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Articles

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The Antitrust, Unfair Competition & Privacy Law Section of the California Lawyers Association is pleased to provide you with the February 2018 edition of its journal, *Competition,* the first edition focusing exclusively on competition issues in the healthcare and pharmaceutical industries. Special thanks to Editor-in-Chief, Anna Fabish, and her team of terrific authors and editors for their hard work in putting this issue together.

This is a busy time for our Section. First, we wrapped up our flagship annual event, the Golden State Antitrust, Unfair Competition & Privacy Law Institute, an all-day conference followed by a reception, dinner and ceremony honoring the "Antitrust Lawyer of the Year." We were thrilled to honor Cheryl Lee Johnson, Deputy Attorney General at the California Department of Justice, as the 2017 "Antitrust Lawyer of the Year," only the third woman to receive this honor. Bravo, Cheryl!

Second, changes are afoot in the structure of our organization. The former Sections of the California State Bar, including this one, have separated from the Bar and launched a new organization: the California Lawyers Association. This change opens a world of possibilities as to what we can do for our profession, the number of lawyers we can reach, and our ability to embrace fully the technological advances now available for our work and our relationships. The good news is that you will continue to receive all of the unique and comprehensive educational materials on competition and privacy law that you currently enjoy as a member of this Section. The better news is that, without the regulatory limitations and costs that came as part of being in an agency of the State of California, we believe you will get *better* service, have more ability to impact how the Sections function, and be far more satisfied with the new entity that serves you. Special thanks to Lee Berger for taking an active role in helping to establish the new organization and ensuring that it will be set up in a way that serves our Section members.

We look forward to making the most of this unique opportunity for evolution and improvement. Please let us know how we can better serve you, and join us as we build a new future for our Section and its members.

With that said, I hope you enjoy this edition of *Competition* as much as I did!

EDITOR'S NOTE

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Competition and privacy law issues in the healthcare and pharmaceutical industries are constantly making headlines—and for good reason. The intersection of healthcare/pharmaceutical regulation and policy with competition, privacy, and intellectual property law is generating a vast universe of intriguing questions. And if the amount of litigation and enforcement efforts in the United States and abroad is any indication, that universe is only growing. There is simply no escaping that hospitals and pharmacies are the foremost frontier for competition and privacy law issues today.

It is therefore with great excitement that I present the Winter 2017-18 issue of *Competition*, focusing solely on this timely and important topic. In preparing the issue, I had the pleasure of working with a tremendous group of authors, comprised of private practitioners, enforcers, academics, and economists. I extend my deepest thanks to them for their hard work and thoughtful commentary. The range of our authors' backgrounds adds a dimension to the analysis presented in this issue of *Competition* that I find both fascinating and helpful as I grapple with many of these topics in my own practice. I hope these articles will be of similar interest and usefulness to you. Thank you also to the team of editors for their insight and assistance in finalizing these articles.

The collection of articles in our Winter 2017-2018 edition examines a sampling of various legal, economic, and policy questions presented by the healthcare and pharmaceutical sectors today:

First, the issue offers several discussions of healthcare merger-related topics. **Lisl Dunlop** provides an in-depth analysis of Certificates of Public Advantage ("COPA") in the wake of the recent high-profile merger of two healthcare systems, Wellmont and Mountain States, in ***Certificates of Public Advantage: Bypassing the FTC in Healthcare Mergers?*** Dunlop provides an overview of state COPA laws, how they offer an alternative route to consolidation, Federal Trade Commission opposition to COPA protection, and the policy arguments for and against this public health-oriented approach to hospital transactions. This edition of Competition also offers two perspectives on a broader topic related to the COPA debate: the role of efficiencies in healthcare mergers under current case law. In their article, ***Where Art Thou, Efficiencies? The Uncertain Role of Efficiencies in Merger Review,*** **Kaley Fendall and David Maas** argue that the current standard is too uncertain, and that courts and enforcers are too unwilling to credit efficiencies. The result, Fendall and Maas argue, is that procompetitive benefits are lost, and that more parties may seek immunity from antitrust review under COPA laws. In ***The Efficiencies Defenestration: Are Regulators Throwing Valid HealthCare Efficiencies Out The Window?*****, Jacob Snow, Ronnie Solomon and Kyle Quackenbush** counter that the Horizontal Merger Guidelines already properly limit the scope of efficiencies to those that are merger-specific and verifiable, any uncertainties in the law notwithstanding. They explain their view that COPA laws should not be used as an excuse to lower the strict requirements for efficiencies and thereby justify otherwise

anticompetitive mergers. Finally, **Eric Emch, Thomas D. Jeitschko, and Arthur Zhou** evaluate the complexity and effectiveness of merger remedies by reviewing agency case filings in the generic drug and other industries. Their article, ***What Past Agency Actions Say About Complexity in Merger Remedies, with An Application to Generic Drug Divestitures,*** uses this analysis to explore how merger remedies proposed by US antitrust agencies typically blur the lines between purely structural and purely behavioral fixes.

Next, this issue of *Competition* addresses two hot topics in privacy law related to the healthcare industry. Recent years have seen a renaissance in digital health technologies, from mobile health apps and medical records hosted in the cloud to Internet-connected medical devices and activity trackers. In ***Digital Health Privacy: Old Laws Meet New Technologies,*** **Reece Hirsch and Jenny Harrison** examine how HIPAA and other longstanding privacy laws are being adapted to regulate this new and ever-evolving technology landscape. **Jay Edelson and Aaron Lawson** address another important topic in healthcare privacy with their article, ***Rethinking Healthcare Data Breach Litigation***. Edelson and Lawson discuss how, in data breach cases, courts and litigators routinely view cases through the lens of identity theft. They suggest that this focus ignores data security, and undercompensates data-breach victims.

