issues.

3. Intrinsic Concerns

Patients may have preferences over the flow and use of personal health information independent of any feedback mechanism.[17] This means that some individuals may feel themselves to be worse off for an almost limitless set of reasons, including almost any detail of the flow of PHI, and incorporation of data related to them in the development of products or services. These are the most difficult to articulate and estimate, as they need not have any external reference or mechanism to benchmark to, at least in part because there is relatively little market data on how consumers might value such things.

4. Autonomy Concerns

Consumer interest in competitive effects themselves are not typically understood to enter preferences directly. However, critics of recent antitrust practice have argued that ill effects of mergers and acquisitions are not limited to consumer welfare calculations but extend to individual and societal autonomy and control. This concern has been specifically extended to large firms' access to and use of data related to individuals.[18] To the extent that these concerns arise socially and politically, they are even less likely to be considered at the individual demand level. Given the extensive regulatory structures outside of antitrust that attempt to manage the social benefits and costs of health care generally, and healthcare data in particular, it is not clear that concerns about autonomy related to patient data should, or will, fall to antitrust enforcement. Even if they do, the question of how antitrust regulators and the courts would attempt to incorporate these issues in merger review is unresolved, and if addressed, is likely to be on an *ad hoc* basis.

IV. DISCUSSION

Antitrust practitioners are grappling with the increased value and prominence of consumer data in competition and market strategy. As assets and important inputs into business decisions, consumer data can be examined using well-understood, traditional antitrust concepts of raising rival's costs or refusal to deal. However, antitrust authorities and other stakeholders have also raised additional questions about consumers' interests in their data from a privacy perspective, and whether there are antitrust implications specific to privacy. Privacy advocates have identified a wide range of possible welfare effects stemming from the commercial collection and use of personal data. Four of these – price discrimination, data security, intrinsic value and autonomy – have been prominent in the privacy debate. As such, they seem likely to also be applied in some form to antitrust analysis with varying degrees of overlap with traditional consumer welfare analysis. Here, we have examined these issues in the context of healthcare, but the analysis is likely to apply similarly to other areas of antitrust.

Price discrimination comports most closely as a part of market power analysis that may be amplified by the presence of data, but the potential feedback effect from consumers' willingness to share data may need to be assessed. Data security represents a more complicated issue, with the relationship between market power and data security risk ambiguous. In addition, accounting for external risks outside the relevant markets amplifies that complication. Intrinsic valuation similarly adds complexity, with consumers potentially having strong preferences about the state and flow of personal data, independent of any directly measurable affects. Market data for assessing the presence of such preferences is scarce and difficult to generate. Finally, there may be diffuse, non-market concerns about individual autonomy at a societal level that present another leap in the difficulty of assessing and thus applying a consistent analytical framework to individual antitrust matters.

17 Lin, Tesary. "Valuing intrinsic and instrumental preferences for privacy." Available at SSRN 3406412 (2019); also Joseph Farrell, "Can Privacy Be Just Another Good?" 10 Journal on Telecommunications and High Technology Law 251, 252-53 (2021).

18 Shoshana Zuboff, The Age of Surveillance Capitalism. Profile Books, 2019.

PBMS: THE MIDDLEMEN WHO DRIVE UP DRUG COSTS

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I. INTRODUCTION

In the past two decades, the Federal Trade Commission has taken a lax approach to Pharmacy Benefit Managers ("PBMs"), the middlemen in prescription drug markets. This has led to tremendous concentration, significantly higher prices, restricted consumer access, and a variety of abusive practices. PBMs transformed from "honest brokers" supposedly negotiating with drug companies to obtain lower costs for insurers and patients into oligopolists using the rebates they extract from drug manufacturers and pharmacies to enrich themselves.

The FTC is now considering conducting a study of PBM practices under Section 6(b) of the FTC Act. This study, which is long overdue, can provide the public with greater insight into PBMs' drug pricing practices, anticompetitive behavior, rebate contracts with drug manufacturers, and onerous contracts with independent pharmacies.

The PBM industry has avoided antitrust scrutiny for far too long. In sum:

- Lax antitrust enforcement has allowed the three largest PBMs to become vertically integrated and form a tight oligopoly.[2] As a result, the PBM market lacks the essential elements for a competitive market: (1) choice, (2) transparency, and (3) a lack of conflicts of interest. PBMs leverage this lack of competition to further their own interests at the expense of patients, payors, employers, unions, and pharmacists.[3]

- The PBM rebate system turns competition on its head with PBMs seeking higher, not lower, drug prices to maximize rebates and profits. **In the past decade, PBM profits have more than doubled and increased to $28 billion annually**.[4] PBMs are supposed to control costs, but because of the perverse incentives the rebate system creates, they frequently deny access to lower cost drugs to maximize rebates available from higher cost drugs.[5] That is why major consumer and patient groups and unions supported the past administration's efforts to eliminate the anti-kickback safe harbor for PBM rebates.[6]

- These middlemen increasingly stifle competition from this country's most accessible and trusted health care professionals – community pharmacists. PBMs create endless schemes to reduce reimbursement, claw back funds, restrict networks, and effectively force pharmacies to provide drugs below cost. **In 2020 alone, PBMs took $9,535,197,775[7] from independent pharmacies who serve Medicare Part D participants**. Community pharmacies are crucial for patients in underserved low-income and rural neighborhoods. These unfair and coercive tactics by PBMs result in inferior health care, less choice, and higher costs.

For the PBM market to function properly for patients, employers, unions, and other stakeholders, we need greater antitrust and consumer protection enforcement. This article elaborates on these harms and concludes with some recommendations to the FTC on how to design its 6(b) study.

II. THE PBM MARKET IS BROKEN

PBMs represent themselves as "honest brokers" or intermediaries between drug manufacturers, health insurers, plan sponsors, and providers. Although PBMs, in theory, have great potential to control prescription drug costs, over time their role has evolved, and they now engage in self-dealing and anticompetitive behavior. Two of the three largest PBMs are in the Fortune 10 and all three in the Fortune 15.[8]

2 *Reforming Biopharmaceutical Pricing at Home and Abroad*, The Council of Economic Advisors, White Paper, February 2018, https://trumpwhitehouse.archives.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf.

3 *How PBMs Make Drug Pricing Problem Worse*, David Balto, August 31, 2016, The Hill, https://thehill.com/blogs/pundits-blog/healthcare/294025-how-pbms-make-the-drug-price-problem-worse/.

4 PBM Accountability Project, *Understanding the Evolving Business and Revenue Models of PBMs*, 2021, https://www.pbmaccountability.org/_files/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true.

5 Charlie Grant, *Hidden Profits in the Prescription Drug Supply Chain*, February 24, 2018, Wall Street Journal.

6 Comments of Consumer Action, Consumer Federation of America, Consumer Reports, NETWORK Lobby for Catholic Social Justice, and Public Research Interest Group PIRG in Support of Department of Health and Human Services Office of Inspector General's ("HHS") proposed new rules to eliminate the safe harbor for rebates in Medicare Part D plans, April 8, 2019, https://docs.wixstatic.com/ugd/1859d0_c7d2ccf1d47d4f65a8965e9bbaed989d.pdf.

7 Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, CMS 4192-F, https://public-inspection.federalregister.gov/2022-09375.pdf.

8 Fortune Rankings, https://fortune.com/fortune500/2021/search/.

Patients pay higher prices for drugs than they should because PBMs are not fulfilling their cost-control function. Unreasonably high out-of-pocket costs force some patients to stop or delay treatment, which hurts patients individually and society as a whole.[9,10]

The PBM market is broken because it lacks the essential elements for a competitive market, namely: (1) choice, (2) transparency and (3) a lack of conflicts of interest.[11]

First, a lack of choice. According to the Council of Economic Advisors ("CEA"), three PBMs – CVS Caremark, Optum Rx, and Express Scripts – control over 80 percent of the market, "which allows them to exercise undue market power against manufacturers and against health plans and beneficiaries."[12] **Indeed, the three largest PBMs have a higher gross margin than any other players involved in the drug supply chain,[13] and in recent years, more of the increase in spending on brand medicines has gone to payers, including PBMs and health plans, than to drug manufacturers**.[14] It is hard to see what value these middlemen have added to our healthcare system in return for their skyrocketing profits.[15]

Second, a lack of transparency. PBM operations are cloaked in secrecy, and they fight tooth and nail against efforts to require transparency. Consider "gag clauses," which PBMs have long used to prevent pharmacists from telling consumers about available lower-cost alternative medications. While Congress finally prohibited PBMs from imposing such clauses, there was simply no pro-consumer reason to deny consumers the necessary information to receive drugs at a lower cost.[16] None.

Even sophisticated buyers are unable to secure specific drug-by-drug rebate information. PBMs prevent payors from auditing rebate information. As the Council of Economic Advisors observed, the PBM market lacks transparency as "[t]he size of manufacturer rebates and the percentage of the rebate passed on to health plans and patients are secret."[17] Without adequate transparency, plan sponsors cannot determine if the PBMs are fully passing on any savings, or whether their formulary choices really benefit the plan and subscribers.

Third, numerous conflicts of interest. PBM rebate schemes create a clear conflict between the PBM, the payor, and patients. All else equal, payors and patients generally prefer the lowest cost drug. But according to a recent Senate Finance Committee Report, "PBMs have an incentive for manufacturers to keep list prices high, since the rebates, discounts, and fees PBMs negotiate are based on a percentage of a drug's list price – and PBMs may retain at least a portion of what they negotiate."[18] PBMs have gone so far as to require additional payments in the event of any reduction in manufacturer list prices.[19,20]

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9 Press Release, Kaiser Family Foundation, *Poll: Nearly 1 in 4 Americans Taking Prescription Drugs Say It's Difficult to Afford Their Medicines, including Larger Shares Among Those with Health Issues, with Low Incomes and Nearing Medicare Age* (Mar. 1, 2019), https://www.kff.org/health-costs/press-release/poll-nearly-1-in-4-americans-taking-prescription-drugs-say-its-difficult-to-afford-medicines-including-larger-shares-with-low-incomes/.

10 Leigh Purvis & Stephen W. Schondelmeyer, *Brand Name Drug Prices Increase More Than Twice As Fast As Inflation in 2018*. AARP Public Policy Institute, November 2019, https://press.aarp.org/Brand-Name-Drug-Price-Increases-2018-Rx-Price-Watch?intcmp=AE-POL-TOENG-TOGL.

11 "*Protecting Consumers and Promoting Health Insurance Competition*," Testimony of David Balto, Before House Judiciary Committee, Subcommittee on Courts and Competition Policy, October 8, 2009, at http://www.dcantitrustlaw.com/assets/content/documents/CAP/protecting%20consumers.pdf.

12 CEA White Paper, *supra* note 2. The Top Pharmacy Managers of 2021, the big get even bigger, Drug Channels, April 2022, https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html.

13 Charley Grant, *Hidden Profits in the Prescription Drug Supply Chain*, February 24, 2018, Wall Street Journal, https://www.wsj.com/articles/hidden-profits-in-the-prescription-drug-supply-chain-1519484401#:~:text=Drug%20distributors%20converted%2046%25%20of,benefit%20from%20higher%20drug%20prices.

14 Brownlee A., *The Pharmaceutical Supply Chain*, 2013-2020, Berkeley Research Group, January 2022, https://www.thinkbrg.com/insihts/publications/pharmaceutical-supply-chain-2013-2020/; Van Nuys K, Ribero R, Ryan M., *Estimation of the Share of Net Expenditures on Insulin Captured by U.S. Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans from 2014 to 2018,* JAMA Health Forum, 2021, https://doi.org/10.1001/jamahealthforum.2021.3409.

15 PBM Accountability Project, Understanding the Evolving Business and Revenue Models of PBMs, 2021, https://www.pbmaccountability.org/_files/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true.

16 On October 10, 2018, President Donald Trump signed into law the "Know the Lowest Price Act of 2018" and the "Patients' Right to Know Drug Prices Act of 2018".

17 CEA White Paper *supra* note 2.

18 Senate Finance Committee. *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug*, 2021, https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf.

19 Sagonowsky, E., UnitedHealthcare demands drug rebates even if pharma cuts list prices: analyst, February 2019, https://www.fiercepharma.com/pharma/letter-to-pharmas-unitedhealthcare-seeks-to-protect-drug-rebates-from-price-reductions.

20 Avalere. (July 20, 2021). "Some Part D Beneficiaries May Pay Full Price for Certain Generic Drugs." https://avalere.com/insights/some-part-dbeneficiaries-may-pay-full-price-for-certain-generic-drugs. In some instances, generic drugs and biosimilars are covered on brand-drug formulary tiers in Medicare Part D instead of a generic, which causes patients to pay for the full cost of their medicine and after learning of this, patients will then purchase more expensive branded drugs because their copays will be less.

Insured patients suffer because they pay the higher list price until they meet the deductible, and then pay co-insurance or co-pays based off the higher list prices. Uninsured patients must simply pay the higher list price.[21]

Conflicts of interest also abound because PBMs are vertically integrated with health insurers, mail order operations, specialty pharmacies, and in the case of CVS, the largest retail and specialty pharmacy chain, and the dominant long-term care pharmacy. All three PBMs own their own specialty pharmacies, which they favor, discriminating against rival pharmacies. These PBMs steer patients to their own pharmacies as a requirement for patients to access their full prescription benefit. And all three PBMs are owned by or affiliated with the three largest insurance companies – United, Aetna, and Cigna. How can they offer fair contracts to their clients when they have a vested interest in driving traffic to their own providers, pharmacies, and insurers? The fox is guarding the henhouse, and the FTC needs to ensure that patients are not paying the price in less choice, inferior service, and higher prices.

III. PBMS' DEMAND FOR REBATES RESULTS IN PATIENTS NOT HAVING ACCESS TO THE MOST EFFICACIOUS AND AFFORDABLE MEDICINES

In pursuit of higher rebates, PBMs routinely exclude certain drugs from their formularies or require prior authorization for drugs that may be best for a patient's condition, even in cases where a more efficacious medication is available. As Robin Feldman, a professor at UC Hastings College of Law, puts it, "the system contains odd and perverse incentives, with the result that higher-priced drugs can receive more favorable health-plan coverage, channeling patients toward more expensive drugs."[22] Uninsured patients face higher prices and insured patients pay higher coinsurance or pre-deductible out-of-pocket costs when list prices rise.[23]

IV. PBMS USE THEIR MARKET DOMINANCE TO HARM COMMUNITY PHARMACIES

PBMs engage in a long list of egregious, unfair, and abusive practices that harm community pharmacies. Consider direct and indirect remuneration ("DIR") fees, a term advanced by the Centers for Medicare & Medicaid Services ("CMS") to ensure that Medicare Part D sponsors and PBMs accurately report rebates and other "price concessions" from manufacturers or other third parties which could not be reasonably determined at the point-of-sale. Because the government is the ultimate payor of prescription drugs under Medicare Part D plans, it wants to know exactly how much Part D and Medicare Advantage drugs cost the plans so the government does not reimburse them too much.

PBMs use DIR fees to claw back money from pharmacies, sometimes more than a year after a medication has been dispensed. After accounting for these fees, some pharmacies are reimbursed for less than their acquisition cost of the drug, meaning that they actually lose money on filling that prescription. That, of course, is financially untenable. No pharmacy would sign on to this agreement unless it had no choice. The foundation for these fees is the inflated price points and unattainable performance established by PBMs. The fact that these fees skyrocketed from practically nothing to over $9 billion demonstrates the PBMs market dominance over pharmacies.

V. LAX ANTITRUST ENFORCEMENT OF THE PBM INDUSTRY HAS LED TO WIDESPREAD ANTI-COMPETITIVE CONDUCT

The U.S. antitrust agencies have effectively placed PBMs in a regulatory free zone. Past leadership at the Department of Justice Antitrust Division ("DOJ") and the FTC have failed to take any meaningful enforcement actions, while permitting massive consolidation and anti-consumer practices. The FTC knew that PBMs "gagged" pharmacists from telling consumers of lower-priced alternatives, yet the FTC did not act. As authors from the Institute for Local Self Reliance have observed:

21 Testimony of Robin Feldman, U.S. Senate Committee on Commerce, Science, & Transportation, Sub Committee on Consumer Protection, Product Safety, & Data Protection, "Ensuring Fairness & Transparency in the Market for Prescription Drugs, May 5, 2022, https://www.commerce.senate.gov/services/files/37DB7CA0-F3FA-4D99-84C0-9C2697F913E3.

22 Robin Feldman, *Why Prescription Drug Prices Have Skyrocketed?*, Washington Post, November 26, 2018, https://www.washingtonpost.com/outlook/2018/11/26/why-prescription-drug-prices-have-skyrocketed/.

23 *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, U.S. Department of Health and Human Services ("HHS"), May 14, 2018, pg. 17.

> The FTC was designed to be a forward-thinking agency that would use its investigatory and rule-making authority to stamp out unfair methods of competition and protect the less powerful from fraud and abuse. But the FTC has been quick to dismiss concerns about the impact of concentration on small independent businesses. The agency has presided over an increasingly consolidated economy and has repeatedly embraced vertical integration despite evidence that such industry structures invite self-dealing and inflict harm on small businesses and the communities they serve.[24]

Ten years ago, the FTC faced a critical decision – whether to approve the merger of two of the three largest PBMs – Express Scripts and Medco. Despite strong opposition from employers, unions, pharmacists and consumer groups, and dozens of congresspersons who raised significant competitive concerns, the FTC approved the merger. The Commission statement is illustrative of its misguided views.[25] The Commission suggested that there were ten competitors in the market, yet by this point its list looks more like a list of fossils – a record of firms that have since been acquired or exited the market. The Commission also suggested the concerns of pharmacies were unfounded because they "negotiate" contracts with PBMs, but no one with any business sense would suggest those are anything more than take it or leave it arrangements. The merging parties suggested that the country would benefit from the larger, merged firm driving down drug prices. The real result was skyrocketing drug prices, rebates, and massive profit increases.

Unfortunately, the FTC decision to green light the *ESI-Medco* merger led to a flood of additional PBM mergers, as the major PBMs devoured their smaller rivals and specialty pharmacies. None of these transactions were challenged by the FTC, yet the underlying structural factors were far worse.