The issue then offers two approaches to causation principles in pharmaceutical antitrust litigation. In ***Causation Principles in Pharmaceutical Antitrust Litigation,*** **Steve Shadowen** analyzes causation law as applied to typical pharmaceutical antitrust cases, such as reverse payment litigation. He argues that, where conduct is unlawful because of its propensity to cause a particular type of injury, plaintiffs satisfy their initial burden on causation by proving that they in fact suffered that type of injury. **Ken O'Rourke and Sarah Trela** argue for a different approach in their article, ***The Proximate Cause Requirement in Private Reverse Payment Antitrust Litigation.*** They suggest that the proximate causation element in private antitrust litigation requires a private plaintiff in a reverse payment case to prove the settlement harmed her. As part of this, O'Rourke and Trela argue, private plaintiffs must show—without resort to presumptions or proxies—that the reverse payment agreement, as opposed to the underlying patent, caused delay in generic entry and higher pharmaceutical prices.

The issue then provides **Professor Michael Carrier**'s discussion of antitrust law's role in addressing rising drug prices. In ***Antitrust's Hidden Hook in Drug Price Increases,*** Carrier argues that although U.S. antitrust law does not directly target high drug prices, antitrust has a crucial role to play in addressing price increases resulting from anticompetitive conduct.

Our healthcare and pharmaceutical themed issue concludes with two pieces discussing certain economics and research underlying many types of competition cases in the healthcare and pharmaceutical sectors. **Dr. Paul Wong**'s article, ***Uncertainty and Scientific Complexity: An Introduction to Economic Forces that Drive Current Debates in Healthcare Antitrust,*** provides an overview of healthcare antitrust economics. He explains how market frictions caused by uncertainty, such as adverse selection and agency, as well as the complexity of medicine, complicate the standard antitrust paradigm and create the need for detailed analyses. These issues, in turn, fuel some of the current debates in healthcare antitrust, including those concerning contracting practices in healthcare, Accountable Care Organizations, and the potential for market power.

Finally, **Professor Robin Feldman, John Gray & Giora Ashkenazi** discuss research related to the intersection of FDA regulation and antitrust law in ***Empirical Evidence of Drug Companies Using Citizen Petitions to Hold Off Competition***. They offer their view of this research as showing that brand-name pharmaceutical companies have been systematically abusing the Food and Drug Administration's citizen petition process to delay and stifle generic competitors.

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WHERE ART THOU, EFFICIENCIES? THE UNCERTAIN ROLE OF EFFICIENCIES IN MERGER REVIEW

By Kaley Fendall and David Maas[1]

I. INTRODUCTION

The role of efficiencies in merger review remains unclear. This ongoing uncertainty is interesting given that antitrust has long been a bastion of law and economics. As Richard Posner put it some 40 years ago, "the application of economics to antitrust has never been particularly controversial among economists. Even among academic lawyers, the appropriateness of placing economics in the foreground of antitrust analysis has been generally accepted."[2] That has also been true when it comes to courts and enforcers analyzing the anticompetitive effects of a merger. But the answer is not as simple when it comes to assessing a merger's *pro*competitive benefits, such as efficiencies. Courts and enforcers have been resistant to accepting efficiencies as a legitimate basis on which to allow an otherwise anticompetitive merger to proceed. This skepticism of efficiencies over the years has resulted in murky jurisprudence and makes it difficult to predict the appropriate weight (if any) that pro-consumer efficiencies are to be assigned in merger analysis.

Given the consensus that antitrust focuses on consumer welfare, it is not surprising that the calls have grown louder for clear recognition of the role that efficiencies play in merger analysis. The Department of Justice's ("DOJ") Antitrust Division has noted for instance, that "the concepts of economic welfare and economic efficiency are closely related to one another. Economists say that an economy is operating at maximum efficiency when society is squeezing the greatest value—the highest level of welfare—out of its scarce resources."[3] In other words, sound antitrust policy promotes allocating resources more efficiently. However, thanks in part to the Supreme Court's *FTC v. Procter & Gamble Co.* decision in the 1960s that cast some doubt on the role of efficiencies in merger analysis,[4] efficiencies have never found solid footing in antitrust jurisprudence.

Courts routinely are hostile to recognizing efficiencies. The circuit split that has developed about the role of efficiencies was the focal point of a cert petition filed with the Supreme Court earlier this year.[5] Unfortunately, the petition was withdrawn and we are left with no more clarity on whether and to what extent efficiencies can support a transaction challenged in court. Despite the cold shoulder given to efficiencies by most courts, antitrust enforcers continue to assert they will credit efficiencies in a proper case.

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1 Kaley Fendall is an associate in the Portland, Oregon office of Davis Wright Tremaine LLP and David Maas is an associate in the Seattle, Washington office of Davis Wright Tremaine LLP. They both specialize in antitrust and litigation. The authors gratefully acknowledge the guidance of Allison Davis and Douglas Ross, as well as the assistance of Kelly Gorton, in preparing this article..