The lack of FTC merger enforcement is only one example of how the FTC failed to address PBM misconduct. When states recognized the rampant consumer protection concerns and proposed legislation to regulate deceptive and anti-consumer conduct of PBMs, FTC staff sided with the PBMs, suggesting that "economic theory" teaches that PBM-pharmacy and PBM-drug manufacturer relationships result in lower prices and that regulation would harm consumers.[26] For example, in the past, the FTC consistently opposed PBM transparency even though both Republican and Democratic administrations have advocated for healthcare transparency. In many cases, the FTC staff has relied on an outdated 2005 FTC mail order study, which Commissioner Julie Brill acknowledged was "antiquated."[27] Ultimately, many states rejected the FTC advocacy and adopted state regulations, but the broad statements in the FTC's own advocacy hamper the ability of states or federal regulators to engage in meaningful PBM regulation.

One of the reasons previous FTC advocacy and nonenforcement has missed the mark is that it has focused on the wrong set of consumers – payors rather than patients. With the vertical integration of the three largest PBMs with an insurer, lowering cost for insurers by sharing rebates does not directly equate to lower prices for patients taking prescription drugs. Under the current system, vulnerable patients are left to pay artificially high prices when their cost sharing is tied to the undiscounted list price of a medicine, rather than the lower net price the PBMs and insurers pay. And uninsured patients are in an even worse predicament. That is why consumer groups and unions supported reform of PBM rebates in the prior administration and continue to call for change.

The lack of enforcement has harmed pharmacies, and this has a direct impact on patients. Patients place tremendous value on their access to community pharmacies. Community pharmacists are consistently ranked as our most trusted health care professionals. And community pharmacies are often the most accessible form of health care services in underserved rural or inner-city markets. Community pharmacies provide essential advice and healthcare monitoring especially for patients taking specialty drugs. Yet despite receiving hundreds of complaints from community pharmacies for the egregious and deceptive actions by PBMs, the FTC has never brought a single enforcement action.

And because antitrust agencies have allowed PBMs to vertically integrate with insurers, mail order operations, and pharmacies, PBMs have financial incentives and the necessary market power to steer patients to their affiliated services.[28] Since PBMs have their own pharmacies

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24 Stacey Mitchell & Zach Freed, *How the FTC Protected the Market Power of Pharmacy Benefit Managers*, February 19, 2021, Pro Market, https://www.promarket.org/2021/02/19/ftc-market-power-pharmacy-benefit-managers/.

25 Statement of Commission Concerning Proposed Acquisition Medco Health Solutions and Express Scripts, Inc., FTC File No. 111-0210, April 2, 2012, https://www.ftc.gov/sites/default/files/documents/public_statements/statement-commission-concerning-proposed-acquisition-medco-health-solutions-express-scripts-inc./120402expressmedcostatement.pdf.

26 FTC Press Release, *FTC Staff: Mississippi Bill That Would Give State Pharmacy Board Authority Over PBMS Likely Would Increase Prices*, March 22, 2011, https://www.ftc.gov/news-events/news/press-releases/2011/03/ftc-staff-mississippi-bill-would-give-state-pharmacy-board-authority-over-pbms-likely-increase.

27 See Commissioner Brill's Letter to the ERISA Advisory Council, August 19, 2014, available at https://www.ftc.gov/system/files/documents/public_statements/579031/140819erisaletter.pdf.

28 Vertical Integration Isn't Great for Health Care Consumers or Purchasers, PURCHASER BUSINESS GROUP ON HEALTH (Aug. 23, 2021) available at https://www.pbgh.org/despite-claims-vertical-integration-isnt-great-for-health-care-consumers-or-purchasers/.

(indeed the largest pharmacy chain, CVS, owns the second largest PBM) PBMs frequently access rival pharmacy patient data and provide it to their pharmacy affiliate in an effort to steer patients away from rivals. Patients may be forced into PBM-owned mail order or 1-800 specialty pharmacy operations that provide an inferior level of service to competing community pharmacies and specialized pharmacies like AIDS Healthcare Foundation pharmacies.[29] Or the PBMs may engage in egregious auditing practices to harm rival pharmacies.

PBMs "offer" independent pharmacies "take it or leave it" contracts, where a pharmacy must choose between accepting unfavorable reimbursement terms, or exclusion from the PBM's network (and patient population). In some cases, pharmacies are coerced into agreeing to below-cost reimbursement. This unsustainable choice has forced many pharmacies to close their doors.[30] This has caused what has been characterized as "pharmacy deserts" and has disproportionately harmed rural and urban African American and Hispanic populations that now lack pharmacies because PBMs have driven the independents out of business, but these PBMs do not put new pharmacies in these locations and instead they steer patients to mail order or long distance driving.[31] This is a significant problem for these vulnerable patients, because many times their community pharmacists were the most accessible providers.[32] The FTC has heard these concerns but has chosen not to take any action to prevent PBM predatory behavior designed to eliminate pharmacy competition.

VI. RECOMMENDATIONS TO THE FTC IN DESIGNING ITS 6(B) STUDY

In designing its 6(b) study, the FTC needs to take a broad approach, including qualitative evidence (as opposed to a narrow focus on market shares, for example), while keeping impact on patients front and center. We strongly encourage the following key steps:

First, the FTC needs to determine the impact of PBM practices on actual consumers, not just payors. Actual consumers are the patients. To this end, the study should account for patient cost, choice, convenience, and service. It is critical for the FTC to consider how PBM conduct harms patients.

Second, the study should evaluate how PBMs have the power to steer patients to affiliated services and simply exclude independent pharmacies from their networks altogether, limiting patient access and choice. Indeed, after CVS and Caremark merged in 2007, there were allegations that CVS Caremark, the PBM arm, used its PBM business to steer patients to CVS retail pharmacies over independent pharmacies.[33]

Third, the FTC needs to study PBMs' rebate contracts with manufacturers. PBMs have a great deal of control in the construction of formularies, and manufacturers pay rebates for preferred position on the formularies. Not only does this practice lead to higher prices, but some branded drugs, generics, and biosimilars are excluded from formularies, which results in patients not being able to obtain more affordable and efficacious drugs.

Fourth, a broad study is necessary to capture allegations of widespread fraudulent and deceptive practices. PBMs are reducing reimbursements to independent pharmacies so much that independent pharmacies dispense prescription drugs to consumers below the independent pharmacies' cost of the drugs. PBM clawbacks of pharmacy revenue have been increasing year after year, causing significant financial strain on these small businesses.[34] The FTC should explore whether vertically integrated PBMs reimburse their own pharmacies at the same level as they reimburse independent pharmacies. Further, it should examine whether there are any other differences in how vertically integrated PBMs treat their own pharmacies versus independent pharmacies.

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29 Dr. Michael Wohlfeiler of the AIDS Healthcare Foundation testified in the CVS-Aetna Tunney Act proceeding that the merger could endanger HIV and AIDS patients because the merged firm could steer its "patients to leave HIV and AIDS specific treatment providers for providers that are unequipped to treat those conditions." *United States v. CVS Health Corp.*, 407 F. Supp. 3d 45, 57 (D.D.C. 2019). AHF has created an extraordinarily successful model for delivery of care to HIV/AIDS patients, a one stop shop model in which AHF functions as a testing, linkage, specialist, health insurer, pharmacy, and price care facility. Patient steering to cookie-cutter models results in fragmentation of care, inferior quality of care, and severance of trusted provider relationships, which is very problematic for vulnerable patients with chronic conditions like HIV.

30 Markian Hawryluk, *The Last Drugstore: Rural America is Losing Its Pharmacies*, WASH. POST (Nov. 10, 2021), https://www.washingtonpost.com/business/2021/11/10/drugstore-shortage-rural-america/.

31 *Id.* Stacy Mitchell & Charlie Thaxton, *The Rebirth of Independent Pharmacies Could Cure Rural Ills*, The American Conservative, November 5, 2019, https://www.theamericanconservative.com/articles/the-rebirth-of-independent-pharmacies/.

32 See, Stacy Mitchell, *Small Pharmacies Beat Big Chains at Delivering Vaccines. Don't Look So Shocked*, Washington Post, February 5, 2021, https://www.washingtonpost.com/outlook/small-pharmacies-beat-big-chains-at-delivering-vaccines-dont-look-so-shocked/2021/02/05/6bb307ec-671b-11eb-886d-5264d4ceb46d_story.html.

33 Reed Abelson & Natasha Singer, *Pressure Grows to Unwind CVS Merger*, Henderson Times News, April 14, 2011, https://amp.blueridgenow.com/amp/28267825007.

34 *Id.*

Fifth, the study should examine whether PBMs' use of firewalls protect independent pharmacies' patient data.

Finally, as part of the study, the FTC needs to conduct a retrospective of the *Express Scripts/Medco* merger, which the FTC cleared in 2012.[35] Since then, concentration levels in the PBM industry have increased. Moreover, the FTC's *Express Scripts/Medco* merger review did not focus on the issue of the competitive effects of different PBM plan designs, or the competitive effects of state law requirements that mandate either transparent plan designs or the inclusion of proposals with transparent plan designs as a component of PBM bids to plan sponsors. The FTC needs to evaluate the competitive impact of different plan designs considering the significant changes in the PBM market and state laws.

35 Press Release, Fed. Trade Comm'n, *FTC Closes Eight-Month Investigation of Express Scripts, Inc.'s Proposed Acquisition of Pharmacy Benefits Manager Medco Health Solutions, Inc.*, Apr. 2, 2012, https://www.ftc.gov/news-events/press-releases/2012/04/ftc-closes-eight-month-investigation-express-scripts-incs.

PHARMACEUTICAL SETTLEMENTS AND JUDICIAL ERROR

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The intersection of patent and antitrust law presents challenges for courts. Some of the most complex issues have arisen in the pharmaceutical industry. What should courts do when drug companies engage in conduct that may be allowed under patent law but threatens significant anti-competitive effects? The question arises in multiple settings.[2] In this article, I focus on patent settlements, analyzing four mistakes courts have made: (1) resurrecting the "scope of the patent" test, (2) bestowing immunity on patent licenses, (3) imposing high causation standards for patent invalidity, and (4) resuscitating a "risk aversion" defense.[3] Courts are continuing to make these errors, as shown by the patent-immunity mistake underlying the D.C. district court's March 2022 decision in *FTC v. Endo Pharmaceuticals*.[4]

I. THE SETTING

The pharmaceutical industry is unique in its complexity, with nuanced markets and regulatory regimes. Unlike other markets, "the consumer who pays does not choose, and the physician who chooses does not pay."[5] This disconnect has created a gap that can be exploited, as brand-name drug firms convince doctors to prescribe expensive drugs even though equally effective cheaper drugs are available.

The industry also is characterized by complicated regulatory regimes. Most relevant here is the Hatch-Waxman Act, Congress's calibration of the patent and antitrust laws in the industry.[6] This legislation fostered innovation through patent term extensions, periods of market exclusivity not based on patents, and an automatic 30-month stay of generic approval.[7] At the same time, the Act increased generic competition by allowing experimentation on a drug during the patent term, letting generics rely on brands' safety and effectiveness studies, and providing 180 days of marketing exclusivity to the first generic to challenge a brand firm's patent.[8]

The setting for this article involves agreements by which brand drug companies pay generic firms to delay entering the market. In 2013, in the case of FTC v. Actavis, the U.S. Supreme Court concluded that these "reverse payment"[9] settlements could have "significant anticompetitive effects" and violate the antitrust laws.[10] In ensuring a robust role for antitrust analysis, the Court handed down one of the most important business cases in the past generation. And it articulated a blueprint for future analysis based on antitrust law's "rule of reason."[11] But given how much brand firms gain from delaying generic entry,[12] the settling parties have every incentive to muddy the waters, claim the ruling is unclear, and resuscitate defenses that the *Actavis* Court seemingly buried. As discussed throughout this piece, courts sometimes take the bait.

II. ERROR 1: RESUSCITATING THE "SCOPE OF THE PATENT" TEST

The most fundamental error involves the "scope of the patent." Between 2005 and 2012, courts upheld reverse-payment settlements that allowed generic entry (even with payment) at or before the end of the patent term. For example, the *Ciprofloxacin* court found that "[t]he essence

2 For a discussion of settings involving "product hopping" (in which a brand firm switches from one version of a drug to another to stifle generic entry), citizen petitions (which are designed to raise safety concerns with the U.S. Food and Drug Administration ("FDA") but have been used to delay generic entry), and Risk Evaluation and Mitigation Strategies ("REMS") programs (which brand firms have employed to deny samples generics need for testing), see Michael A. Carrier, *Three Challenges for Pharmaceutical Antitrust*, 59 Santa Clara L. Rev. 615 (2020).

3 For a discussion of two additional errors that preceded the Supreme Court's decision in *FTC v. Actavis*, 570 U.S. 136 (2013), see Carrier, *supra* note 2, at 618-20 (discussing the policy in favor of settlement and presumption of patent validity, both of which courts treated as dispositive in upholding settlements).

4 2022 WL 951640 (D.D.C. Mar. 30, 2022). For a discussion of more justifiable analysis, see Herbert Hovenkamp, Mark D. Janis, Mark A. Lemley, Christopher R. Leslie, & Michael A. Carrier, IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law § 16.01[D], at 16-36 to 16-41 (form of payment), § 16.01[D], at 16-41 to 16-47 (pleading standard), § 16.01[J], at 16-66.48 to 16-66.62 (causation) (3d ed. 2017 & 2021 Supp.).

5 Drug Product Selection, Staff Report to the FTC 2-3 (Jan. 1979).

6 Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355). For a discussion of another regime — state drug product selection laws — see Carrier, *supra* note 2, at 617-18.

7 See generally Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37, 43-45 (2009).

8 21 U.S.C. § 355(j)(5)(B)(iv).

9 These are called "reverse payments" because the consideration flows from patentee to alleged infringer (unlike typical settlements in which alleged infringers pay patentees).

10 570 U.S. 136, 137 (2013).

11 *Id.* at 159-60.

12 Brand firms can make millions each day generic entry is delayed, sharing some of the extra profits with the settling generic. The FTC found that reverse-payment settlements cost consumers $3.5 billion a year. FTC, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions 10 (2010).

of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent"[13] and the *Tamoxifen* court found that the settlement did not "unlawfully extend the reach" of the patent.[14]

The Court in *Actavis* correctly rejected the scope test, understanding that "[t]he patent . . . may or may not be valid, and may or may not be infringed" but that "*an invalidated* patent carries with it no . . . right . . . [to] permit the patent owner to charge a higher than competitive price for the patented product."[15] Importantly, the Court made it clear that the relevant question was not merely what rights patent law would have conferred. It concluded that "[i]t would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent policy, rather than by measuring them against procompetitive antitrust policies as well."[16] Instead, "patent and antitrust policies are both relevant in determining the proper 'scope of the patent monopoly' — and consequently antitrust immunity — that is conferred by a patent," as "[w]hether a particular restraint lies beyond the limits of the patent monopoly is a *conclusion* that flows from [traditional antitrust] analysis and not . . . its starting point."[17]

It thus seemed clear after *Actavis* that the scope-of-the-patent test no longer provided a justification that the settling parties could rely on. But the difficulties of finally burying this argument are revealed by the lure of the claim that generic entry before patent expiration is procompetitive. On its face, and with *Actavis* receding ever further into the rearview mirror, courts are tempted to find that pre-expiration entry provides "extra" competition that is good for the consumer.

One example[18] of this error was provided by the Federal Trade Commission ("FTC") Administrative Law Judge ("ALJ") in *In the Matter of Impax Laboratories*.[19] In that case, the ALJ concluded that it was "procompetitive" for a settlement to permit a generic "to enter the market eight months before the original patents expired."[20] Such entry allowed "consumers [to] benefit[] . . . by having uninterrupted and continuous access" to the generic, which was "on the market and available to consumers" because the generic "had the foresight to negotiate licenses to future patents."[21] The ALJ stated that entry before the end of the patent term "can be considered in assessing the [settlement's] competitive consequences."[22] And the ALJ even downplayed the anticompetitive harm at the heart of *Actavis* by claiming that "the magnitude or extent of such harm is largely theoretical, based on an inference" that the generic's entry date would have been earlier without the reverse payment, and that this theoretical harm was outweighed by the settlement's "substantial . . . real world procompetitive benefits."[23]

Generic entry before the end of the patent term is procompetitive only if the patent is valid and infringed. But whether there is a valid, infringed patent is *precisely* the inquiry short-circuited when a brand pays a generic to drop its patent challenge. And given that 89 percent of patents in settled litigation cover not the active ingredient but only ancillary aspects (with the majority of these patents ultimately overturned),[24] the revival of the scope test threatens significant harms.

13 *In re Ciprofloxacin*, 544 F.3d 1323, 1336 (Fed. Cir. 2008).

14 *In re Tamoxifen*, 466 F.3d 187, 213 (2d Cir. 2006).

15 570 U.S at 147 (emphasis in original).

16 *Id.* at 148.

17 *Id.* at 149 (emphasis in original).

18 For another example, see Carrier, *supra* note 2, at 632 (discussing *FTC v. AbbVie Inc.*, 107 F. Supp. 3d 428, 436 (E.D. Pa. 2015), where court upheld settlement that "allow[ed] [generic] to enter the . . . market almost six years" before patent expired even though court recognized that "the FTC correctly alleges that something of large value passed" from brand to generic).

19 Dkt. No. 9373 (FTC ALJ Chappell May 18, 2018).

20 *Id.* at 144, 146.

21 *Id.* at 146.

22 *Id.*

23 *Id.* at 156-57.

24 C. Scott Hemphill & Bhaven Sampat, Drug Patents at the Supreme Court, 339 Science 1386, 1387 (2013) (finding companies less likely to win on secondary patents (32%) than on active ingredient patents (92%)).

III. ERROR 2: BESTOWING IMMUNITY ON PATENT LICENSES

The second error involves bestowing immunity on patent licenses. In March 2022, the D.C. district court in *FTC v. Endo Pharmaceuticals* dismissed the FTC's case against Endo on this ground.[25] The court found that brand firm Endo "had a valid license and a right to exclude, which allowed it to maintain a patent monopoly and charge supracompetitive prices."[26] The court stated that "[t]he Patent Act provides Endo the right" to decide to exclusively license its patent.[27] And because "the Patent Act expressly provides for both exclusive licenses and patent monopolies," the court concluded that the FTC "failed to allege that the [a]greement or the resulting patent monopoly violate" antitrust law.[28]

The setting in *Endo* was not exactly the same as one where a brand pays a generic to delay entering the market. Instead, Endo (1) withdrew its branded product in response to the FDA's safety concerns, (2) provided a license only to generic firm Impax, and (3) obtained injunctions that, for years, kept all the other potential generics off the market.[29] As a result, the case involved a *generic* monopoly, and the generic's sharing monopoly profits with the brand.[30]

But this different setting does not affect the question of immunity. The *Actavis* Court, relying on cases analyzing patent-based conduct as far back as the 1920s, concluded that antitrust law has a robust role to play within the scope of the patent. In other words, the fact that patent law allows the conduct is not dispositive. Antitrust law does not bestow immunity on patent-based conduct.

In addition to emphasizing antitrust's role within the scope of the patent, the Court cited numerous precedents to explain how "patent-related settlement agreements can sometimes violate the antitrust laws."[31] For that reason, "the Court has struck down overly restrictive patent licensing agreements — irrespective of whether those agreements produced supra-patent-permitted revenues."[32]

It thus should not be a surprise that the lower courts have appropriately recognized that "formally classifying an agreement a 'license' ought not halt further inquiry into the actual nature of the underlying arrangement";[33] that settling parties "cannot shield themselves with the argument that patent licenses are common and authorized, if such licenses disguise unlawful reverse payments";[34] and that exclusive licenses "can be worth money, and granting them can thus be the equivalent of transferring money," which is why "[t]he issue is not whether the *form* of the payment was legal, but whether the *purpose* of the payment was legal."[35]

For example, the court in *King Drug Co. of Florence v. Smithkline Beecham Corporation* explained that "the 'right' defendants seek is not in fact a patentee's right to grant licenses, exclusive or otherwise," but "[i]nstead . . . is a right to use valuable licensing in such a way to induce a patent challenger's delay," which was "rejected" by Actavis.[36] Just because a patent holder "may generally have the right to grant licenses, exclusive or otherwise, does not mean it also has the right to give a challenger a license along with . . . a promise not to compete.'"[37] "[E]ven exclusive

25 2022 WL 951640 (D.D.C. Mar. 30, 2022).

26 *Id.* at *11.

27 *Id.*

28 In addition to relying on immunity, the *Endo* court's framework for analysis was highly questionable. Instead of recognizing that the cases on which it relied supported the general point — not limited to reverse-payment settlements — of longstanding antitrust scrutiny of patent-based conduct (including licenses), it pulled miscellaneous phrases from the decades-old rulings to manufacture a 6-part test having no support in the caselaw.

29 *Id.* at *2.

30 See Complaint for Injunctive and Other Equitable Relief, *FTC v. Endo Pharms. Inc.*, Case No.: 1:21-cv-217-RCL (filed Jan. 25, 2021) at ¶ 3 (Impax agreed to pay Endo percentage of profits, "but only so long as [it] refrain[ed] from competing"); ¶ 4 (agreement's purpose was "to ensure that Endo, the gatekeeper to competition in the . . . market, ha[d] every incentive to preserve Impax's monopoly," which "eliminate[d] any potential for . . . competition, allowing Endo and Impax to share in the monopoly profits"); ¶ 99 (agreement "amount[ed] to an incumbent competitor (Impax) paying its only potential challenger (Endo) to stay off the market").

31 570 U.S. at 149.

32 *Id.* at 150.

33 *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 265 (D. Mass. 2014).

34 *Id.*

35 *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 245 (D. Conn. 2015).

36 791 F.3d 388, 406-07 (3d Cir. 2015).

37 *Id.* at 407.

licenses," the court concluded, "cannot avoid antitrust scrutiny where they are used in anticompetitive ways."[38] Relatedly, the Intellectual Property Guidelines issued by the U.S. Department of Justice and FTC, while recognizing possible efficiencies from the "integration of . . . [patents] with complementary factors of production,"[39] warn of "antitrust concerns" from licensing arrangements between "potential competitors."[40] In short, patent licenses are not immune from antitrust scrutiny.

IV. ERROR 3: IMPOSING HIGH CAUSATION STANDARDS FOR PATENT INVALIDITY

The third error involves the analysis of patent invalidity in determining causation. The plaintiff in *Actavis* was the FTC. As a government agency, the FTC does not need to demonstrate causation because it automatically has standing. In contrast, private plaintiffs need to make such a showing. And some courts have required plaintiffs to "prove precisely how, absent the illegal settlement agreement, generic entry would have happened earlier."[41] Plaintiffs have offered three alternative paths to showing this: patent litigation resulting in a finding of invalidity or noninfringement, generic entry "at risk" during the patent litigation, and a settlement without payment allowing earlier entry. Courts applying a rigid approach to causation require plaintiffs to select among these paths and "prove specifically how entry would have occurred in the absence of the illegal settlement agreement."[42]

For example, in *In re Wellbutrin XL Antitrust Litigation*, the Third Circuit rejected the plaintiffs' argument that the generic would have launched at risk since this did not "take into account [a] blocking patent."[43] The court stated that the plaintiffs were required to "show that the launch would have been legal" because "if the launch were stopped because it was illegal," then the plaintiffs' injury "would be caused not by the settlement but by the patent laws prohibiting the launch."[44]

The court also rejected plaintiffs' "litigation-based scenario" by which the generic would have prevailed in patent litigation. Downplaying *Actavis* and drawing curious distinctions, the court asserted that "[w]hile the size of the reverse payment may have some relevance in determining how confident a litigant is in the strength of its case," it "is far from dispositive," especially where "the settlement is complex and multi-faceted" and "there are multiple plausible ways to interpret the reverse payment."[45]

In requiring plaintiffs to prove that the patent definitively would have been ruled invalid, courts have imposed a standard that is nearly impossible to prove and flies in the face of the Court's direction in *Actavis* that patent validity need not be litigated.[46]

V. ERROR 4: RESUSCITATING A "RISK AVERSION" DEFENSE

The fourth error involves resuscitating the argument rejected in *Actavis* that brand firms have offered based on their desire to settle because of risk aversion. Such an argument can only be considered in the context of Actavis, in particular its emphasis on the instructive role played by payment. The Court in *Actavis* found that the settlement at issue had the "potential for genuine adverse effects on competition" since "payment in return for staying out of the market . . . keeps prices at patentee-set levels."[47] In addition, the Court highlighted the harms from a payment to a

38 *Id.*

39 U.S. Dept. of Justice & FTC, Antitrust Guidelines for the Licensing of Intellectual Property § 2.3 (2017).

40 *Id.* § 3.1.

41 Kevin B. Soter, Note, *Causation in Reverse Payment Antitrust Claims*, 70 Stan. L. Rev. 1295, 1314 (2018).

42 *Id.* Another example was provided by the only completed trial on a reverse-payment settlement since *Actavis*, in which the jury found that "[h]ad it not been for" the settlement, AstraZeneca would not have "agreed with Ranbaxy that Ranbaxy might launch a generic version of Nexium before May 27, 2014" given the plaintiffs' failure to offer "direct evidence that the FDA was likely to grant final approval to Ranbaxy's generic Nexium product within the proposed timeline" as well as evidence that Ranbaxy would "never" have launched generic Nexium at risk. Jury Verdict in Favor of Defendants Against Plaintiffs Returned, *In re Nexium Antitrust Litig.*, No. 12-md-02409 (D. Mass. Dec. 8, 2014), ECF No. 1374; *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 272 (D. Mass. 2014). For a discussion of how a generic manufacturer could slow its responsiveness in obtaining FDA approval after entering into a settlement, see Hovenkamp et al., *supra* note 4, § 16.01[J], at 16-66.43 n.267.

43 868 F.3d 132, 165 (3d Cir. 2017).

44 *Id.*

45 *Id.* at 168.

46 See *infra* notes 49-50 and accompanying text.

47 570 U.S. at 154.

generic, which "in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product."[48]

The Court revealed its strong preference for determining patent strength by examining the payment rather than the patent. The "size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself."[49] Even strong patents are not immune from the concern with payments, because an unexplained payment on a "particularly valuable patent . . . likely seeks to prevent the risk of competition," with this consequence "constitut[ing] the relevant anticompetitive harm."[50] In other words, the Court made clear that risk aversion was not an acceptable justification for a reverse-payment settlement.

In identifying the avoidance of the risk of competition as an antitrust violation, the Court dispensed with the risk-aversion defense long advocated by settling parties (and economists), including in *Actavis* itself. For example, in *Actavis*, a group of economists filed an amicus brief that asserted that reverse payments "may . . . be necessary for brand companies to overcome bargaining disadvantages caused by risk aversion."[51] The brief also stated that "[b]rand companies are likely to be more risk averse than their generic challengers because they usually have significantly more to lose from a negative trial outcome."[52] And it contended that "the size of a reverse payment generally does not provide a reliable benchmark to determine whether the payment is anticompetitive."[53] Faced squarely with these justifications, the Court refused to accept them.[54]

In direct contravention of *Actavis*, the Third Circuit in *In re Wellbutrin XL Antitrust Litigation* was "persuaded" by an economists' amicus brief that "explains why risk aversion makes it difficult to use the size of a settlement as a proxy for the brand-name's likelihood of success in litigation," even finding that this reasoning (which the Supreme Court rejected in calling the "prevent[ion of] the risk of competition" the "relevant anticompetitive harm"[55]) "serves as an effective rebuttal to the [plaintiffs'] claim that the size of the reverse payment is a 'surrogate'" for patent weakness.[56]

VI. CONCLUSION

Drug patent settlement cases can be challenging for courts. Although some courts have correctly applied *Actavis*, others have not. The scope-of-the-patent, causation, and risk-aversion arguments have continued to plague courts, while the patent immunity one beguiled the D.C. district court just a short time ago. Although the issues are complex, courts would benefit from applying analysis consistent with *Actavis*.

48 *Id.* at 153-54.

49 *Id.* at 158.

50 *Id.* at 157.

51 Brief of Antitrust Economists as Amici Curiae in Support of Respondents at 3, *FTC v. Actavis* (filed Feb. 28, 2013).

52 *Id.* at 20.

53 *Id.* at 21.

54 See generally Hovenkamp et al., *supra* note 4, § 16.01[D], at 16-26 ("[T]he Court did not accept as a justification risk aversion or the patentee's desire to convert an uncertain patent right into a certain one without litigation.").

55 570 U.S. at 157.

56 868 F.3d at 168-69.

NEW FTC COMMISSIONER'S POTENTIAL IMPACT ON HEALTHCARE ANTITRUST REVIEW

BY AMANDA WAIT & ANTONIA MORDINO[1]

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I. INTRODUCTION

On May 11, 2022, Alvaro Bedoya was confirmed by the U.S. Senate to the Federal Trade Commission. He was sworn in as a Commissioner on May 16. Commissioner Bedoya joins the Commission from Georgetown Law, where he was a professor and the Founding Director of the Center on Privacy & Technology. He previously served as Chief Counsel of the U.S. Senate Judiciary Subcommittee on Privacy, Technology, and the Law. Commissioner Bedoya is widely recognized as an expert on technology and privacy issues and has written extensively about the racially disparate effects of surveillance and data collection, including the impact of police facial recognition technology.

The addition of Alvaro Bedoya to the Commission likely will empower FTC Chair Khan to pursue even more aggressive antitrust enforcement in the healthcare industry and to further develop and utilize novel theories of harm in healthcare markets.

II. POTENTIAL EXPANDED THEORIES OF ANTITRUST HARM

Since the departure of Commissioner Rohit Chopra on October 12, 2021, the Commission had been operating with two Republican and two Democratic Commissioners. While cases that were subject to tie votes and, therefore, ultimately not brought by the Commission are not reliably reported publicly, the lack of a majority likely prevented the Commission from pursuing at least some claims that it could have pursued with a Democratic majority.

For example, in February 2022, the FTC voted 4-0 to issue a complaint challenging the proposed merger of Lifespan and Care New England. By way of background, Lifespan and Care New England are the two largest general acute care hospital systems in Rhode Island. The FTC alleged that the combination would result in market shares in excess of 70 percent for inpatient general acute care and behavioral health services in Rhode Island and certain surrounding Massachusetts counties.[2] The parties abandoned the transaction shortly after the FTC filed its suit to block the proposed transaction.[3]

The face of the complaint outlines the typical allegations of reductions in product and service line competition we have seen in hospital mergers for years. What makes this case particularly illustrative, however, is the Commissioner statements accompanying the issuance of the complaint. Concurring statements issued alongside the complaint, however, demonstrate how the two Democratic Commissioners would have filed a case with expanded theories of harm, but lacked the votes to obtain a majority to do so. The then-two Democratic Commissioners — Chair Khan & Commissioner Slaughter — wrote separately to explain that they also "would have supported an allegation that the effect of the proposed transaction may be to substantially lessen competition in a relevant labor market in violation of the Clayton Act."[4] The two Republican Commissioners — Commissioners Phillips & Wilson — explained their view that the evidence did not support the labor market allegations.[5] Given this 2-2 divide within the Commission, the complaint was issued without the labor market allegations.

This *Lifespan/CNE* complaint and accompanying Commissioner statements provides a potential glimpse into the future of hospital mergers at the FTC. With the addition of Commissioner Bedoya last week, Chair Khan has the Democratic majority and accompanying votes to include these labor market and other novel theories of harm in Commission enforcement actions.[6]

This tie vote deadlock has also extended into Commission industry studies. On February 17, 2022, the Commission deadlocked on a vote to study the impact of pharmacy benefit managers ("PBMs") on independent and specialty pharmacies.[7] PBMs are companies that communicate be-

2 Complaint ¶5, *In the Matter of Lifespan Corp., et al.*, F.T.C. Dkt. No. 9406 (Feb. 17, 2022), *at* https://www.ftc.gov/system/files/ftc_gov/pdf/d_9406_lifespan-cne_p3_complaint_public_redacted.pdf.

3 See Statement Regarding Termination of Attempted Merger of Rhode Island's Two Largest Healthcare Providers (Mar. 2, 2022), *at* https://www.ftc.gov/news-events/news/press-releases/2022/03/statement-regarding-termination-attempted-merger-rhode-islands-two-largest-healthcare-providers.

4 Concurring Statement of Commissioner Slaughter and Chair Khan Regarding *FTC and State of Rhode Island v. Lifespan Corporation and Care New England Health System* (Feb. 17, 2022), *at* https://www.ftc.gov/system/files/ftc_gov/pdf/public_statement_of_commr_slaughter_chair_khan_re_lifespan-cne_redacted.pdf.

5 Concurring Statement of Commissioners Noah Joshua Phillips and Christine S. Wilson Regarding Lifespan Corporation and Care New England Health System (Feb. 17, 2022), at https://www.ftc.gov/legal-library/browse/cases-proceedings/public-statements/concurring-statement-commissioners-noah-joshua-phillips-christine-s-wilson-regarding-lifespan.

6 See Amanda Wait & Mark Angland, Data Privacy Expert Confirmed to Federal Trade Commission, https://www.nortonrosefulbright.com/en-us/knowledge/publications/404aca20/data-privacy-expert-confirmed-to-federal-trade-commission.

7 See Samantha Liss, FTC Fails to Get Enough Votes to launch study into PBM Practices (Feb. 17, 2022), *at* https://www.healthcaredive.com/news/ftc-fails-to-get-enough-votes--study-pbm-practices/619060/.

tween insurance companies, pharmacies, and drug manufacturers. PBMs are typically used to secure lower drug costs for insurers by negotiating with pharmacies and drug manufacturers. Pharmacy and patient advocacy groups, however, claim that some PBM practices contribute to prescription price increases and less competition in the market for prescriptions.[8] Republican-appointed Commissioners Noah Phillips & Christine Wilson voted against the study, citing concerns about the study's design and questioning process.[9] Although the claim was blocked when there were only four commissioners, we expect Commissioner Bedoya's confirmation to allow the Commission to pursue more healthcare investigations such as this going forward.

Importantly, we believe staff likely will include and expand upon innovative theories of harm in the review of hospital and other healthcare transactions, such as theories relating to vertical restraints, cross-market theories, and labor market theories.

A. Vertical Foreclosure

Vertical restraint theories of harm are based on the potential harms that may arise when mergers or agreements involve firms at different levels of a chain of production or distribution. Historically, antitrust enforcers have focused on so-called "vertical foreclosure" theories — i.e. could a firm foreclose competitors from a segment of either the upstream market for inputs, the downstream market for customers, or both. Since the 1982 Merger Guidelines, very few vertical mergers have been deemed anticompetitive. The 2020 Vertical Merger Guidelines reflected this lenient stance on vertical restraints. But on September 15, 2021, shortly after Chair Khan was confirmed, the Commission withdrew its approval of the Vertical Merger Guidelines. In the statement withdrawing the Vertical Merger Guidelines, Chair Khan and Commissioners Slaughter and Chopra suggested that the 2020 guidelines allowed for courts to give too much credit to the elimination of double marginalization and other procompetitive benefits of vertical mergers.[10] On January 18, 2022, the Commission and the Antitrust Division of the Department of Justice ("DOJ") announced that the agencies would be drafting new horizontal and vertical merger guidelines.[11] These new guidelines will likely be more critical of vertical mergers.

B. Cross-Market Theory

Cross-market theories of harm arise from the merger of two companies in separate geographic markets. In healthcare antitrust, a cross-market merger would include a merger between hospitals that are located far enough away from each other that their service areas do not overlap. Under current antitrust jurisprudence, a merger must have an anticompetitive effect within the relevant geographic market to be deemed to violate Section 7 of the Clayton Act. While neither antitrust agency has ever challenged a merger on a cross-market theory, the cross-market theory of harm alleges that these mergers may increase hospitals' bargaining power when negotiating with health insurers that operate on a larger geographic market. We understand FTC investigating staff have pursued cross-market theories in multiple non-public healthcare investigations.