2 Richard J. Posner, *The Economic Approach to Law,* 53 Tex. L. Rev. 757, 758 (1975).

3 Discussion Paper, Welfare Standards and Merger Analysis: Why not the Best?, Justice Dept. March 2006, available at https://www.justice.gov/atr/welfare-standards-and-merger-analysis-why-not-best.

4 386 U.S. 568 (1967).

5 Petition for Certiorari, *U.S. v. Anthem,* 2017 WL 1832038 (2017).

The Merger Guidelines issued by the Federal Trade Commission ("FTC") and the DOJ recognize efficiencies and the enforcers invite parties to present efficiencies in connection with merger review. The degree to which enforcers credit efficiencies, however, is shrouded in uncertainty because the vast majority of their publicly available positions are in contested merger proceedings where they tend to take a narrow and hostile view of efficiencies.

Where does this leave parties considering a merger who believe they have a strong case to make that their transaction will result in cognizable efficiencies? They have limited practical guidance on how to present a winning efficiencies argument to the enforcers, and an uphill battle to convince a court to credit an efficiencies argument. The uncertainty is unfortunate because rapid changes in technology and significant advances in healthcare have opened the door to many potential efficiency enhancing transactions that could benefit consumers through new products and services, increased access, and improvements in quality.

II. THE QUESTIONABLE TREATMENT OF EFFICIENCIES BY THE COURTS: A REVIEW

The friendliest treatment of efficiencies by an appellate court in a healthcare case, came in the Eighth Circuit's decision in *FTC v. Tenet Healthcare Corp.*[6] The court of appeals reversed a decision blocking the merger of two hospitals in Poplar Bluff, Missouri. The court based its reversal on the FTC's failure to prove Poplar Bluff was the relevant geographic market. But the court also stated that the district court erred when it failed to consider "evidence of enhanced efficiency in the context of the competitive effects of the merger."[7] The appellate court saw this evidence as demonstrating that the merger would create a more efficient healthcare delivery system capable of providing more and better care in the area. Even if payers were reaping the benefit of a price war in a small corner of the healthcare market in southeastern Missouri, that benefit had to be balanced against improved quality of care that subscribers would see if the hospitals were to merge.[8] While this decision seemed to portend the development of a more sophisticated framework for recognizing efficiencies, it achieved very little traction in later district and appellate court decisions.

Even where the FTC has not disputed that a merger will result in large-scale efficiencies, some of which would be passed on to consumers, courts have found that defendants' claimed efficiencies are not substantial enough to rebut the FTC's case. For instance, in *FTC v. Cardinal Health, Inc.*, defendants asserted—and the FTC's own expert agreed—that a merger between wholesaler distributors of prescription drugs would result in tremendous cost savings that would be passed on through to the consumer in the form of lower prices and improved services.[9] But the court found the FTC also presented evidence to suggest that the efficiencies claimed by defendants were not "merger-specific," and that many of the "savings anticipated from the mergers could also

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6 186 F.3d 1045 (8th. Cir. 1999)

7 *FTC v. Tenet Healthcare Corp.*, 186 F.3d 1045 (8th. Cir. 1999)

8 *Id.* at 1054.

9 *FTC v. Cardinal Health, Inc., et al.*, 12 F. Supp.2d 34 (D.D.C. 1998)

be achieved through continued competition in the wholesale industry." Noting that the "critical question raised by the efficiencies defense is whether the projected savings from the mergers are enough to overcome the evidence that tends to show that possibly greater benefits can be achieved by the public through existing, continued competition," the court held that defendants did not meet this burden.[10]

While the D.C. Circuit acknowledged in *FTC v. H.J. Heinz Co.* that "the trend among lower courts is to recognize the [efficiencies] defense," it also found that "the high market concentration levels present in this case require in rebuttal proof of *extraordinary efficiencies*, which the appellees failed to supply."[11] According to the court, "given the high concentration levels, the court must undertake a rigorous analysis of the kinds of efficiencies being urged by the parties in order to ensure that those 'efficiencies' represent more than mere speculation and promises about post-merger behavior."[12] Additionally, the court held that the "asserted efficiencies must be 'merger-specific' to be cognizable as a defense," and "cannot be achieved by either company alone."[13] While the court ultimately found it did not need to decide whether defendants' claimed efficiencies defense was sufficient (as it was reviewing the district court's denial of preliminary injunctive relief), it at least recognized that efficiencies may be "sufficiently concrete" to offset a prima facie showing under Section 7.[14]

The Ninth Circuit has been similarly skeptical of the efficiencies. In *Saint Alphonsus Medical Center v. St. Luke's Health System*,[15] the Ninth Circuit found that a hospital-physician group merger violated the antitrust laws, stating that only "extraordinary efficiencies" that could not be achieved without the merger could even conceivably offset anticompetitive concerns. The Ninth Circuit's rigorous and narrow view seemed to question whether efficiencies would ever justify a highly concentrative merger.[16] Proponents of a meaningful efficiencies defense were not pleased.[17] In the wake of *St. Luke's,* the Third Circuit similarly rejected an efficiencies defense in a hospital merger case, questioning whether the defense "even exists."[18]

Most recently, in a decision blocking the proposed merger of two large national insurers—Anthem and Cigna—a panel of the D.C. Circuit walked back that court's prior recognition of an efficiencies defense in *FTC v. Heinz*. With two of the four largest commercial health insurers merging, it was hard to dispute the merger's anticompetitive

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10 *Id.* at 43-44.