C. Labor Market Implications

Labor market theories of harm are a recent development that focus on the potential anticompetitive effects of wage-fixing and no-poach agreements. Wage-fixing agreements are agreements among employers to not compete for employees on terms of compensation, and no-poach agreements are agreements among employers to not recruit certain employees. Some of the earliest no-poach investigations were in healthcare contexts. The DOJ filed its first criminal charges for wage-fixing and no-poach agreements in late 2020 and early 2021 and there has been an increase in the number of investigations and criminal indictments concerning alleged wage-fixing or no-poach agreements in recent years. The Commission's September 15, 2021 statement explains that revised Merger Guidelines "should consider harms in labor markets, a topic not previously addressed in merger guidelines."[12]

Our antitrust team is seeing these theories appear in questions that are being asked in Second Requests and other investigations. While we have not yet seen many enforcement actions under these theories, these types of claims are more likely with a Democratic majority on the Commission.

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8 See The Commonwealth Fund, Pharmacy Benefit Managers and Their Role in Drug Spending (April 22, 2019), at https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending.

9 See Samantha Liss, FTC Fails to Get Enough Votes to launch study into PBM Practices (Feb. 17, 2022), *at* https://www.healthcaredive.com/news/ftc-fails-to-get-enough-votes--study-pbm-practices/619060/.

10 Statement of Chair Lina M. Khan, Commissioner Rohit Chopra, and Commissioner Rebecca Kelly Slaughter on the Withdrawal of the Vertical Merger Guidelines (Sept. 15, 2021), https://www.ftc.gov/system/files/documents/public_statements/1596396/statement_of_chair_lina_m_khan_commissioner_rohit_chopra_and_commissioner_rebecca_kelly_slaughter_on.pdf.

11 Statement of Chair Lina M. Khan Regarding the Request for Information on Merger Enforcement (Jan. 18, 2022), https://www.ftc.gov/system/files/documents/public_statements/1599783/statement_of_chair_lina_m_khan_regarding_the_request_for_information_on_merger_enforcement_final.pdf.

12 *Id.* at 8.

D. Novel Theories Relating to Data Use and Rights

Chair Kahn has also suggested that the Commission should fully exercise all the legal authorities granted by Congress by using substantive rulemaking.[13] The Commission has rarely used rulemaking as an enforcement tool, relying on the adjudication process to bring claims on a case-by-case basis. A Democratic majority on the Commission will likely broaden theories of harm and rulemaking powers.

Commissioner Bedoya's background in privacy and data may broaden the scope of both merger and non-merger investigations even further. In his confirmation statement, Bedoya focused on antitrust law enforcement against potential privacy concerns, such as smartphone geolocation technology.[14] While his statement focused on privacy, he also suggested that the Commission should use enforcement to eliminate product and treatment scams related to COVID and opiate addictions.

Technology has become a vital part of all industries and companies, including healthcare industries. Commissioner Bedoya's confirmation will likely lead to a stronger focus on technology in antitrust reviews of healthcare industries. The focus on technology could have a different effect depending on the type of antitrust investigation. In a merger review investigation, the merging parties could see more questions regarding technologies used in their healthcare practices. The Commission staff could ask whether those technologies are also used by third-parties and how the merger might impact the parties' incentives to continue to allow third-party access to these technologies. The Commission will likely investigate how a merger may foreclose third-party or competitor access to healthcare technology and/or data.

In fact, we have already seen allegations relating to the use of data rights in a recent DOJ merger challenge. On February 24, 2022, the DOJ challenged UnitedHealth Group Inc.'s acquisition of Change Healthcare Inc. According to the DOJ's complaint, UnitedHealth operates "the largest health insurance company in the United States; a large network of physician groups, outpatient surgical centers, and other healthcare providers […]; a pharmacy benefit manager (PBM) […]; and a healthcare technology business that facilitates […] the transmission, analysis, and review of health insurance claims."[15] Change is an "independent supplier of technologies used by healthcare providers to submit health insurance claims."[16] The complaint alleges that the acquisition is anticompetitive because it would give UnitedHealth access to rival health insurer's information on insurance claims and also questioned what UnitedHealth could do with "secondary data rights" to impact competition.[17]

In a non-merger investigation, the Commission could ask more questions about the use of technology as a tool to facilitate collusion in healthcare industries. Complex algorithms, artificial intelligence, and other technological advances could be used in stealthy attempts to fix prices or restrict the services offered by healthcare providers.

III. CONCLUSION

Commissioner Bedoya will bring a different perspective to the Commission based on his strong background in privacy and technology. Because Commissioner Bedoya does not have much experience in merger review, we expect that his confirmation will empower Chair Khan to expand the Commission's theories of both merger and non-merger antitrust enforcement that may ultimately make healthcare investigations more comprehensive and more expensive.

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13 Statement of Chair Lina M. Khan In the Matter of R360 Network Commission File No. 1823171 (May 17, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/1923171R-360StatementKhan.pdf.

14 Opening Statement of Alvaro M. Bedoya, Nominee to the Federal Trade Commission, *at* https://www.commerce.senate.gov/services/files/F047A749-6887-4383-A54A-7DA1459DC10B.

15 Complaint ¶2, *United States v. UnitedHealth Group Inc., et al., at* https://www.justice.gov/opa/press-release/file/1476676/download.

16 Complaint ¶2, *United States v. UnitedHealth Group Inc., et al., at* https://www.justice.gov/opa/press-release/file/1476676/download.

17 See, e.g. Complaint ¶11, *United States v. UnitedHealth Group Inc., et al., at* https://www.justice.gov/opa/press-release/file/1476676/download.

PATIENTS v. HOSPITALS: WHY DEFINE MARKETS AT ALL IF EVERY MARKET SATISFIES THE SSNIP TEST?

BY KEN FIELD & STEVEN TENN[1]

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I. INTRODUCTION

It is axiomatic that hospital merger cases are won or lost on geographic market definition. Of course, many antitrust economists and lawyers will tell you that enforcement decisions turn on competitive effects analysis and defining the relevant geographic market is mostly an afterthought. But the government has been wildly successful in convincing the courts to adopt the Horizontal Merger Guidelines, so market definition is now step one in court and the Hypothetical Monopolist SSNIP Test and concentration presumptions are now entrenched law. Moreover, as the government and courts love to remind us, no merger that triggers those presumptions has ever been saved by claimed efficiencies.

Given the strength of the presumption and the government's remarkable success relying on it, why would the Federal Trade Commission now risk undermining the Hypothetical Monopolist Test by defining a patient-based geographic market in recent litigation? Perhaps they are merely acknowledging the decreasing importance of market definition at the agencies but, more likely, they may be overcorrecting for their one loss in the past two decades and inadvertently risking their ability to succeed over the next two decades. But we are getting ahead of ourselves.

II. BACKGROUND ON GEOGRAPHIC MARKET DEFINITION IN HOSPITAL MERGERS

A. Merger Guidelines' Hypothetical Monopolist Test

As the 2010 Horizontal Merger Guidelines ("Merger Guidelines") explain, the Federal Trade Commission ("FTC") and the Department of Justice's ("DOJ's") Antitrust Division usually define geographic markets based on the Hypothetical Monopolist Test.[2] This is an iterative approach where one starts with a candidate geographic market and then tests whether a hypothetical monopolist of that candidate market would be able to profitably impose a small but significant non-transitory increase in price ("SSNIP"), often taken to be 5%. If so, then the candidate market is a relevant geographic market within which the proposed transaction can be analyzed. If not, one expands the candidate market and then repeats the analysis until the candidate market is sufficiently large to pass the test.[3]

A key motivation for using the Hypothetical Monopolist Test to define the relevant geographic market is that doing so results in a market that is sufficiently large that competition within it matters in the sense that, by construction, the elimination of all intra-market competition would result in at least a small but significant price increase (absent mitigating factors such as efficiencies and entry/repositioning).[4]

The FTC and DOJ typically define geographic markets based on supplier location when price discrimination based on customer location is not possible.[5] When price discrimination based on customer location is possible the agencies may instead delineate geographic markets based on customer location.

When analyzing hospital mergers, the FTC generally focuses on payers representing commercial patients.[6] For commercial patients, hospital prices are typically negotiated via bilateral bargaining between hospital systems and payers, who contract for provider networks on behalf of their members. It makes little sense to apply the Merger Guidelines' discussion regarding price discrimination by customer location because payers are a hospital system's customers and the location of a payer's headquarters (or other physical location) is irrelevant as it does not impact competition. As an alternative, one can potentially use the locations where payers' members reside, since payers consider the preferences of their members when negotiating contracts with providers.

Rarely, if ever, do negotiated prices between a hospital system and a payer vary depending on where an individual patient resides. Rather, the same negotiated price applies to all of a payer's members covered by a negotiated contract. When a hospital system negotiates with a payer, both sides generally know where the payer's members reside (although the hospital system's information may be more limited than the payer's). Consequently, while direct price discrimination based on member location is likely not possible in the hospital context, negotiated prices indirectly incorporate member location. Since negotiated prices reflect the aggregate preferences of all a payer's members

2 U.S. Department of Justice and Federal Trade Commission's 2010 Horizontal Merger Guidelines (August 19, 2010).

3 In this article, we focus on high level conceptual issues and do not address the specifics of how the Hypothetical Monopolist Test may be implemented. For such discission, see Steven Tenn & Sophia Vandergrift, "Geographic Market Definition in Urban Hospital Mergers: Lessons from the Advocate-NorthShore Litigation," *Antitrust Source* (December 2017).

4 Under the Merger Guidelines, such mitigating factors are analyzed separately from the market definition and competitive effects analyses. Merger Guidelines, § 9 and 10.

5 Merger Guidelines, § 4.2.

6 Most hospital mergers are investigated by the FTC rather than the DOJ.

covered by a given contract, price discrimination is likely possible only at the payer-contract level rather than for a particular subgroup of those members.

B. Hackensack-Englewood Litigation

In hospital merger challenges, the FTC has most often delineated geographic markets based on hospital location.[7] In its latest hospital merger litigation, however, in which the FTC challenged Hackensack Meridian Health's ("Hackensack's") proposed acquisition of Englewood Healthcare Foundation ("Englewood"), the FTC's economic expert's geographic market was based on patient location.[8] This geographic market included all hospitals that serve residents of Bergen County, New Jersey, where Englewood and two of Hackensack's hospitals are located. During the litigation, the FTC claimed that a geographic market based on hospital location that included only Bergen County hospitals also passes the Hypothetical Monopolist Test, and that both hospital and patient-based approaches result in valid geographic markets under the Merger Guidelines.[9] As part of their decision granting the FTC's request for a preliminary injunction, the district court judge concluded that commercially insured patients in Bergen County comprise a relevant geographic market for analyzing the proposed merger.[10] On March 22, 2022, the Third Circuit Court of Appeals concluded that the district court did not error in defining this patient-based geographic market.[11]

III. CONSIDERATIONS WHEN DELINEATING HOSPITAL OR PATIENT-BASED GEOGRAPHIC MARKETS

Relying on the Hypothetical Monopolist Test to delineate the geographic market is a meaningful exercise only to the extent this approach addresses a question relevant to assessing the competitive impact of a proposed merger. As explained below, this test addresses a very different question depending on whether the geographic market is based on hospital or patient location. The Hypothetical Monopolist Test applied to a geographic market based on hospital location addresses a question analogous to the competitive effects analysis of a proposed merger. In contrast, the Hypothetical Monopolist Test applied to a geographic market based on patient location addresses a question largely irrelevant to understanding the competitive impact of a proposed merger. We believe this distinction should be a key consideration when geographic markets are defined for proposed hospital mergers.

A. The Hypothetical Monopolist Test Applied to a Geographic Market Based on Hospital Location Addresses a Question Analogous to the Competitive Effects Analysis of a Proposed Merger

When the geographic market is based on hospital location, the Hypothetical Monopolist Test addresses whether a merger between the merging parties and other geographically proximate hospitals is likely to result in a meaningful price increase (absent mitigating factors such as efficiencies and entry/repositioning). That is, the Hypothetical Monopolist Test addresses the same issue as the competitive effects analysis described in the Merger Guidelines,[12] but for a larger merger that includes both the merging parties and additional competitors. Since a larger merger will result in greater anticompetitive effects than a smaller merger (all else equal), satisfying the Hypothetical Monopolist Test provides a necessary, but not sufficient, condition for the proposed merger to result in at least a small but significant price increase. Thus, the market definition exercise can be viewed as an intermediate step towards addressing the ultimate issue of whether a proposed merger is likely anticompetitive.

This relationship between market definition and the competitive effects analysis provides a rationale for the Merger Guidelines' presumption that a merger that sufficiently increases concentration in a relevant antitrust market is likely anticompetitive, where the Merger Guidelines define a sufficient increase in concentration as a change in the Herfindahl-Hirschman Index ("HHI") of market concentration of at least 200 points and a post-merger HHI of at least 2500.[13] If a geographic market based on hospital location satisfies the Hypothetical Monopolist Test then, by construction, sufficient consolidation between the hospitals located within the delineated market will result in meaningful anticompetitive

7 In *Cabell-Huntington-St. Mary's and Hackensack-Englewood*, the FTC defined a geographic market based on patient location. In all other hospital merger challenges since 2015 the FTC defined a geographic market based on hospital location.

8 United States District Court for the District of New Jersey Opinion, *FTC v. Hackensack Meridian Health, Inc. and Englewood Healthcare Foundation* (August 4, 2021) at 35.

9 Answering Brief of the Federal Trade Commission, *FTC v. Hackensack Meridian Health, Inc. and Englewood Healthcare Foundation* (October 29, 2021) at 24-39.

10 United States District Court for the District of New Jersey Opinion, *FTC v. Hackensack Meridian Health, Inc. and Englewood Healthcare Foundation* (August 4, 2021) at 44.

11 United States Court of Appeals for the Third Circuit Opinion, *FTC v. Hackensack Meridian Health, Inc. and Englewood Healthcare Foundation* (March 22, 2022) at 20.

12 Merger Guidelines, § 6.

13 Merger Guidelines, § 5.3.

effects (again, absent mitigating factors such as efficiencies and entry/expansion). This close relationship between the market definition and competitive effects analyses provides a logical basis for the Merger Guidelines' structural presumption.

A necessary, but not sufficient, requirement for a hospital merger to result in meaningful anticompetitive effects is that patients face meaningful travel costs to be treated at more distant hospitals.[14] If this were not the case, and patient travel costs were sufficiently low, then it would always be possible for patients to find an attractive alternative provider since the United States contains numerous high-quality hospitals. Consequently, in this situation economic theory indicates that payers would respond to the preferences of their members and would choose to exclude the merging parties (or, analogously, the hypothetical monopolist of a candidate geographic market based on hospital location) from their provider networks rather than accept a small but significant price increase. While geographic proximity is not the only dimension of hospital differentiation that matters to patients, it is fundamental in the sense that meaningful anticompetitive effects from a hospital merger cannot arise in the absence of meaningful patient travel costs.

Patient willingness to incur travel costs is accounted for in the analysis when the Hypothetical Monopolist Test is used to define a geographic market based on hospital location. If patient travel costs are sufficiently low, and consequently hospitals outside of the candidate geographic market are viewed by payers (and their members) as relatively attractive alternatives to the merging parties, then economic theory indicates that a hypothetical monopolist of the hospitals within the candidate market would not be able to raise price by a small but significant amount.[15] In contrast, if patient travel costs are sufficiently high, then payers (and their members) will not view hospitals outside of the candidate geographic market as attractive alternatives and consequently a hypothetical monopolist of the hospitals within the candidate geographic market would be able to raise price by a small but significant amount. In this manner, the Hypothetical Monopolist Test applied to a candidate geographic market based on hospital location accounts for patient travel costs, a fundamental driver of whether anticompetitive effects from the proposed transaction are likely to occur.

B. The Hypothetical Monopolist Test Applied to a Geographic Market Based on Patient Location Addresses a Question Largely Irrelevant to Understanding the Competitive Impact of a Proposed Merger

The Hypothetical Monopolist Test addresses a very different question when market definition is based on patient location. The thought experiment is whether a hypothetical monopolist that is the only potential provider of hospital services for a given patient population would be able to increase price by a small but significant amount. For example, in Hackensack-Englewood the FTC's economic expert considered patients residing in Bergen County, rather than the entire area from which the merging parties attracted patients, which included other portions of New Jersey and New York.

The assumption that the hypothetical monopolist is the only potential provider of hospital services to a target patient group is a remarkably broad proposition. It implies that the hypothetical monopolist not only owns the set of hospitals located close to where those patients reside, but also the next closest alternatives to those hospitals, and the next closest alternatives after that, and so on until the hypothetical monopolist owns all hospitals that the target patient group views as potential choices. Thus, this test involves a thought experiment involving a much higher degree of hospital consolidation than any real-world merger.

An implication of this is that patient travel costs are not a relevant consideration when the geographic market definition is based on patient location. As discussed above, the thought experiment in this formulation of the Hypothetical Monopolist Test involves a merger between every hospital that could potentially treat the target population at issue, regardless of where those hospitals are located. Consequently, patient travel costs are largely irrelevant because there are no other providers that patients could travel to as an alternative to being treated by the hypothetical monopolist.

Since the hypothetical monopolist is assumed to own all potential hospitals from which the target patient group may choose, those patients are left with only a single alternative to the hypothetical monopolist: the "no treatment" option of forgoing hospital services altogether. For patients considering certain elective procedures, it is conceivable (but not necessarily likely) that choosing not to be treated is a reasonable alternative to being treated by the hypothetical monopolist of hospital services. For many hospital services, including services involving life threatening situations, the "no treatment" option is not a viable option. Consequently, for virtually any patient population one might consider defining a geographic market around, it is likely the case that the payers of that population would rather accept a small but significant price increase rather than forgo hospital services for their members altogether.

14 Travel costs refer to any costs associated with a patient receiving care in a different location, including both direct time and monetary costs incurred as well as any patient preferences associated with receiving care in different locations.

15 Intuitively, in the absence of travel costs one could treat all hospitals in the United States as being collocated, resulting in a plethora of hospital choices that would prevent meaningful anticompetitive effects from arising.

This implication can be readily observed from the Willingness to Pay analysis that has been used in prior hospital merger litigations, most recently by the FTC's economic expert in Hackensack-Englewood.[16] Willingness to Pay captures how the exclusion of one or more hospital systems from a payer's provider network impacts the attractiveness of that provider network from the patients' perspective (which the payer takes into account when it negotiates prices with providers). As typically estimated, Willingness to Pay to include a given hospital system becomes arbitrarily large as that hospital system's share approaches 100 percent.[17] This has important implications for the Hypothetical Monopolist Test when applied to a candidate market based on patient location, since the hypothetical monopolist of that candidate market has, by construction, a 100% share.[18] Consequently, Willingness to Pay to include the hypothetical monopolist in the payer's provider network is arbitrarily large, which according to economic theory would dramatically improve the bargaining position of the hypothetical monopolist when negotiating with a payer and allow it to increase price by at least a small but significant amount.[19] This implies that any candidate market based on patient location likely passes the hypothetical monopolist test, independent of the available data or the facts of the case.

In virtually any hospital merger, the key competitive issue is whether payers view other providers as being sufficiently close alternatives for the merging parties, not whether payers view the "no treatment" option as a sufficiently close alternative to their members being treated at a hospital. For this reason, applying the Hypothetical Monopolist Test to a candidate market based on patient location does not address a question relevant for understanding the competitive implications of a proposed merger.

This weak relationship between the question addressed by the Hypothetical Monopolist Test applied to a geographic market based on patient location and the question addressed in a competitive effects analysis of a proposed transaction provides little support for applying the Merger Guidelines' structural presumption to such geographic markets. More generally, the logical implication of any candidate market based on patient location likely passing the Hypothetical Monopolist Test is that such a finding is essentially meaningless. This is a significant disadvantage of defining hospital geographic markets based on patient location, and potentially explains why the FTC has, historically, more frequently chosen to rely on geographic markets based on hospital location.

C. Patient Migration and Substitution to Outside the Market

When the Hypothetical Monopolist Test is used to define a geographic market based on hospital location, a candidate market that passes the test may not closely correspond to the geographic area of focus of the merging parties or other industry participants.[20] It is well recognized, and explicitly acknowledged by the Merger Guidelines, that antitrust markets may not correspond to how industry participants define "markets" in other applications.[21] Nonetheless, this may be perceived as a weakness of the approach, with the merging parties in hospital merger litigations often arguing that the FTC's geographic market is gerrymandered or otherwise fails to consider practical realities.

In particular, applying the Hypothetical Monopolist Test to a candidate market based on hospital location often results in geographic markets that are not self-contained. That is, a meaningful fraction of patients living in the geographic market may receive care from hospitals outside the geographic market, and a meaningful number of patients living outside the geographic market may receive care from hospitals located within the geographic market. Relatedly, a significant fraction of patients whose first choice is a hospital in the defined market may have as their second choice a hospital located outside of the market. That is, hospitals outside of the defined market may be substitutes for hospitals inside the market. It is widely recognized that it is not necessary for a geographic market to be self-contained for it to pass the Hypothetical Monopolist Test.[22] Rather, it is only necessary for the set of hospitals located within a candidate market to be sufficiently close substitutes. Nonetheless, such markets may suffer from bad optics and, consequently, may be challenging for the FTC to defend in litigation.

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16 Memorandum in Support of Federal Trade Commission's Motion for a Preliminary Injunction, *FTC v. Hackensack Meridian Health, Inc. and Englewood Healthcare Foundation* (March 22, 2021) at 25-26.

17 See, e.g. Cory Capps et. al., "Competition and Market Power in Option Demand Markets," *Rand Journal of Economics* (2003).

18 We assume that shares are measured only for hospital services and exclude the "no treatment option" from the share calculation. This is a common approach when considering hospital services.

19 Steven Tenn, "Introduction to the Economic Analysis of Hospital Mergers," Newsletter for the Economics Committee of the ABA Section of Antitrust Law (2019).

20 Competition in hospital markets is often modelled in two stages. In the first stage payers and providers negotiate prices, and then in the second stage hospitals compete to attract patients. A hospital's geographic area of focus may differ depending on which stage of competition it is considering.

21 Merger Guidelines at 8.

22 See e.g. Kenneth Elzinga & Anthony Swisher, "Limits of the Elzinga–Hogarty Test in Hospital Mergers: The *Evanston Case," International Journal of the Economics of Business* (2011).

This perceived limitation can potentially be avoided by defining markets based on patient location. By construction, there is no patient inflow or outflow from the geographic market because it includes the entire target patient population regardless of where they receive care. Similarly, there is no substitution to outside of the market because it includes all hospitals that treat the target patient population regardless of where those hospitals are located.

For example, in the Hackensack-Englewood matter the merging parties were located relatively near New York City, and a meaningful fraction of patients residing in Bergen County, New Jersey were treated at hospitals located in the state of New York or in other counties in New Jersey. Had the FTC's economic expert defined a geographic market consisting of hospitals located in Bergen County, then that market would be subject to the critique that it excludes significant competitors outside of Bergen County. By defining a geographic market consisting of patients residing in Bergen County, the FTC's economic expert avoided such criticism since the market includes all hospitals that treat patients residing in Bergen County, including hospitals located in New York or other counties in New Jersey. This approach allowed the FTC's economic expert to appear to be more conservative even though, as discussed above, a geographic market based on any patient population is likely to pass the Hypothetical Monopolist Test.

D. Inferences from Market Shares and Concentration

Regardless of whether a geographic market is based on hospital or patient location, it is often useful to consider shares and concentration from both approaches since they measure different aspects of patient preferences. Shares based on hospital location speak to the available hospital options and choices of patients with a preference for receiving care in a given geographic area. Of course, since hospitals located outside of the geographic area are excluded, such shares do not speak to the hospital options and choices of those who prefer to receive care outside that geographic area. Similarly, shares based on patient location speak to the available hospital options and choices of patients residing in a given geographic area, but do not reflect the hospital options and choices of other patients since they are excluded from the share calculation.

To the extent that patients generally prefer to receive care close to where they live, then shares based on hospital location may be quite similar to those based on patient location. If that is the case, then calculating shares based on both approaches and demonstrating the similarity of shares can be quite informative. Conversely, if shares based on hospital location are meaningfully different from shares based on patient location, then it is likely the case that it will be important to address the underlying reasons for that result.

IV. HOSPITAL MERGER ENFORCEMENT GOING FORWARD

The outcome of the Hackensack-Englewood litigation may have a significant impact on the trajectory of the FTC's hospital merger enforcement program. Specifically, the Third Circuit's finding that it is appropriate to define geographic markets based on patient location will likely incentivize the FTC to define such geographic markets more frequently in future hospital merger litigations. While the FTC may find this beneficial in the short run, doing so could erode a key advantage that the FTC currently enjoys in hospital merger litigations: the courts' willingness to endorse the Merger Guidelines' presumption that mergers that sufficiently increase concentration are anticompetitive.

It has long been debated whether market definition should be deemphasized in merger analysis, and instead greater focus should be placed on the ultimate question of competitive effects. The revised 2010 Merger Guidelines can be viewed as a step in this direction, as they explicitly note that the antitrust agencies need not start their analysis with market definition and that competitive effects can be analyzed without first defining a relevant market.[23]

Nonetheless, the Merger Guidelines' presumption that a merger is likely anticompetitive if it significantly increases concentration within a properly defined market continues to play a key role in hospital merger litigations. The Merger Guidelines' presumption shifts the burden of showing that a proposed merger is likely not anticompetitive to the merging parties (rather than the FTC's burden being to show that this is not the case). This burden shifting is a key reason why the FTC has suffered only a single loss that was not reversed on appeal since the agency rebooted its hospital merger enforcement program two decades ago.[24] Notably, the district court in the FTC's sole loss found that it had failed to properly define the geographic markets at issue.[25]

23 Merger Guidelines at 7.

24 The FTC abandoned its challenge to the merger between Jefferson Health and Albert Einstein Healthcare Network following an adverse district court decision. See, https://www.ftc.gov/legal-library/browse/cases-proceedings/181-0128-thomas-jefferson-university-matter.

25 United States District Court for the Eastern District of Pennsylvania Opinion, *FTC v. Thomas Jefferson University et al.* (December 8, 2020) at 60-61.

By construction, a merger that sufficiently increases concentration in a geographic market based on hospital location, and which passes the Hypothetical Monopolist Test, would allow the combined firm to increase price by at least a small but significant amount (absent mitigating factors). However, this is not necessarily true for geographic markets based on patient location. Since virtually any candidate geographic market based on patient location likely passes the Hypothetical Monopolist Test, any such conclusion is essentially meaningless and addresses an issue largely irrelevant to whether a proposed merger is likely anticompetitive (for the reasons explained earlier in Section III).

This disconnect between market definition and the competitive effects analysis when a geographic market is based on patient location diminishes the value of the market definition exercise. Consequently, the courts may respond to the FTC's reliance on geographic markets based on patient location by giving greater weight to competitive effects, and less weight to market definition and the Merger Guidelines' presumption. If so, the FTC may find it more challenging to win hospital merger litigations going forward, since it would become its burden to demonstrate that a merger is likely anticompetitive (rather than the merging parties' burden being to show that this is not the case). Thus, while hospital systems wishing to merge may view the FTC's reliance on patient-based geographic markets as a negative development in the short run, since the FTC will have an easier time satisfying the Hypothetical Monopolist Test for such markets, this may ultimately be a pyrrhic victory for the FTC that reduces their ability to block hospital mergers over the longer term.

We conclude by noting that market definition generally plays a less prominent role in the FTC's investigations of proposed mergers compared to hospital merger litigations. Consequently, the FTC's potential undermining of the import of market definition and the Merger Guidelines' presumption by defining patient-based geographic markets is likely to affect primarily whether it will be successful in merger litigations rather than FTC decisions regarding whether to take enforcement action. But, since the FTC takes litigation risk into account when making enforcement decisions, any lessening of its ability to win hospital merger litigations likely would eventually be internalized by the FTC and result in less aggressive FTC enforcement for hospital mergers going forward.

LABOR MARKETS IN HEALTHCARE TRANSACTIONS: A WORK IN PROGRESS

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I. INTRODUCTION

"We will fight for American workers, including in connection with illegal mergers that substantially lessen competition for laborers. Going forward, you can expect efforts like these to continue and increase."[2] So said Assistant Attorney General Jonathan Kanter recently in a joint workshop with the Federal Trade Commission. This sentiment, which once may have been considered outside the antitrust mainstream, is now widely shared among antitrust enforcers and policymakers alike. In just the last few years, the Biden Administration, Mr. Kanter's predecessors at the Department of Justice, the FTC, and the U.S. Treasury Department have all weighed in on the importance of competition in labor markets.

Historically, labor has often been treated as an afterthought in agency merger reviews, if considered at all. Frequently lumped in with other "deal synergies," reductions in headcount were line items among the transaction benefits touted by merging parties as a means for the merged firm to lower its costs. Until recently, improved labor costs were commonly highlighted as a key driver in many deals, and presented to the antitrust agencies as a reason to expect the deal to make the combined firm more competitive. Merging parties now take that approach with the agencies with caution.

Still, the agencies are wading into relatively uncharted waters. They have no clear mandate from the courts to challenge deals based on lost competition for labor, as antitrust litigation alleging anticompetitive behavior by employers in labor markets has been relatively rare and principally concerned conduct like "no poach" agreements or industries like sports leagues that raised idiosyncratic issues.[3] But the agencies' shift in focus now puts labor competition in play for mergers across all industries, and particularly in healthcare, where deals are often closely scrutinized and agency staff have demonstrated a willingness to investigate and challenge even small or "under the radar" transactions.

So it is fair to ask: what grounds do the U.S. antitrust agencies have for challenging a merger where competition for employees might be reduced? And what, if any, steps can merging parties take to head off a potential fight with agency staff over the impact their transaction will have on labor markets? In this paper, we attempt to answer those questions, at least preliminarily, and peer down the road ahead.

II. THE BIDEN ADMINISTRATION AND ANTITRUST AGENCIES' GROWING EMPHASIS ON LABOR MARKETS IN MERGER REVIEWS

A. Leadership Across the Administration Turns Eye Toward Labor Markets

It is no secret that the Biden administration and leadership at the U.S. antitrust agencies are focused on labor markets, turning a source of potential cost savings for merging parties into a wellspring of FTC and DOJ staff questions.[4] President Biden's Executive Order in July 2021 underscored the importance of competition in labor markets.[5] As a result of that order, the U.S. Treasury Department released a report in March concluding that "uncompetitive firm behavior in labor markets" can hurt workers, create barriers to mobility, and weaken the economy as a whole.[6] The Treasury Department found that many American labor markets display high concentration levels and raised concerns specifically about healthcare labor markets, citing "evidence that hospitals exerted considerable monopsony power" -- i.e. buyer market power over suppli-

2 Flavia Fortes, *US DOJ to Boost Efforts to Protect Competition in Labor Market, Kanter Says*, MLex (Dec. 6, 2021), https://content.mlex.com/#/content/1342523?referrer=search_linkclick.

3 E.g. *Banks v. Nat'l Collegiate Athletic Ass'n*, 977 F.2d 1081, 1084 (7th Cir. 1992).

4 On July 9, 2021, President Biden signed an executive order on Promoting Competition in the American Economy. News Release, The White House, Fact Sheet: Executive Order Establishing the White House Task Force on Worker Organizing and Empowerment (Apr. 26, 2021), https://www.whitehouse.gov/briefing-room/statements-releases/2021/04/26/fact-sheet-executive-order-establishing-the-white-house-task-force-on-worker-organizing-and-empowerment/.

5 *Id.*

6 U.S. Dep't Of Treasury, The State Of Labor Market Competition (Mar. 2022), https://home.treasury.gov/system/files/136/State-of-Labor-Market-Competition-2022.pdf.

ers.[7] The report found that despite a growing population, the total number of hospitals fell from 7,156 in 1975 to 6,093 in 2021 nationwide.[8] As this consolidation occurred, the Treasury Department concluded that hospitals gained buyer power in labor markets, particularly where mergers resulted in much higher market concentration.[9]

U.S. Attorney General Merrick Garland recently spoke about labor markets in merger analysis at a White House Roundtable, stating that "[o]ur review will ensure, among other things, that merger guidelines fully address the potential for mergers to harm labor market competition."[10] AG Garland also highlighted a plan for increased collaboration between the Justice Department and the Department of Labor to promote competitive labor markets and worker mobility.[11] Federal Trade Commission Chair Lina Khan has similarly emphasized that the FTC will ensure that it is using all available tools to tackle unfair methods of competition that affect workers: "One of my top areas of focus at the FTC is ensuring that we consider labor markets when investigating potentially illegal mergers."[12] The FTC and DOJ also recently launched a joint initiative to revise their merger guidelines, in part to ensure that merger investigations account for harms to workers and labor market competition.[13]

B. Labor Markets Begin to Feature in Merger Challenges

There have been instances where labor market issues have arisen in cases under past administrations alongside more traditional competitive effects. For example, in DOJ's challenge to the 2006 acquisition of Pacificare Health Systems by UnitedHealth Group, in addition to concerns about anticompetitive effects in markets for the sale of commercial health insurance, DOJ alleged that the merger would adversely impact markets for the purchase of physician services in Arizona and California.[14] DOJ was satisfied, however, that divestiture and other remedies ordered in that case resolved both types of concerns.[15]

In 2017, the D.C. Circuit affirmed DOJ's successful challenge of a merger between health insurers Anthem and Cigna.[16] Among other deal benefits, the merging parties claimed that they would be able to bargain for lower rates from healthcare providers post-merger. But, far from finding that this was a merger efficiency that should count in favor of the transaction, the Court described such bargaining power as an exercise of monopsony power in the merging firms' supply markets.[17] In her concurring opinion, Judge Millett challenged the dissent opinion's suggestion that an exercise of increased bargaining power short of monopsony is beneficial: "securing a product at a lower cost due to increased bargaining power is not a procompetitive efficiency when doing so 'simply transfers income from supplier to purchaser without any resource savings.'"[18]

The DOJ's recent challenge to the proposed merger between Penguin Random House and Simon & Schuster, two large book publishers, reflects the evolving approach to labor markets in merger enforcement. There, labor concerns are front-and-center: DOJ's theory of the case

7 *Id.* at 41. In economic terms, a market with a single buyer has "monopsony power" to pay lower prices for its inputs (i.e. what it buys). In a labor market, monopsony power may exist if workers have only one option (or very few options) for employment (e.g. a classic "company town"). As the sole buyer of labor, the monopsonistic firm can hire fewer workers at a lower wage than in a competitive labor market where workers have many choices. *See generally* Council of Economic Advisers (CEA), *Labor Market Monopsony: Trends, Consequences, and Policy Responses* (Oct. 2016), https://obamawhitehouse.archives.gov/sites/default/files/page/files/20161025_monopsony_labor_mrkt_cea.pdf. While fewer workers may translate into less output for the firm, the lower wages may reduce overhead and thus be profit-maximizing. In short, "by recruiting less aggressively, paying less, and sacrificing some employment, employers with monopsony power can shift some of the benefits of production from wages to profits." *Id.* at 2.

8 U.S. Dep't Of Treasury, The State Of Labor Market Competition, 41 (Mar. 2022), https://home.treasury.gov/system/files/136/State-of-Labor-Market-Competition-2022.pdf.

9 I*d.* at 41-42. At least one commentator has suggested that fewer hospitals in a market also increases the likelihood of collusion harming workers. E.g. Alan Krueger, *Reflections on Dwindling Worker Bargaining Power and Monetary Policy*, Luncheon address to FRB Kansas City's Jackson Hole Symposium, (Aug. 24, 2018), https://www.kansascityfed.org/documents/6984/Lunch_JH2018.pdf.

10 Merrick B. Garland, Att'y Gen., Remarks at the White House Roundtable on the State of Labor Market Competition in the U.S. Economy, MLex (Mar. 7, 2022), https://content.mlex.com/#/content/1364094?referrer=search_linkclick.