11 *FTC v. H.J. Heinz Co.*, 246 F.3d 708, 720 (D.C. Cir. 2001) (emphasis added).

12 *Id.*

13 *Id.* at 721-22.

14 *Id.* at 727.

15 778 F.3d 775 (9th Cir. Feb. 10, 2015).

16 *See* Thomas L. Greaney and Douglas Ross, *Navigating Through the Fog of Vertical Merger Law: A Guide to Counselling Hospital-Physician Consolidation Under the Clayton Act,* 91. U. Wash. L. Rev. 199, 209 (Mar. 2016).

17 *See, e.g.,* Int'l Ctr. For Law & Econ, *The Ninth Circuit Botched Its Efficiencies Analysis In The* FTC v. St Luke's *Antitrust Case*, available at http://laweconcenter.org/home/119-the-ninth-circuit-botched-its-efficiencies-analysis-in-the-ftc-v-st-lukes-antitrust-case.html.

18 *FTC v. Penn State Hershey Medical Center*, 838 F.3d 327, 348 (3d Cir. 2016).

effects. "[T]he centerpiece of [the parties'] defense [was the] contention that Anthem and Cigna national account customers will save a combined total of over $2 billion in medical expenditures because Cigna members will be able to access the more favorable discounts that Anthem has negotiated with its provider network."[19] The district court rejected the argument, holding that "the claimed medical cost savings are not cognizable efficiencies since they are not merger-specific, they are not verifiable, and it is questionable whether they are 'efficiencies' at all."[20]

On appeal, Anthem didn't take issue with the district court's finding that the government had made a prima facie showing the merger was anticompetitive. It put all of its eggs in the efficiencies basket. In a split decision, the D.C. Circuit rejected Anthem's argument. The majority cited *FTC v. Procter & Gamble Co.*[21] for the proposition that efficiencies "cannot be used as a defense to illegality" because Congress "struck the balance in favor of protecting competition."[22] The dissent highlighted the discord in modern antitrust regarding efficiencies and the questionable legacy of *Procter & Gamble*. Judge Kavanaugh stated that the Supreme Court's decision in *United States v. General Dynamics Corporation*[23] marked the shift to modern antitrust analysis, which "focuses on the effects on the consumers of the product or service, not the effects on competitors."[24] Judge Kavanaugh asserted that in light of *General Dynamics* courts must "consider the efficiencies and consumer benefits of the merger."[25] This spirited dissent figured prominently in the petition for certiorari that Anthem filed with the Supreme Court.[26] Unfortunately, Anthem withdrew the petition before the Supreme Court could consider reentering the fray to provide clarity on the proper role of efficiencies in merger analysis.[27]

III. THE AGENCIES' "RECOGNITION" OF EFFICIENCIES

The Horizontal Merger Guidelines plainly state that the agencies will consider efficiencies. Section 10 of the Guidelines, entitled "Efficiencies," lays out in detail the agencies' position on efficiencies. The agencies "will not challenge a merger if cognizable efficiencies are of a character and magnitude such that the merger is not likely to be anticompetitive in any relevant market."[28] The Guidelines highlight two major limitations on the kinds of efficiencies the enforcers will credit: (1) the efficiencies must

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19 *Anthem v. Cigna,* 236 F.Supp.3d 171, 181 (D.D.C. Feb. 18, 2017).

20 *Id.*

21 386 U.S. 568 (1967).

22 *U.S. v. Anthem, Inc.*, 855 F.3d 345, 353 (D.C. Cir. 2017).

23 415 U.S. 486 (1974).

24 *U.S. v. Anthem, Inc.*, 855 F.3d 345, 376 (D.C. Cir. 2017).

25 *Id.*

26 Petition for Certiorari, *U.S. v. Anthem, Inc.*, available at http://sourceonhealthcare.org/wp-content/uploads/2017/05/Anthem-Petition-for-Cert.pdf.

27 *See* J. Gardner Amrsby, *Anthem Terminates $54 Billion Cigna Merger after Delaware Chancery Court Denies Injunction,* [Q: is this citation incomplete?]

28 Horizontal Merger Guidelines §10.

be merger specific (*i.e.,* not attainable independently or through another transaction without anticompetitive effects); and (2) the efficiencies must not be speculative.

The Guidelines describe the merger specificity requirement as follows:

> The Agencies credit only those efficiencies likely to be accomplished with the proposed merger and unlikely to be accomplished in the absence of either the proposed merger or another means having comparable anticompetitive effects. These are termed merger-specific efficiencies. Only alternatives that are practical in the business situation faced by the merging firms are considered in making this determination. The Agencies do not insist upon a less restrictive alternative that is merely theoretical.[29]

The verifiability requirement is similarly laid out in plain terms:

> Efficiencies are difficult to verify and quantify, in part because much of the information relating to efficiencies is uniquely in the possession of the merging firms. Moreover, efficiencies projected reasonably and in good faith by the merging firms may not be realized. Therefore, it is incumbent upon the merging firms to substantiate efficiency claims so that the Agencies can verify by reasonable means, the likelihood and magnitude of each asserted efficiency, how and when each would be achieved (and any costs of doing so), how each would enhance the merged firm's ability and incentive to compete, and why each would be merger-specific.
>
> Efficiency claims will not be considered if they are vague, speculative, or otherwise cannot be verified by reasonable means. Projections of efficiencies may be viewed with skepticism, particularly when generated outside of the usual business planning process. By contrast, efficiency claims substantiated by analogous past experience are those most likely to be credited.[30]

If we were to judge based on the Merger Guidelines alone, it might look as though efficiencies are firmly part of the merger review process. Many private practitioners see it otherwise. There is limited transparency when it comes to deals that the enforcers decide *not* to challenge, so the public rarely knows when an efficiencies argument succeeds in persuading an enforcement agency to allow an otherwise anticompetitive merger to proceed. When push comes to shove and the FTC or DOJ decides to challenge a proposed merger, they invariably take a narrow view of cognizable efficiencies.

For example, in 2011, the DOJ sought to enjoin H&R Block, which offered do-it-yourself tax return software, from acquiring a company with a similar product, TaxACT.[31] H&R Block asserted that the acquisition of TaxACT would result in

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29 *Id.*

30 *Id.*

31 *See United States v. H&R Block, Inc.*, 833 F. Supp. 2d 36, 42 (D.D.C. 2011).

efficiencies and management improvements that would "lead to better, more effective, and/or cheaper H&R Block digital products post-merger" and that the merged company would better able to compete with Intuit (by far the largest seller of do-it-yourself tax return software).[32] The Court acknowledged that a sufficient showing of efficiencies may rebut the government's showing of likely anticompetitive effects, but noted that "[h]igh market concentration levels require 'proof of *extraordinary* efficiencies,' … and courts 'generally have found inadequate proof of efficiencies to sustain a rebuttal of the government's case.'"[33] The Court discounted evidence proffered by H&R Block demonstrating millions of dollars in annual efficiencies in ten different areas as a result of the acquisition and instead credited the government's expert witness, who concluded that with one exception, "the proposed efficiencies identified by the defendants are either not merger-specific or not verifiable."[34] Most of the efficiencies, in the Court's view, could be achieved independently, or those efficiencies that were merger-specific were not verifiable and based merely upon self-serving "management judgements" as to what would generate cost savings.[35] The Court granted the government's motion and enjoined the acquisition.

In the same year, the FTC opened a proceeding and filed a complaint to enjoin OSF Healthcare Systems' acquisition of Rockford Health System. Both defendants were not-for-profit healthcare systems that operated hospitals.[36] Defendants challenged the injunction arguing that the acquisition would achieve a number of efficiencies, including: (1) annual, recurring cost savings based on the consolidation of clinical operations; (2) one-time capital avoidance savings; and (3) clinical effectiveness and best practices.[37] The FTC conversely asserted that such efficiencies were "speculative, unreliable, and not merger-specific."[38] The Court concluded that the healthcare systems' efficiencies defense could ultimately prevail, but because its job was to preserve the status quo, it granted the government's motion finding that "the FTC vigorously and cogently criticized this defense with expert testimony of its own."[39] OSF Healthcare System then abandoned the proposed transactions.

Recent hospital merger decisions have come to similar results, finding an inadequate showing of efficiencies by the parties.[40] These cases showcase the high burden of demonstrating non-speculative and merger-specific efficiencies that satisfy the enforcers and/or a court.

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32 *Id.* at 80-81.

33 *Id.* at 89 (emphasis added).

34 *Id. at 90.*

35 *Id.*

36 *FTC v. OSF Healthcare Sys.*, 852 F. Supp. 2d 1069, 1071 (N.D. Ill. 2012).

37 *Id.* at 1089.

38 *Id.*

39 *Id.*

40 *See, e.g., FTC v. Penn State Hershey Med. Ctr.,* 838 F.3d 327, 350 (3d Cir. 2016); *FTC v. Advocate Health Care,* No. 15 C 11473, 2017 U.S. Dist. LEXIS 37707, at *1 (N.D. Ill. Mar. 16, 2017).

In 1995, then FTC Commissioner Christine Varney stated that efficiencies justifications "should play a role in [the FTC's] analysis" but only "as a matter of prosecutorial discretion."[41] That certainly seems to be how both the enforcers and the courts have treated efficiencies: a dispensation available only from the enforcers, and at their discretion.

IV. A WINNING EFFICIENCIES ARGUMENT: WHAT WOULD IT LOOK LIKE?

Given that efficiencies have never won the day in court, practitioners and parties have to speculate about what a winning argument would be.

In healthcare mergers, there are often efficiencies that improve the quality of, or access to, care. For instance, when a hospital with excess volume merges with one that is underutilized (*i.e.,* an average daily census with large numbers of empty beds), the result is a more efficient allocation of patients to beds in a way that improves access to and potentially also the quality of cared delivered in the area. The FTC has not given a clear roadmap for how to present a winning quality of care argument. For instance, the FTC is sometimes but not always receptive to quality of care experts used to support efficiencies:

> Though quality of care experts may play an important role in hospital merger cases, their role generally is limited to reviewing the case-specific evidence and explaining its implications to the judge; testimony that hospital mergers (or some subset thereof) generally have a positive or negative impact on quality is suspect. Thus, just as with other defenses, quality-related claims in hospital merger matters often turn on ordinary course documents, executive testimony, and other case-specific evidence.[42]

The FTC seems more interested in a quantitative approach to quality efficiencies. As then-Director of the Bureau of Competition Deborah Feinstein stated in June 2014, the FTC is interested in specific measurable evidence that supports quality improvement efficiencies:

> In assessing quality arguments, we examine a variety of evidence. We look at the comparative quality of the hospitals merging. If the acquired hospital already has strong quality measurements comparable to those of the acquiring hospital, we may question the ability of the acquiring hospital to improve those metrics. If the acquiring hospital has made prior acquisitions, we will want to see whether those mergers resulted in quality improvements. The parties must explain more than just the processes and practices that the acquiring hospital system can transfer to

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41 Christine Varney, *New Directions at the FTC: Efficiency Justifications in Hospital Mergers and Vertical Integration Concerns,* available at https://www.ftc.gov/es/public-statements/1995/05/new-directions-ftc-efficiency-justifications-hospital-mergers-vertical.