11 *Id.*

12 Lina M. Khan, Chair, Fed. Trade Comm'n, Remarks at White House Roundtable on the State of Labor Market Competition in the U.S. Economy (Sept. 22, 2021), https://www.ftc.gov/system/files/ftc_gov/pdf/Opening%20Remarks%20of%20Chair%20Lina%20M.%20Khan%20at%20WH%20Labor%20Roundtable.pdf.

13 Press Release, Federal Trade Commission, Federal Trade Commission and Justice Department Seek to Strengthen Enforcement Against Illegal Mergers (Jan. 18, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/01/federal-trade-commission-justice-department-seek-strengthen-enforcement-against-illegal-mergers.

14 Compl., *United States v. UnitedHealth Group, Inc.*, 1:05-cv-02436 (D.D.C. Mar. 3, 2006) at 31-43, 44-53, https://www.justice.gov/atr/case-document/complaint-229.

15 Competitive Impact Statement, *United States v. UnitedHealth Group, Inc.*, 1:05-cv-02436 (D.D.C. Mar. 3, 2006), https://www.justice.gov/atr/case-document/competitive-impact-statement-214.

16 *United States v. Anthem, Inc.*, 855 F.3d 347, 348 (D.C. Cir. 2017).

17 *Id.* at 370-371.

18 *United States v. Anthem, Inc.*, 855 F.3d 347, 371 (D.C. Cir. 2017) (quoting Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law, 106 (2016)).

is premised on the transaction's impact on authors, particularly authors of anticipated top-selling books.[19] The complaint alleges that the deal would give Penguin Random House control of close to half the market for the acquisition of publishing rights to anticipated top-selling books, "leaving hundreds of authors with fewer alternatives and less leverage."[20] The case only alleges harm to consumers indirectly. Given competition from a wide range of other publishers (many beyond traditional book publishers), DOJ likely would have faced an uphill battle showing that the transaction would lead to higher prices on books to consumers.[21]

Meanwhile at the FTC, two Commissioners recently raised labor markets as a competitive concern in a healthcare merger. In voting out the FTC's challenge to the merger of Lifespan Corp. and Care New England Health System, Chair Khan and Commissioner Slaughter's concurrence stated that, in addition to harm to healthcare services markets, they would have supported an allegation that the merger would substantially lessen competition in labor markets: "We take seriously concerns about competition in labor markets and will be vigilant in probing the effects mergers may have on competition for workers' labor. We applaud the staff for their thorough and diligent investigation of the labor market implications of this transaction, and we expect such analysis to continue in future cases."[22]

The FTC also wrote to Texas regulators in September 2020 warning that if the state allowed two competing hospitals in rural West Texas to merge, it would result in depressed wages for registered nurses.[23] The FTC did not mince words, arguing that mergers generating large increases in employer concentration have meaningful and statistically significant harmful effects on employee wages, and that the transaction would result in serious competitive and consumer harm and lower wage growth for nurses.[24] Despite the FTC's concerns, however, Texas allowed the hospitals to close the deal.[25]

III. DO THE ECONOMICS SUPPORT THE AGENCIES' LABOR MARKET CONCERNS?

Against this backdrop, the economics of labor markets will play a key role in determining whether courts go along with the agencies and block deals. Certain recent economic studies -- several by the same group of authors -- claim to find that labor market concentration may be widespread and concentration may lead to lower wage growth.[26] One paper by Azar et al. attempts to estimate concentration in labor markets based on share of posted vacancies (as opposed to employment shares). To navigate the tricky task of identifying geographic labor markets, Azar et al. used commuting zones by 6-digit Standard Occupational Classification ("SOC") occupation as a proxy.[27] On the high end, the authors estimated that 60 percent of U.S. labor markets are "highly concentrated" and another 11 percent are "moderately concentrated."[28] However, the study's

19 Compl. at 2, *United States v. Bertelsmann SE & Co. KGaA et al.*, 1:21-cv-02886 (D.D.C. Nov. 2, 2021).

20 *Id.* at 7.

21 *Id.* at 17-21.

22 Comm'r Slaughter and Chair Khan, Concurring Statement, *FTC and State of Rhode Island v. Lifespan Corporation and Care New England Health System* (emphasis added), 2, FTC File No. 2110031 (Feb. 17, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/public_statement_of_commr_slaughter_chair_khan_re_lifespan-cne_redacted.pdf. Notably, in its decision denying the merging parties' application under separate Rhode Island legislation, the Rhode Island Attorney General expressly cited potential harm to Rhode Islanders working in skilled healthcare jobs as a basis for his decision. Decision, Rhode Island Att'y Gen., Denial of Initial Application of Rhode Island Academic Health Care System Inc. et al. (Feb. 17, 2022), https://www.riag.ri.gov/media/2996/download.

23 FTC Staff, Comment to Texas Health and Human Services Commission Regarding the Certificate of Public Advantage Applications of Hendrick Health System and Shannon Health System (Sept. 11, 2020), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-texas-health-human-services-commission-regarding-certificate-public-advantage/20100902010119texashhsccopacomment.pdf. A COPA is a written certificate typically issued by a state department of health under state law and regulations that seek to displace federal (and sometimes state) antitrust laws. Alexis Gilman, *FTC to Study the Impact of COPAs*, Crowell (Oct. 29, 2019), https://www.cmhealthlaw.com/2019/10/ftc-to-study-the-impact-of-copas/.

24 FTC Staff, Comment to Texas Health and Human Services Commission Regarding the Certificate of Public Advantage Applications of Hendrick Health System and Shannon Health System (Sept. 11, 2020), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-texas-health-human-services-commission-regarding-certificate-public-advantage/20100902010119texashhsccopacomment.pdf.

25 Brian Bethel, *Hendrick Health System-Abilene Regional Medical Center Merger Moves Forward*, Report News, https://www.reporternews.com/story/news/2020/10/05/hendrick-hospital-medical-center-abilene-regional-hospitals-merger-approved/3625154001/, (last updated Oct. 5, 2020).

26 José Azar & Ioana Marinescu & Marshall Steinbaum & Bledi Taska, *Concentration in US labor markets: Evidence from Online Vacancy Data*, Labor Economics, vol. 66 (2019), https://www.nber.org/system/files/working_papers/w24395/w24395.pdf.

27 The paper defines a labor market as a six-digit SOC ("Standard Occupational Classification") by commuting zone (e.g. accountants and auditors in the Philadelphia commuting zone). Commuting zones were developed by the USDA to capture local economies and local labor markets in a way that is more economically meaningful than county boundaries. *Id.* at 9-10.

28 Under the FTC and DOJ's 2010 Horizontal Merger Guidelines, moderately concentrated markets have HHI between 1500 and 2500 and highly concentrated markets have HHI above 2500. In this case, market shares are based on the share of job vacancies of all the firms that post vacancies in that market. *Id.* at 9.

underlying assumptions and focus appear to have a significant impact on its findings, particularly in their application to healthcare. For example, when considering the percentage of workers that actually face highly concentrated markets, the study found that only 28 percent of employment is in markets that are either highly or moderately concentrated, meaning 72 percent of employment is in markets that would be considered "unconcentrated" under the current DOJ and FTC Merger Guidelines.[29] Moreover, when examining market concentration levels faced by workers in common occupations, the study found that registered nurses faced the lowest concentration of the 30 occupations examined.[30]

Another paper by Azar et al. finds that higher labor market concentration leads to lower wages for workers, concluding that an increase in the Herfindahl–Hirschman index ("HHI") of 200 in a market of 2,000 (moderately concentrated) is associated with a 1.4 percent decrease in wages.[31] The sole source of data for the analysis was a single website, CareerBuilder.com, from which the authors pulled posted wage information that does not contain all vacancies in the occupations they studied, and, as they concede, could lead to overestimation of labor market concentration.[32] The authors also acknowledge that "the correct geographic definition for labor market competition for hiring is still an open question," although they believe the results would be similar if other "plausible" geographic labor market definitions were applied.[33] This study also found -- consistent with the first Azar study above -- that markets for registered nurses were among the lowest concentrated , averaging just over 2,000 HHI.[34]

A study by Qui et al. found that reducing concentration of a labor market from the 75th percentile (0.045) to the median level (0.017) would imply an 8.7 percent increase in wages and a 2.0 percent increase in the probability of being covered by work-based health insurance.[35] The study used core-based statistical area ("CBSA") data as proxy to define geographic local labor markets, Dun & Bradstreet ("D&B") data on location, industry, and annual sales to calculate product market concentration, and employment-based HHI (rather than vacancy-based as found in the Azar study) to estimate local market concentration.[36] However, another analysis in the Qui et al. study yielded a different result – estimates from their ordinary least squares ("OLS") analysis, which uses various fixed effects (e.g. comparing workers within the same product-market-year but different occupations) and observable controls (e.g. worker demographics), show a very small positive effect on wages, or at worst, a neutral effect.[37] These results taken together may imply an inconclusive link between labor market concentration and wages. Interestingly, the study also found that current average labor market concentration levels are below what they were in the year 2000.[38]

Kevin Rinz's 2018 paper weighed in on the concentration debate by studying the relationship between national and local industrial markets, as a proxy for labor markets.[39] Using North American Industry Classification System ("NAICS") industries within commuting zones and trends from the Census Bureau's Longitudinal Business Database ("LBD"), Rinz compared concentration trends between 1976 and 2015. He found that while increases in local industrial concentration can reduce earnings, on average, local industrial concentration was lower in 2015 than in 1976, even as national industrial concentration increased.[40] According to Rinz, major firms have expanded into the same markets (i.e. cities), thus reducing local concentration. As a result, average annual earnings were 1.2 percent higher in 2015 than they would have been if average local industrial concentration had remained at its 1976 level.[41]

How does this all apply to healthcare? The conclusions one might draw from these studies with respect to merger effects on healthcare labor markets are unclear. Other studies suggest that hospital mergers may have adverse wage effects in certain cases.

29 *Id.* at 15.

30 *Id.* at 14-15.

31 Azar, José & Marinescu, Ioana Elena and Steinbaum, Marshall, *Labor Market Concentration*, 16 (2018), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3088767.

32 *Id.* at 20.

33 *Id.* at 18.

34 *Id.* at 11-12, Figure 4.

35 Yue Qui & Aaron J. Sojourner, *Labor-Market Concentration and Labor Compensation,* 22 (2019), https://ssrn.com/abstract=3312197.

36 Core-based statistical area data is a geographic area as defined by the U.S. Office of Management & Budget. *Id.* at 6.

37 *Id.* at 15-17, 23, 31-32, 57. Ordinary least squares (OLS) analysis is a statistical method of analysis that estimates the relationship between one or more independent variables and a dependent variable. *Id.* Qui et al. also ran the OLS analysis using commuting zone data to define geographic local labor markets and found that the results were qualitatively similar. *Id.* at 6, 57, 58.

38 *Id.* at 4.

39 Rinz, Kevin, *Labor Market Concentration, Earnings Inequality, and Earnings Mobility*, Technical Report (2018), U.S. Census Bureau Center for Administrative Records Research and Applications, https://www.census.gov/content/dam/Census/library/working-papers/2018/adrm/carra-wp-2018-10.pdf.

40 *Id.* at 3-4.

41 Rinz, *supra*, at 28.

In what may be the most extensive examination of hospital merger effects on wages, Prager and Schmitt examined the labor market impacts of hospital mergers nationwide over a 10-year period.[42] Their study found that wage growth slowed following hospital mergers leading to significant increases in employer concentration, but only for workers whose skills were industry-specific. The study found that wages for employees who were closely tied to the medical profession (e.g. nurses) experienced a slowdown in growth, but wages for employees whose skills were more transferable to other industries (e.g. cleaning or maintenance) did not.[43] In particular, hospital mergers within the same market resulted in slowdowns in wage growth, but only for workers whose employment prospects were closely linked to hospitals and only in mergers that dramatically increased employer concentration (the top quartile of mergers in terms of concentration).[44] The authors of the study note that the wage growth slowdown found in their study may only apply in a narrow set of circumstances (i.e. highly concentrative mergers and industries in which skills have limited transferability).[45]

A separate 2010 study attempted to track the impact of employer concentration in the nurse labor market based on changes in wages at Veterans Affairs ("VA") hospitals, which are set on a local level. This study suggested that upstream demand for specialized labor (nurses) to individual hospitals is relatively inelastic.[46] In other words, changes in prices (or wages) produced small changes in demand for jobs. The study estimated that a 10 percent decline in nurses' wages only decreased employment by about 1 percent in the short run.[47] An important consideration, however, is that the data source used in this study – limited to VA hospital wages – may not be a fair predictor of the effects of private mergers on nurse wages, particularly in areas where nurses have options beyond hospitals, such as nursing homes. So while inelastic demand could have implications in merger analysis, the study leaves many unanswered questions.

It is debatable whether these studies accurately reflect reality and can be reconciled with real-world experience in healthcare. For nurses in particular, there is a well-documented shortage crisis for hospitals nationwide. A study done by New York-based consultant Mercer, found that if current trends continue, 29 states will not be able to fill demand for nurses in the next five years.[48] The crisis is especially dire in Pennsylvania, which by 2026, will lead the nation with a shortage of 20,345 nurses.[49] As demand for healthcare workers has soared, their wages have risen substantially nationwide,[50] with one study analyzing Western Pennsylvania finding that the average hourly wage paid to a medical staffing agency for a nurse assistant position rose 444 percent between 2019 and 2021, (from $9 per hour to $49 per hour).[51]

IV. THE WAY FORWARD

It is clear that the antitrust agencies will increasingly focus on labor markets in mergers across all industries, and healthcare deals will be no exception. As with conventional merger analysis, we can safely expect antitrust regulators to apply HHI screens to healthcare labor markets to identify mergers significantly increasing concentration. They will likely use such assessments to determine whether a merger warrants a Second Request or potentially a court challenge on the basis that lost competition for employees will lead to lower wages or reduced benefits.

42 Elena Prager and Matt Schmitt, *Employer Consolidation and Wages: Evidence from Hospitals*, 3, American Economic Review, 111(2): 397-427 (2021), https://www.kellogg.northwestern.edu/faculty/research/researchdetail?guid=02d42579-ffeb-11e8-91be-0242ac160003.

43 Over the four years after a merger where the market concentration was significantly increased, nominal wages were 4 percent lower for skilled workers and 6.8 percent lower for nurses and pharmacy workers than they would have been absent the merger. Post-merger annual wage growth of 1 percent and 1.7 percent points represents a reduction compared to the average annual nominal wage growth of 3 percent to 4 percent. *Id.* at 3.

44 *Id.* at 34.

45 *Id.* at 14.

46 Douglas O. Staiger, Joanne Spetz, & Ciaran S. Phibbs, *Is There Monopsony in the Labor Market? Evidence from a natural experiment,* Dartmouth Scholarship. vol. 1780 (2010), https://digitalcommons.dartmouth.edu/cgi/viewcontent.cgi?article=2783&context=facoa.

47 *Id.* at 231.

48 Cassie Lenski, *Major US healthcare labor shortages projected in every state by 2026, mental health professionals grow in high demand, Mercer report shows Mercer* (2021), https://www.mercer.com/newsroom/us-projected-to-have-major-healthcare-labor-shortages-in-every-state-mental-health-professionals-grow-in-high-demand.html; Kris Mamula, *Staffing Woes Driving Western Pennsylvania Hospitals' Struggles with Costs,* Post-Gazette (Feb. 28, 2022), https://www.post-gazette.com/business/career-workplace/2022/02/28/western-pennsylvania-nursing-hospital-staffing-expenses-labor-shortgage-covid-19-salaries/stories/202202240158.

49 *Id.*

50 Kylie Logan, *Nursing salaries surge 4% to combat burnout and worker shortages*, Fortune (Nov. 19, 2021), www.fortune.com/2021/11/19/nursing-shortage-salary-increases-average-pay/.

51 Lenski, *supra.*

But the agencies still face several important hurdles in using labor markets as the basis for challenging a healthcare merger. First, defining labor markets geographically is far from straightforward, particularly in healthcare, where a "one size fits all" approach is unlikely to succeed. For example, even if the markets from which hospitals draw patients are relatively narrow, the area from which those same hospitals draw labor, particularly nurses, may be much broader.

Second, regional (or even nationwide) effects may swamp any potential local harm to labor from the merger as nurses now come not only from a hospital's local areas, but through travel-nurse agencies that recruit nationwide. The demand for travel nurses exploded during the pandemic with about 30,000 open positions for travel nurses nationwide in 2021.[52] This phenomenon is fueled by wages: travel nurses can make up to 10 times their salaries compared with local employment options.[53] The constraints from both the nursing shortage and attractiveness of travel nursing positions have forced hospital executives to increase staff nurse salaries, and also to take more qualitative steps to attract and retain staff. For example, hospitals are offering non-traditional monetary perks (e.g. sign-on bonuses) and non-monetary benefits (e.g. scheduling flexibility) to recruit and retain staff.[54]

Third, on the "product market" dimension, healthcare labor markets may not be limited simply to the merging parties and their direct competitors. For example, in a hospital merger, the labor market may need to be more broadly construed than simply hospital-based nursing jobs to include a wide range of alternative roles, such as home healthcare, hospice nursing, specialist nursing facilities, nursing homes, physicians' offices, and other nursing positions. In fact, there may be a very broad range of healthcare roles to which a hospital nurse may choose to switch should wages or other conditions of employment change post-merger.

Fourth, reductions in labor costs may still be creditable efficiencies from a merger. Although the Supreme Court has never endorsed an efficiencies "defense" that would allow an otherwise anticompetitive merger to proceed, and lower courts have typically either set an impossibly high threshold or given efficiencies little credit,[55] the agencies have traditionally considered efficiencies arguments in a merger investigation.[56] Consistent with the current Merger Guidelines, the Third Circuit outlined a four-part test for a cognizable efficiencies defense in its recent decision affirming the FTC's successful challenge of Hackensack Meridian's acquisition of Englewood Health:

> For the efficiencies defense to be cognizable, the efficiencies must (1) "offset anticompetitive concerns in highly concentrated markets"; (2) "be merger-specific" (i.e. the efficiencies cannot be achieved by either party alone); (3) "be verifiable, not speculative"; and (4) "not arise from anticompetitive reductions in output or service."[57]

Under the last factor, merging parties must show that reduced headcount or elimination of duplicative employment positions would lower costs but not as a result of lost competition for employees. But the reality is that most hospital mergers would not be expected to reduce demand for nurses because, absent strong evidence that a merger will result in reduced output, the number of patients, procedures, and nurse-focused tasks should remain the same, if not increase, following many hospital combinations. Still, merging parties should expect FTC or DOJ staff to probe whether any labor cost savings result from lost competition for upstream supply of employees.

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52 Alexandre Tanzi, *U.S. Travel Nurses Are Being Offered as Much as $8,000 a Week*, Bloomberg (Aug. 31, 2021), https://www.bloomberg.com/news/articles/2021-08-31/there-s-a-market-for-8k-a-week-nurses-in-u-s-as-delta-spreads#:~:text=There%20are%20about%2030%2C000%20open,a%20health%2Dcare%20staffing%20firm.

53 Leticia Miranda, *Rural Hospitals Losing Hundreds of Staff to High-Paid Traveling Nurse Jobs*, NBC News (Sept. 15, 2021), https://www.nbcnews.com/business/business-news/rural-hospitals-losing-hundreds-staff-high-paid-traveling-nurse-jobs-n1279199.

54 Blake Farmer, *Worn-Out Nurses Hit the Road for Better Pay, Stressing Hospital Budgets — and Morale*, NPR (Oct. 20, 2021), https://www.npr.org/sections/health-shots/2021/10/20/1046131313/worn-out-nurses-hit-the-road-for-better-pay-stressing-hospital-budgets-and-moral; Sam Campbell, *How flexible scheduling in healthcare benefits staff, patients, and organizational outcomes*, When I Work (July 29, 2020), https://wheniwork.com/blog/flexible-scheduling-in-healthcare.

55 "Contrary to endorsing such a defense, the Supreme Court has instead . . . cast doubt on its availability." *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 347 (3d Cir. 2016); *see also* Penn State, 838 F.3d at 327 ("Because we conclude that the Hospitals cannot show that their claimed efficiencies will offset any anticompetitive effects of the merger, we need not decide whether to adopt or reject the efficiencies defense.").

56 Deborah Feinstein, Former Director of the FTC Bureau of Competition, noted in 2017, that the FTC "routinely consider[s] efficiency arguments, especially with respect to quality improvement claims" and that "the FTC does decide not to pursue cases based on [its] assessment of these claims" during the investigation phase. Deborah Feinstein, To Know Where You're Going, Look at Where You've Been, AAI Healthcare Roundtable: Competition and Healthcare – Enforcement and Policy Priorities, Washington, D.C. (Feb. 22, 2017), https://www.ftc.gov/system/files/documents/public_statements/1120623/feinstein_aai_speech_2-22-17.pdf . The 2010 FTC and DOJ Horizontal Merger Guidelines issued by the FTC and DOJ acknowledged efficiencies as a potential defense in horizontal mergers, but those Guidelines have now been withdrawn by both agencies. U.S. Dep't of Justice & Fed. Trade Comm'n, Horizontal Merger Guidelines (2010), ftc.gov/os/2010/08/100819hmg.pdf.

57 *FTC v. Hackensack Meridian Health and Englewood Healthcare Foundation*, 21-2603 (3d Circuit Oct. 29, 2021) (quoting *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 348-349 (3d Cir. 2016)) (citation omitted).

Fifth, economic models such as those described above may be vulnerable to attack or distinguishable from the specific facts of a hospital merger for the reasons noted as well as others. Among other things, they rely on assumptions about travel distances that may not apply to healthcare workers. They also face limitations based on the available data, which may have led to biased or misleading results.

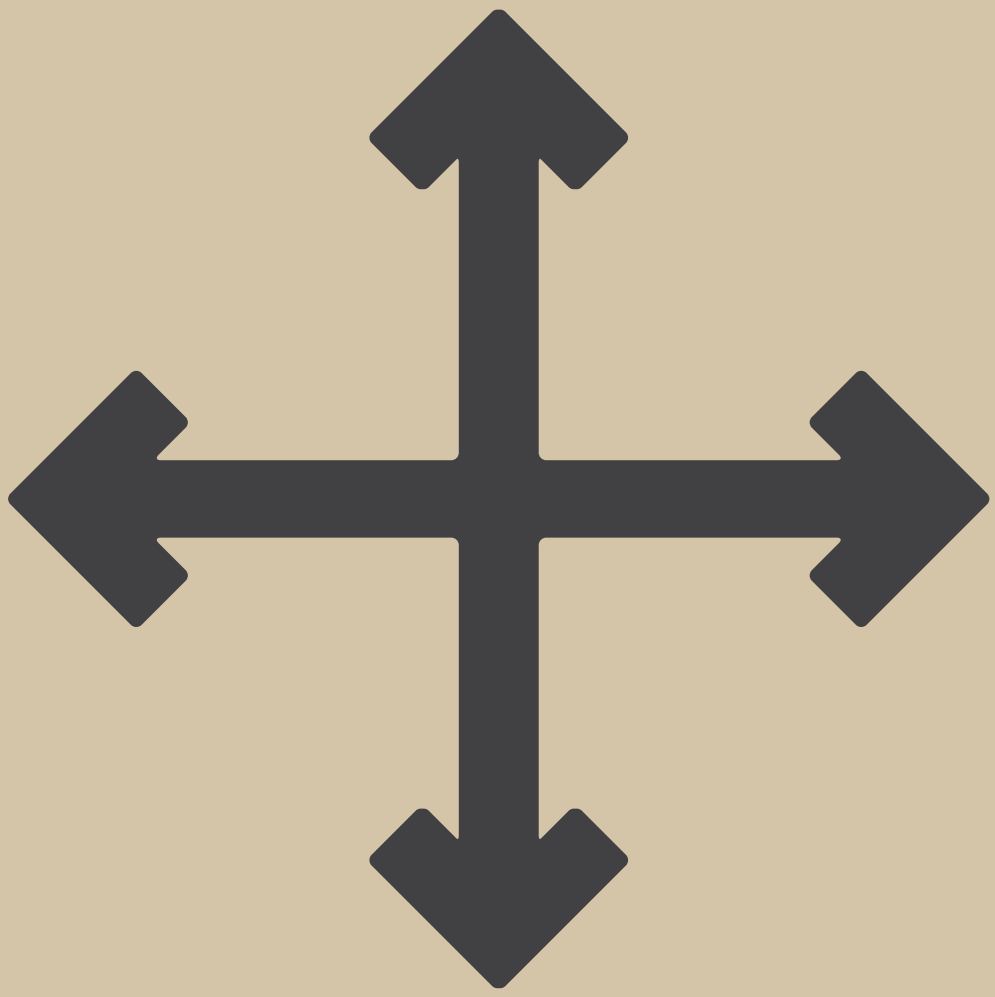
Finally, external forces may prevent any attempted reduction in wages or non-monetary benefits or perks following a healthcare deal. Galvanized by concerns with safety, pay, and staffing shortages in hospitals, nurses are increasingly turning to union membership for help.[58] Nurses have taken action over pay and staffing issues, with multiple healthcare strikes across the country in 2021.[59] Already facing nursing staffing shortages, nurses' unions can provide further constraints on merging hospitals that might seek to lower wages or reduce non-monetary benefits.

Merging parties should factor these labor market concerns and potential strategies into their merger plans, both in their advocacy before the agencies and potential contingencies for a court challenge.

58 Kathleen Gaines, *Should I Join a Nurses Union? Pros and Cons*, Nurse.org (Jan. 20, 2022), https://nurse.org/articles/pros-and-cons-nursing-unions/. Nursing membership was 20 percent in 2021. *Id.*

59 Most notably a 10-month strike at Tenet Healthcare-owned St. Vincent Hospital in Massachusetts, resulting in a new contract that increased wages. Dave Muoio, *Nurses Vote to End 10-Month Strike at Tenet Healthcare's St. Vincent Hospital*, Fierce Healthcare (Jan. 4, 2022), https://www.fiercehealthcare.com/hospitals/nurses-strike-tenet-healthcare-st-vincent-hospital-vote-to-end-10-month-strike-at-tenet#:~:text=Vincent%20Hospital,-By%20Dave%20Muoio&text=Nurses%20at%20Tenet%20Healthcare%2Downed,-from%20the%20Massachusetts%20Nursing%20Association.

EVOLVING ANTITRUST ANALYSIS OF HOSPITAL MERGERS: HOW DIFFERENCES BETWEEN PATIENT AND INSURER PERSPECTIVES COULD CREATE "CROSS-MARKET" EFFECTS



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I. INTRODUCTION

Markets for inpatient hospital services are generally considered to be geographically compact. Patients are unwilling to travel far for certain services, so providers separated by long distances are considered unlikely to compete with each other. Despite this, empirical academic studies have found some evidence of price increases following mergers of hospital systems that are too distant to serve as close substitutes for most patients — mergers referred to as "cross-market" mergers.[2] "Cross-market" mergers can be defined as health system mergers, or components of these mergers, that combine providers that are not substitutes from the point of view of patients — i.e. mergers in which the merging systems are not located within the same market as defined by patients' willingness to substitute between hospitals.[3]

Recent actions by the FTC and the California Attorney General reflect growing attention placed on mergers that expand healthcare systems, even when such mergers combine providers that are unlikely to compete for inpatient discharges. In the merger of Cedars-Sinai Health System and Huntington Hospital, for example, the California AG demanded several concessions from the merging parties before allowing their merger to proceed, despite the fact that the geographic overlap between the two systems was limited.[4] The California AG's office stated that it was concerned about the potential for pricing power that could extend across distant providers — and proposed remedies designed to neutralize that potential.[5] Separately, in the merger of Beaumont Health with Spectrum Health in Michigan, the FTC conducted a lengthy review of the merger, despite the fact that, as with Cedars-Sinai and Huntington, there is little geographic overlap between the systems.[6] Neither the FTC nor the parties commented on specific substantive issues that would have led to the extended review. However, the FTC signaled last year that it may be interested in theories of harm related to "the cross-market effects" of mergers.[7] In response to the U.S. Department of Justice and Federal Trade Commission's recent request for information on merger enforcement, twenty-three state attorneys general, and the academic economists Leemore Dafny & Nancy Rose submitted comments recommending greater scrutiny of cross-market mergers between healthcare providers, and expressing the concern that such mergers have led to higher prices.[8]

The sense in which these mergers are "cross-market" depends on a tension between defining the set of relevant competitors from the point of view of patients, while examining competitive effects on prices negotiated by *insurers*. As practitioners are well aware, insurers, not patients, negotiate network inclusion and provider pricing (at least for commercial plans). Antitrust analysis took a significant step in this direction with the shift from patient flow-based analyses of market effects to willingness-to-pay-based analyses, which used patient choices to gain insight into the value to *insurers* of including a provider in their networks.[9] The insight that prices and network inclusion are negotiated by insurers well before an individual patient selects a hospital for treatment of a specific health consideration refined the set of relevant competitors. For example, although some patients may be willing to travel significant distances for care, employers and enrollees may not be willing to select a health plan that only includes more distant providers in-network — meaning that insurers cannot use those providers as substitutes in forming

2 See, e.g. Leemore Dafny, Katherine Ho & Robin S. Lee, "The Price Effects of Cross-Market Hospital Mergers: Theory and Evidence from the Hospital Industry" *RAND Journal of Economics*, 2019, 50: 286; and Matthew Lewis & Kevin Pflum, "Hospital systems and bargaining power: Evidence from out-of-market acquisitions," *RAND Journal of Economics*, 2017, 48 (3): 579-610.

3 Keith Brand & Ted Rosenbaum, "A Review of the Economic Literature on Cross-Market Health Care Mergers," *Antitrust Law Journal*, 2019, 82: 533–549.

4 "Attorney General Becerra Conditionally Approves Affiliation Agreement Between Cedars-Sinai and Huntington Memorial Hospital," *State of California, Department of Justice*, December 10, 2020, available at https://oag.ca.gov/news/press-releases/attorney-general-becerra-conditionally-approves-affiliation-agreement-between.

5 "Attorney General Becerra Conditionally Approves Affiliation Agreement Between Cedars-Sinai and Huntington Memorial Hospital," *State of California, Department of Justice*, December 10, 2020, available at https://oag.ca.gov/news/press-releases/attorney-general-becerra-conditionally-approves-affiliation-agreement-between. An attempted merger, abaondoned in 2018, between Atrium Health and UNC Health Care may have raised similar issues. See UNC Health Care - Atrium Health merger collapses - Carolina Journal - Carolina Journal.

6 See, e.g. "Beaumont-Spectrum Merger Delayed by FTC Backlog, Officials Say," *Detriot News*, September 24, 2021, available at https://www.detroitnews.com/story/news/local/oakland-county/2021/09/24/beaumont-spectrum-merger-delayed-ftc-backlog-officials-say/5847833001/.

7 The FTC has already stated that it will broadly consider the possible "cross-market effects of a transaction" in second requests. *See*, "Making the Second Request Process Both More Streamlined and More Rigorous During this Unprecedented Merger Wave," *FTC*, September 28, 2021, *available at* https://www.ftc.gov/news-events/blogs/competition-matters/2021/09/making-second-request-process-both-more-streamlined.

8 See "Request for Information on Merger Enforcement, Public Comments of 23 State Attorneys General," April 21, 2022; and Leemore Dafny & Nancy Rose, "Response to DOJ-FTC Merger Guidelines Request for Information," April 21, 2022.

9 See Joseph Farrell, David Balan, Keith Brand & Brett Wendling, "Economics at the FTC: Hospital Mergers, Authorized Generic Drugs, and Consumer Credit Markets," *Review of Industrial Organization*, 2011, 39: 271-296; David Dranove & Andrew Sfekas, "The Revolution in Health Care Antitrust: New Methods and Provocative Implications," *The Milbank Quarterly*, 2009, 87: 607-632.

a marketable provider network.[10] In other words, the set of hospitals that some patients may view as substitutes at the point of care may not be substitutes for insurers.

Despite significant improvements, however, an analysis that focuses on patient choice at the point at which they need care can still fail to reflect the set of providers that insurers would consider when constructing networks. While the standard method generally finds that provider markets are more compact than patient flows may indicate, the emerging cross-market merger literature suggests that the opposite may also be true — providers that are not substitutes for patients seeking care may be part of the set of competitors that is relevant for assessing the competitive impact of a merger on insurers and their negotiations with providers. In particular, if employers or other plan sponsors view hospitals as substitutable in meeting the overall needs of their enrollee base, insurers marketing to these groups may, as a result, find that they can substitute between a larger set of hospitals in constructing a hospital network.

After first reviewing the impact of the insurer perspective in standard hospital merger analysis, the remainder of this article will address how economic models of insurer behavior can generate potential cross-market effects by positing scenarios in which provider mergers may impact provider-insurer negotiations, without combining hospital systems that patients would consider close substitutes. These scenarios are split into two groups: mechanisms by which a cross-market merger would affect the set of options available to insurers in constructing provider networks; and mechanisms under which cross-market mergers would affect bargaining between insurers and providers without altering the set of possible provider networks.

II. THE IMPACT OF THE INSURER PERSPECTIVE ON STANDARD MARKET DEFINITION IN HOSPITAL MERGERS

Economists and antitrust practitioners generally use a two-stage model to examine competition between health care providers. In the first stage, insurers assemble networks of providers, negotiating both network inclusion and allowed reimbursement. In the second stage, because patients are at least partially insulated from the price of care as long as they stay in-network, providers compete with each other for patients on the basis of non-price characteristics, such as quality of care. Providers that are especially valuable to patients in this second stage (e.g. because they offer services with few nearby substitutes) will have bargaining leverage to negotiate higher prices with insurers in the first stage of competition. Such providers will increase the marketability of insurers' health plans to plan sponsors (e.g. employers) and enrollees, all else equal.[11]

Mergers between providers that serve as substitutes from the patient's and enrollee's perspective will tend to increase those providers' bargaining leverage with insurers, allowing them to negotiate for higher prices.[12] Antitrust analyses generally begin with the second stage — calculating providers' post-merger increase in value to patients, and then translating that increase in value into their likely post-merger ability to negotiate higher prices in the first stage.[13]

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10 Although, the fact that *many* patients do not view two hospitals as substitutes, does not mean that insurers could not negotiate lower prices by threatening to offer a narrow network plan that would exclude the hospital and threaten some, if not all, of its patient base. The FTC's 2020 defeat in its challenge to the merger of Jefferson Health and Albert Einstein Healthcare Network stemmed from such a divergence. The Court opined that "insurers, not patients seeking and receiving medical care, are the payors," and the FTC had failed to prove that insurers could not avoid a price increase by looking to hospitals outside its proposed market. The Court further opined that, despite the FTC's analysis suggesting a small but significant and non-transitory increase in price ("SSNIP") would be possible, testimony from insurers demonstrated that such a price increase could be defeated by insurers. Memorandum Opinion, *FTC v. Thomas Jefferson University, et al.*, December 8, 2020.

11 Hospitals may be considered substitutes from both an insurer's and a patient's perspective even if patients are unlikely to be able to select between hospitals at the time they are seeking care due to the earlier selection of narrow network plans. In its complaint in *FTC v. Methodist Le Bonheur*, the FTC noted that narrow networks were common in the region and patients in narrow networks may not have had access to both systems. The FTC argued that the hospitals were still substitutes for insurers which could assemble viable networks excluding one or the other merging party, but not both. The merger would eliminate the option of excluding one system, and with it insurers' ability to play the two hospitals off each other in constructing a network. Administrative Part 3 Complaint, *FTC v. Methodist Le Bonheur Healthcare, a corporation, and Tenet Healthcare Corporation, a corporation*. This case can be distinguished from cross-market mergers because the hospitals could be considered substitutes from the point of view of individuals even if they limit their ability to make this substitution at the point of care by selecting a narrow network plan. The choice between alternative hospitals would in this instance be made in conjunction with plan choice.

12 See Joseph Farrell, David Balan, Keith Brand & Brett Wendling, "Economics at the FTC: Hospital Mergers, Authorized Generic Drugs, and Consumer Credit Markets," Review of Industrial Organization, 2011, 39(4): 271-296.