42 Jeffrey H. Perry & Richard H. Cunningham, *Effective Defenses of Hospital Mergers in Concentrated Markets,* Antitrust, Spring 2013 at 43.

an additional hospital; they need to address the specifics of how those processes and practices will benefit patients through improved care.[43]

This focus on quantifiable quality metrics has intuitive appeal. However, without a roadmap from the enforcers on which quality metrics parties should consider and how parties can balance these metrics against any competitive effects, quality improvement efficiencies remain especially elusive. Healthcare providers considering transactions with quality improvements in mind are faced with no reliable means of assessing the likely outcome of antitrust review. The expense of complying with a second request can be prohibitive in some transactions, and in any case averages around $4 million.[44] Without a clearer sense of when and how efficiencies arguments can carry the day, some deals with strong pro-consumer efficiencies may die in pipeline.

V. WHAT ARE THE CONSEQUENCES OF NOT GIVING MORE WEIGHT TO EFFICIENCY CLAIMS?

We can't identify the deals that don't get off the ground because of the enforcers' and courts' restrictive approach to evaluating efficiencies. We can see the ebb and flow of contested mergers, which gives some sense of the kinds of deals that die despite efficiencies. Sometimes efficiencies are driven by large scale changes in industries. For instance, in 1995 former Commissioner Varney noted that efficiencies arguments for hospital mergers were "more facially plausible" because after a hospital construction boom in the 1960s, payers "put[] cost-containment pressures on hospitals, [which] … along with technological advances … shortened in-hospital treatment time and forced more outpatient based treatments, [leading] many hospitals [to] have excess capacity."[45] As we are seeing drastic changes in the way healthcare is delivered—more integrated value-based care, the introduction of machine learning and artificial intelligence, the rapid development of new medical technology—it seems that we are in or entering another era when efficiency arguments for provider mergers should be given more credit. But the opposite seems to be happening: courts and enforcers seem to be construing efficiencies with increasing skepticism.

One result of this skepticism of efficiencies may be more interest in "COPA" laws. (The acronym COPA is derived from a certificate of public advantage—an approval given to a transaction by a state authority that then operates under the state action doctrine to immunize the deal from antitrust condemnation). The FTC has filed highly critical comments in a number of recent COPA proceedings. For instance, when West Virginia enacted a COPA law and then granted a COPA to the merger of the only two hospitals in Huntington, West Virginia, the FTC loudly voiced its disapproval. The FTC stated that the law "would mainly serve to encourage mergers and conduct that likely would not

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43 Deborah Feinstein, FTC Director of Competition, Speech at Fifth National Accountable Care Organization Summit, June 19, 2014.

44 Peter Boberg & Andrew Dick, *Findings from the Second Request Compliance Burden Survey,* The Threshold, Sept. 2014, available at http://www.crai.com/publication/findings-second-request-compliance-burden-survey.

45 *See* Christine Varney, New Directions at the FTC: Efficiency Justifications in Hospital Mergers and Vertical Integration Concerns, May 2, 1995.

pass muster under the antitrust laws."[46] The FTC eventually dismissed its administrative complaint challenging the merger but issued a strong statement admonishing politicians and providers to be wary of seeking a COPA to avoid traditional antitrust enforcement:

> Proponents of cooperative agreement laws claim that antitrust enforcement undermines the policy goals of the Affordable Care Act to improve quality and lower costs through greater coordination among healthcare providers. This is fundamentally incorrect. The ACA [Affordable Care Act] did not repeal the antitrust laws, and it certainly does not condone mergers that substantially lessen competition.[47]

The FTC declared that "antitrust enforcement is consistent with—not an impediment to—the goals of the ACA."[48]

When two large health systems in Tennessee and Virginia—Wellmont Health System and Mountains States Health Alliance—proposed merging, the Tennessee Department of Health sent a letter to the FTC requesting its participation in and comments on COPA proceedings regarding the merger.[49] The FTC submitted testimony and comments to both the Tennessee and Virginia Departments of Health in their respective COPA proceedings.[50] The FTC's views throughout the proceedings have been clear: it feels the merger would create a "behemoth hospital system" with "tremendous market power" that would harm competition.[51] The FTC took issue with the efficiencies the parties presented, claiming that they were speculative and not merger specific.[52]

The FTC highlighted at a hearing before the Virginia health authority that it was "aware of no analysis comparing the impact this merger would have on residents of

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46 Letter from Marina Lao, Ginger Jin, and Markus H. Meier, to Del. Mike Pushkin (Mar. 9, 2016), available at www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-west-virginia-house-delegates-regarding-sb-597-competitive-implications-provisions/160310westvirginia.pdf#sthash.zATqMkLP.dpuf.

47 Statement of FTC In re Cabell Huntington Hospital, Inc., FTC No. 9366, July 6, 2016, available at https://www.ftc.gov/system/files/documents/public_statements/969783/160706cabellcommstmt.pdf.