13 See Joseph Farrell, David Balan, Keith Brand & Brett Wendling, "Economics at the FTC: Hospital Mergers, Authorized Generic Drugs, and Consumer Credit Markets," Review of Industrial Organization, 2011, 39(4): 271-296; David Dranove & Andrew Sfekas, "The Revolution in Health Care Antitrust: New Methods and Provocative Implications," *Milbank Quarterly*, 2009, 87(3): 607-632; "Mergers Markets," Federal Trade Commission, Guide to Antitrust Laws, available at https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/mergers/markets; *FTC v. Advocate Health Care Network*, 841 F.3d 460 (7th Cir. 2016); *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327 (3d Cir. 2016); *ProMedica Health System, Inc. v. Federal Trade Commission*, 749 F. 3d 559 (6th Cir, 2014).

III. CROSS-MARKET MERGER EFFECTS MAY BE GENERATED IF A MERGER ALTERS THE SET OF AVAILABLE SUBSTITUTES FOR INSURERS, EVEN IF NOT FOR PATIENTS

In a conventional analysis of hospital merger effects, a post-merger price increase is evaluated through an analysis of patient substitution, under the assumption that insurers' networks will be close to complete — they will include all or almost all providers in a market. In that case, the value of the merged system to a patient is the difference between the value of the full network and the value of the full network except for the merged system. This is compared to the value of the entities premerger, which is the sum of the value added by the inclusion of each individual hospital in an otherwise complete network. The change in value to insurers is assumed to be an aggregation of the change in value to individual patients — in other words, the set of hospitals that are substitutes for patients are also assumed to be substitutes for insurers. However, theoretical models of insurer network formation and marketing posit ways in which insurer and patient perspective on providers may diverge.[14]

Could an insurer construct a similarly profitable network with one or the other of the merging parties, even if patients would not consider them substitutes? Taking into account how insurers assemble networks can affect which hospitals are considered substitutes *for insurers*. In particular, hospitals that are not substitutes from a patient's perspective could be substitutes from an insurer's perspective, generating cross-market price effects. If insurers are able to market plans with either one or the other of two merging parties, they may be substitutes to insurers assembling a network. A merger would eliminate this alternative, raising the possibility of an anticompetitive price increase even if the merger does not combine providers that are substitutes from a patient perspective.

Hypothetical scenario under which hospitals that are not substitutes from the point of view of patients might be substitutes from the point of view of insurers are posited in Dafny, Ho & Lee (2019).[15] In particular, the article considers an insurer marketing health plans to employers with employees who live in different geographies. If, for example, there is an employer which will offer its employees plans that have one or the other of two hospitals, but will not offer plans that lack both, then the loss of the combined system to an insurer would be greater than the sum of the loss of each hospital individually.[16] If either of the two hospitals decided to try to raise prices, the insurer could drop it and still market the partial network to employers, giving the insurer leverage over the two providers. This leverage would disappear in a merger that combined the two hospitals.

For this hypothetical possibility (i.e. providers that are substitutes from the point of view of insurers without being substitutes for patients) to hold in the real world, several relevant fact patterns would need to be true. First, there must be some link between the geographic regions where the health systems are located. In the hypothetical above, there would need to be a meaningful number of employers with operations that span the different regions, or whose employees reside across different regions.[17] Further, to establish the potential for anticompetitive harm, it should be demonstrated that employers actually approach insurance coverage this way — i.e. that plan sponsors be willing to select plans that leave some of their employees without a nearby option — and that insurers have considered playing the merged entities off each other as a result.

Would a merger change the ability of an insurer to substitute one merging hospital or system for a nonmerging hospital or system? This question addresses whether the merger changes an insurer's ability to play one merging party off against a party not involved in the merger. For example, two community hospitals may be close substitutes from the perspective of patients, allowing insurers to swap one out for the other in a narrow network plan.[18] If one hospital were purchased by a hospital system, which then bargained as an all-or-nothing unit with insurers, an insurer may no longer threaten to replace it with its competitor.

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14 See Katherine Ho & Robin Lee, "Equilibrium provider networks: Bargaining and exclusion in health care markets," *The American Economic Review*, 2019, 109(2): 473-522; Keith Brand & Ted Rosenbaum, "A Review of the Economic Literature on Cross-Market Health Care Mergers," *Antitrust Law Journal,* 2019, 82: 533–549. In these cases, while the insurer perspective may be different from that of patients seeking care, insurers ultimately market their plans to plan sponsors and enrollees. Their ability to substitute between hospitals in network formation will depend on the extent to which their customers will view plans with different hospitals as acceptable substitutes.

15 Leemore Dafny, Katherine Ho & Robin S. Lee, "The Price Effects of Cross-Market Hospital Mergers: Theory and Evidence from the Hospital Industry" *RAND Journal of Economics*, 2019, 50: 286.

16 Leemore Dafny, Katherine Ho & Robin S. Lee, "The Price Effects of Cross-Market Hospital Mergers: Theory and Evidence from the Hospital Industry" *RAND Journal of Economics*, 2019, 50: 286 at 294.

17 See Leemore Dafny, Katherine Ho & Robin S. Lee, "The Price Effects of Cross-Market Hospital Mergers: Theory and Evidence from the Hospital Industry" *RAND Journal of Economics*, 2019, 50: 286.

18 Indeed, some evidence suggests that insurers may have strong incentives to only include one of the two hospitals in their network. See, e.g. Ho, Kate & Robin S. Lee, *Equilibrium Provider Networks: Bargaining and Exclusion in Health Care Markets*, 109 American Economic Review 2 (2019).

Ho & Lee (2019) consider a model in which insurers and health systems negotiate network inclusion of the systems constituent hospitals as a unit. Under the assumption that all system hospitals will either be placed in or out-of-network, they conclude that an insurer may decide to include the acquired hospital in-network, as part of negotiating the inclusion of the larger health system — which may be necessary for a marketable network.[19] A community hospital, which insurers may have been able to swap out for the acquired hospital pre-merger, may no longer be used as a replacement and leverage in negotiations.[20] Under this theory of competitive effects, the non-merging community hospital might then be excluded from possible narrow network plans.[21] This mechanism has been discussed as an update to the standard two-stage model that may result in different price effects when insurers choose to create narrow networks.[22]

Antitrust practitioners may recognize this as a claim of anticompetitive tying — requiring the purchase of products in different markets as a condition of purchase for a product over which the seller possesses market power.[23] Under this theory, a health system with a "'must have' hospital in just one of its markets" would gain "the ability to raise rates on hospitals even in geographic markets in which it does not have a dominant competitive position."[24] In the case of a specific merger, the potential competitive effect through this mechanism would depend on several factors, including the use of narrow networks and the bargaining leverage of any "must-have" facilities. For instance, how large is the patient population for which the hospital is a "must-have" and what would be the cost of failing to include it in-network, both in terms of lost enrollees or increased reimbursement.

Are both parties necessary for a viable network, even if patients would consider them substitutes or at least, not complements? If so, they may be complements to insurers creating a network, and the merger may have procompetitive effects from the removal of hold-out opportunities for providers in negotiations with insurers.

Two parties can be complementary if they are both needed to create a viable network — for example, if they both offer specialized services, like cardiac care and pediatric intensive care that do not overlap and that patients value highly.[25] In such a case two providers may be complements even if they are geographically proximate and might be substitutes at the point of care for overlapping services.

In the setting of cross-market mergers, complementarity may be delivered if geographically distant hospitals are both needed to create a network that serves large employers with a dispersed workforce. The combination of these geographically distant hospitals could even make them better substitutes, i.e. fiercer competitors, for other hospital systems that have facilities in similarly distributed locations.

In either case, mergers between complementary providers will not, in general, be expected to result in price increases. Each provider on its own has leverage to hold out for higher prices, because it serves an important role in completing an insurer's network. But when two complementary providers merge, they can only use that leverage once — they can no longer separately hold out for higher prices.[26]

Analyses of patient choices alone will not capture provider complementarity. Other evidence is required, such as insurer documents discussing the need to have both merging providers in a network, evidence showing that the merging providers do not overlap for important services, evidence showing that each merging provider brings some element to the table that the other provider does not offer, or in the

19 This bargaining mechanism, where an insurer bargains with providers knowing it may be able to swap out a provider with a competing provider, is laid out in Katherine Ho & Robin Lee, "Equilibrium provider networks: Bargaining and exclusion in health care markets," *The American Economic Review*, 2019, 109(2): 473-522.

20 Indeed, some evidence suggests that insurers may have strong incentives to only include one of the two hospitals in their network. See, e.g. Ho, Kate & Robin S. Lee, *Equilibrium Provider Networks: Bargaining and Exclusion in Health Care Markets*, 109 American Economic Review 2 (2019).

21 See, e.g. Jaime S. King & Erin C. Fuse Brown, *The Anti-Competitive Potential of Cross-Market Mergers*, 11 SAINT LOUIS UNIV. J. HEALTH LAW & POLICY, 43 (2017). See also, Glenn Melnick, Katya Fonkych, *Hospital Prices Increase in California, Especially Among Hospitals in the Largest Multi-Hospital Systems*, INQUIRY: J. HEALTH CARE ORG., PROVISION, & FIN (2016).

22 See Katherine Ho & Robin Lee, "Equilibrium provider networks: Bargaining and exclusion in health care markets," *The American Economic Review*, 2019, 109(2): 473-522.

23 See, e.g. Jaime S. King & Erin C. Fuse Brown, *The Anti-Competitive Potential of Cross-Market Mergers*, 11 SAINT LOUIS UNIV. J. HEALTH LAW & POLICY, 43 (2017); Keith Brand & Ted Rosenbaum, "A Review of the Economic Literature on Cross-Market Health Care Mergers," *Antitrust Law Journal*, 2019, 82: 533–549; and "Request for Information on Merger Enforcement, Public Comments of 23 State Attorneys General," April 21, 2022.

24 "Request for Information on Merger Enforcement, Public Comments of 23 State Attorneys General," April 21, 2022, pp. 51-2.

25 For example, an individual considering a health plan may value access to a hospital with a high-quality cardiac care program, even though that individual may not use inpatient cardiac services during the year after a plan is purchased. See, e.g. Cory Capps, David Dranove & Mark Satterthwaite, "Competition and Market Power in Option Demand Markets," *RAND Journal of Economics*, 2003, 34(4): 737–763; Robert Town & Gregory Vistnes "Hospital Competition in HMO Networks," *Journal of Health Economics*, 2001, 20(5): 733–753.

26 See Kathleen Easterbrook, Gautam Gowrisankaran, Dina Older Aguilar & Yufei Wu, "Accounting For Complementarities In Hospital Mergers: Is A Substitute Needed For Current Approaches?" *Antitrust Law Journal*, 2019, 82: 497–531.

particular case of cross market mergers, documents showing that insurers need in-network facilities in specific geographies to construct a marketable plan.

IV. CROSS-MARKET MERGERS AND THE EFFECT ON PROVIDER BARGAINING POWER AND OBJECTIVE

In addition to the above mechanisms, in which a cross-market merger might change the bargaining *leverage* of merging parties there are also theories under which a cross-market merger might impact prices by changing the merged entities skill or objective in insurer negotiations. For example, if one of the merging parties has more skilled negotiators or access to better information, the merger may extend that advantage to the other party. One academic study has suggested such a mechanism, arguing that an independent hospital may achieve higher prices through access to better negotiators or better information when it joins a larger system.[27] It is also theorized that different owners may pursue different objectives in negotiating with insurers, including placing more emphasis on increasing revenue with less concern on community response to increased prices.[28]

The price impact of a cross-market merger that changed bargaining skill or objectives would not be captured through standard merger analyses such as a change in concentration or patient willingness-to-pay analyses. The history of prior acquisitions may reveal past post-merger price increases, but any such increase would have to account for pro-competitive factors that could explain higher prices such as changes in quality or expanded services. Price increases could also reflect a pro-competitive benefit if patients prefer to receive care at a hospital that is part of a larger system, perhaps under the assumption that member hospitals have access to a broader set of resources.

V. ARE DEPARTURES FROM THE STANDARD METHOD NECESSARY?

A greater focus on the potential gap between patients' preferences and insurers' decisions may lead to important changes in the types of health system mergers that are challenged and that survive review. In some cases, mergers of relatively distant providers may come under additional scrutiny, while mergers of providers with some overlap may be shown not to raise competitive concerns. It is important to note, however, that in many cases the difference between the two may not be large enough to justify a departure from a conventional patient-based analysis. Arguments for differences between the two may require local conditions such as evidence of the popularity of narrow insurer networks. Additionally, critics have questioned whether health systems have the level of sophistication necessary to recognize their potential leverage from links between hospitals in different geographic areas — though those questions will depend on the facts of each case.[29]

Although the economic tools remain under development for quantifying substitutability and complementarity in insurer networks beyond patient substitutability, antitrust practitioners should pay attention to both the empirical and theoretical developments around the potential for cross-market merger effects. The price impact of mergers between hospitals that are geographically proximate varies widely — with some mergers followed by higher prices and some mergers followed by lower prices (relative to benchmark hospitals).[30] Mergers between more geographically distant hospitals would reasonably be expected to have similarly different price effects. To assess whether an individual merger is more or less likely to raise prices, the specific features of the merging entities, other providers, and impacted insurers, employers and patients should be compared to the proposed theoretical mechanisms under which cross-market mergers may impact prices. Enforcement agencies considering a more aggressive stance against health system consolidation may look at cross-market mergers as an area in need of increased scrutiny. However, with an understanding of the conceptual underpinnings, antitrust practitioners may also be able to address agencies' merger concerns including with a more complete analysis of post-merger competitive constraints imposed by non-merging entities outside the affected patient-based markets.

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27 See Matthew Lewis & Kevin Pflum, "Hospital systems and bargaining power: Evidence from out-of-market acquisitions," *RAND Journal of Economics*, 2017, 48(3): 579-610.

28 See "Request for Information on Merger Enforcement, Public Comments of 23 State Attorneys General," April 21, 2022, pp. 52-3.

29 See Jeffrey Brennan, "Cross-Market Hospital Mergers: An Antitrust Theory Challenged by Facts and Law," CPI Antitrust Chronicle, May 2019; David Argue & Lona Fowdur, "An Examination of New Theories on Price Effects of Cross-Market Hospital Mergers," *American Hospital Association*, https://www.aha.org/position-paper/2021-05-10-examination-new-theories-price-effects-cross-market-hospital-mergers.

30 Chris Garmon, "The Accuracy of Hospital Merger Screening Methods," *The RAND Journal of Economics*, 2017. 48(4): 1068-1102.

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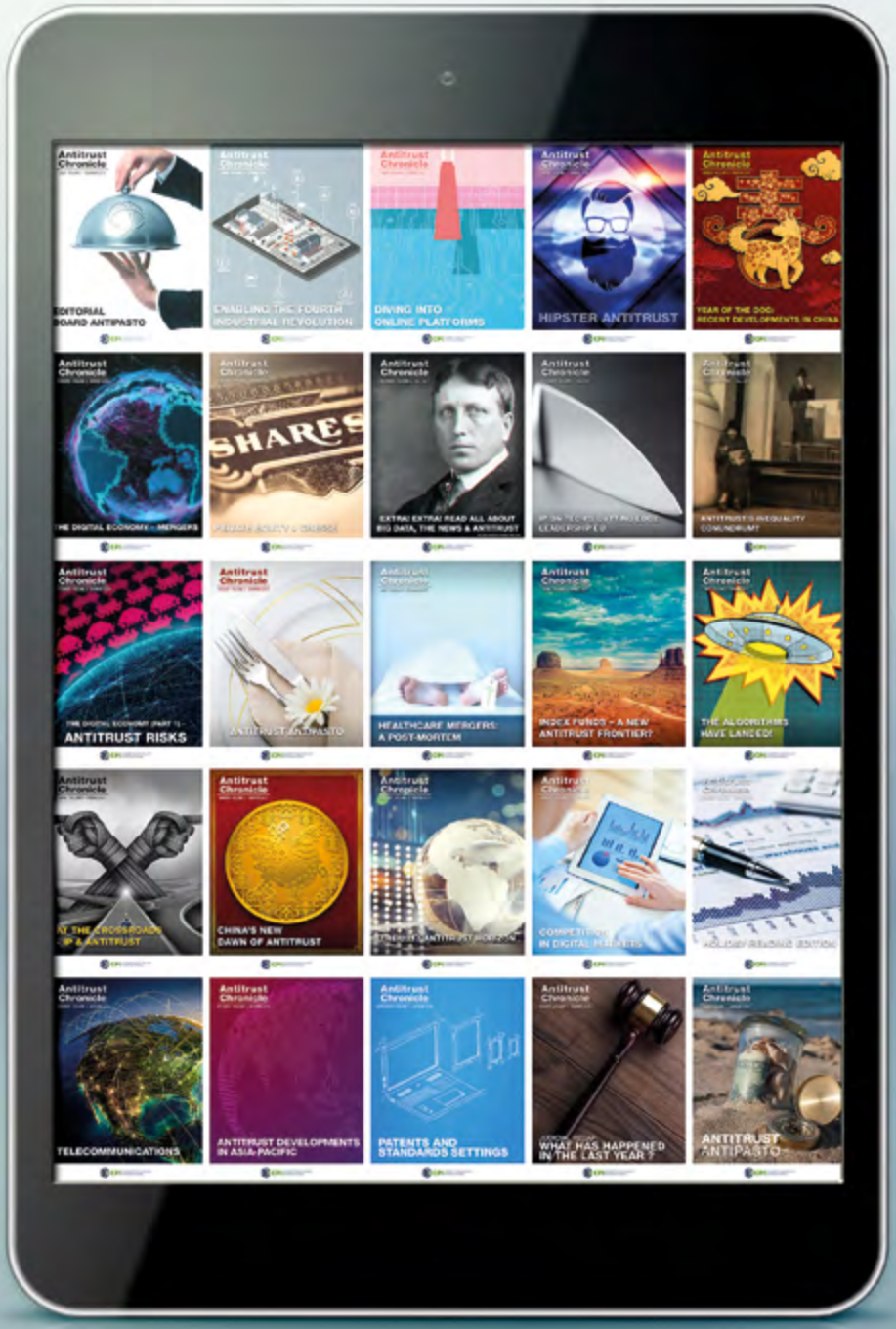


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