48 *Id.*

49 *See* Letter from John J. Dreyzehner to FTC Secretary Donald S. Clark Requesting An Advisory Opinion Regarding the Effect of the Sale of A Merged Hospital Entity Operating Pursuant To A Certificate of Public Advantage, available at https://www.ftc.gov/public-statements/2015/12/letter-alexis-gilman-assistant-director-mergers-iv-division-bureau.

50 *See* FTC Submissions and Testimony on Wellmont Health System/Mountain States Health Alliance, available at https://www.ftc.gov/enforcement/cases-proceedings/151-0115/wellmont-healthmountain-states-health.

51 *See, e.g.*, FTC Staff Supplemental Submission to the Tennessee Department of Health Regarding the Certificate of Public Advantage Application of Mountain States Health Alliance and Wellmont Health System, Jan. 6. 2017, available at https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-supplemental-submission-tennessee-department-health-regarding-certificate-public-advantage/170105mshatennesseesuppcmt.pdf.

52 *See* FTC Supplemental Public Comment in Virginia Opposing Health Systems' Cooperative Agreement Application, Jan. 13, 2017, available at https://www.ftc.gov/system/files/documents/cases/ftc_staff_supplemental_submission_to_virginia_1-13-17.pdf.

Southwest Virginia to other possible mergers or affiliations that likely are available."[53] That common refrain from the FTC—couldn't you achieve these efficiencies in a deal with someone else?—is understandable but disconnected from business realities. Parties considering a merger often engage consultants to assess options in the market. Once a transaction is in the pipeline the merging parties often engage economists to assess the potential competitive effects and efficiencies of the deal. As a practical matter, parties cannot feasibly have their consultants and economists assess the potential efficiencies of *other* potential counterparties whose data is not available (and who may not be interested in a merger). It's easy for the enforcers to say there *might* be another deal out there that could achieve the same efficiencies. It is difficult for a party to prove the negative: that no such alternative exists. The same is true when the FTC suggests efficiencies could be achieved by some arrangement short of a merger: it is difficult for parties to prove the negative that they would not actually realize those efficiencies without the merger. Given the hostile reception accorded to efficiencies' arguments at the FTC, it should not be surprising that when parties propose a transaction and seek to justify it by relying on efficiencies, they will consider seeking a COPA and cutting short the antitrust process.

The FTC's view on COPAs has been clear. The agency doesn't like them. Curiously, on November 1, 2017, the FTC issued a staff notice seeking empirical research and public comments on COPAs.[54] Only time will tell whether the agency is genuinely open to reconsidering its views on COPAs, or is simply seeking ammunition for a renewed attack on them. But so long as parties believes that strong efficiencies arguments will usually founder at the FTC, and always perish in court, COPAs will continue to be popular.

VI. CONCLUSION

The federal enforcers seem to think efficiencies are adequately considered in merger analysis. If this is the end of the road for efficiencies, then they might as well be called the Hail Mary pass of healthcare mergers. It remains difficult for parties to get any traction with efficiencies that might justify an otherwise anticompetitive merger. Until there is more useful guidance from courts and enforcers on what a successful efficiencies argument looks like, parties will continue to push for alternatives, such as COPAs.

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53 *See* Testimony of Mark Seidman, Deputy Assistant Director, Mergers IV Division, Before the Southwest Virginia Health Authority, available at https://www.ftc.gov/system/files/documents/cases/161003mshatestimony.pdf.

54 *See* Staff Letter, *FTC Staff Seeks Empirical Research and Public Comments Regarding Impact of Certificates of Public Advantage*, Nov. 1, 2017, available at https://www.ftc.gov/news-events/press-releases/2017/11/ftc-staff-seeks-empirical-research-public-comments-regarding.

CERTIFICATES OF PUBLIC ADVANTAGE: BYPASSING THE FTC IN HEALTHCARE MERGERS?

By Lisl Dunlop[1]

I. INTRODUCTION

Over the past several years, faced with rising costs, pressures to improve quality, changes to insurance reimbursements, and other regulatory developments, the healthcare field has witnessed increasing consolidation. This is particularly true for physician practice groups and hospitals. But, this consolidation also has been subject to increased scrutiny from federal antitrust regulators. Whether it is a merger between the two leading providers of general acute care inpatient hospital services near Chicago, Illinois[2] or the acquisition of a clinic employing 60 physicians in North Dakota,[3] healthcare entities in regions with few competitors face significant antitrust obstacles in their efforts to merge.

At the same time, state policymakers have recognized that collaboration among healthcare providers, including mergers, can lead to better public health outcomes while reducing costs. To promote such collaborations, some states have stepped in and enacted laws that permit competing hospitals or healthcare systems to apply for a Certificate of Public Advantage ("COPA") under which they can engage in joint activities, including merger transactions, that otherwise may be prohibited by the federal antitrust laws.[4] According to the states, the benefits of these arrangements to state healthcare goals outweigh the potential harms resulting from lost competition.

The Federal Trade Commission ("FTC") staunchly opposes COPA laws. Because the antitrust laws do not prohibit all competitor collaborations, only anticompetitive ones, the FTC believes that COPAs are unnecessary to permit procompetitive transactions

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2 *See FTC v. Advocate Health Care,* No. 15 C 11473, 2017 WL 1022015 (N.D. Ill. Mar. 16, 2017) (granting motion for preliminary injunction to block the parties from consummating their proposed merger).

3 Press Release, FTC, FTC and State Attorney General Challenge Physician Group Acquisition in North Dakota (June 22, 2017), *available at* https://www.ftc.gov/news-events/press-releases/2017/06/ftc-state-attorney-general-challenge-physician-group-acquisition.

4 *See, e.g.,* N.Y. State Dep't of Health, Certificate of Public Advantage (last visited Oct. 25, 2017), https://www.health.ny.gov/health_care/medicaid/redesign/copa/; Tenn. Dep't of Health, Certificate of Public Advantage (last visited Oct. 25, 2017), https://www.tn.gov/health/article/certificate-of-public-advantage.

and merely serve to protect anticompetitive ones.[5] While the FTC maintains that there is strong economic evidence supporting its view that consolidation harms healthcare pricing and quality, several states have rejected FTC concerns and granted COPAs to merging healthcare providers.[6]

There has been limited experience with COPA-enabled mergers to date, so it remains to be seen whether COPAs will actually deliver the public health outcomes and other public benefits sought by state regulators. Given the current uncertainty and complexity of healthcare markets today, however, permitting states to experiment with different models and to have greater visibility and control over healthcare entities within their own borders may make public health goals more attainable, even at the cost of an independent competitive environment.

II. THE CURRENT STATE OF HEALTHCARE MERGER ANTITRUST ENFORCEMENT

Beginning with its success in challenging the consummated *Evanston Northwestern/ Highland Park* merger in 2008,[7] the FTC has logged a consistent track record of success in litigating against merging healthcare entities. Most recently, in 2016, the FTC litigated two merger challenges almost simultaneously—one in Pennsylvania and the other in Illinois—winning preliminary injunctions against both at the appeals level.[8] Today, the FTC's approach to healthcare merger enforcement, and the economic literature supporting that approach, have clearly been accepted by the federal courts.

Notably, in the course of this impressive history of merger challenges, the FTC and the courts have given short shrift to hospitals' claims that their transactions result in efficiencies and cost-savings that outweigh the potential anticompetitive effects

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5 *See, e.g.,* Letter from Marina Lao, Director, FTC Office of Policy Planning, et al. to Center for Healthcare Policy and Resource Development, Office of Primary Care and Health Systems Management, New York State Department of Health (Apr. 22, 2015), *available at* https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-center-health-care-policy-resource-development-office-primary-care-health-systems/150422newyorkhealth.pdf; FTC Staff Submission to the Tenn. Dep't of Health Regarding the Certificate of Pub. Advantage Application of Mountain States Health Alliance & Wellmont Health Sys. (Nov. 21, 2016), *available at* https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-submission-tennessee-department-health-regarding-certificate-public-advantage-application/161122wellmontcommenttenn.pdf.

6 *See, e.g.,* Press Release, Tenn. Dep't of Health, Tennessee Grants Certificate of Public Advantage for Wellmont Health System, Mountain States Health Alliance (Sept. 19, 2017), *available at* https://www.tn.gov/assets/entities/health/attachments/COPA_PRESS_RELEASE_Announcement_91917.pdf; Press Release, FTC, FTC Dismisses Complaint Challenging Merger of Cabell Huntington Hospital and St. Mary's Medical Center (July 6, 2016), *available at* https://www.ftc.gov/news-events/press-releases/2016/07/ftc-dismisses-complaint-challenging-merger-cabell-huntington (explaining the Commission vote to dismiss the complaint in light of West Virginia's March 2016 passage of a law permitting certain "cooperative agreements" between hospitals within the state, the West Virginia Health Care Authority's decision to approve a cooperative agreement between the hospitals, and the West Virginia Attorney General concurrence with that decision).

7 *In the matter of Evanston Northwestern Healthcare Corp. & ENH Med. Grp., Inc.,* FTC Docket No. 9315, available at https://www.ftc.gov/enforcement/cases-proceedings/0110234/evanston-northwestern-healthcare-corporation-enh-medical-group.

8 *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327 (3d Cir. 2016); *FTC v. Advocate Health Care Network,* 841 F.3d 460 (7th Cir. 2016).

of a merger. The courts have endorsed FTC requirements that claimed efficiencies be merger-specific, verifiable and not themselves result in anticompetitive outcomes. Where transactions lead to clear increases in concentration, the FTC and the courts have required the efficiencies to offset the potential anticompetitive harm to be "extraordinary" and subject to a high level of proof.[9] In fact, going further, several appellate courts have questioned whether efficiencies can ever be sufficient to overcome competitive concerns.[10]

The various court decisions also agree with the FTC that the healthcare policy dictates of the *Affordable Care Act* do not support a drive by hospitals to "unite and survive."[11] The FTC has consistently rejected this concept in numerous speeches, advocacy letters and merger challenges, arguing that there is nothing in healthcare policy that displaces the antitrust laws, and collaborations seeking to advance the aims of healthcare policy can be equally effective operating within the existing antitrust framework.[12]

As a result, in the current enforcement landscape it is very difficult for transactions leading to high levels of concentration in acute care hospital markets and physician markets to pass antitrust muster, even where there are significant overriding considerations of continued survival of local services, better management of the care continuum, and potential public health or other benefits that may be gained from a transaction.

III. BACKGROUND TO COPA LAWS

Under the state action doctrine, state governments and certain private actors may be immunized from antitrust liability by the operation of a state regulatory scheme. The FTC has had considerable experience and success in narrowly confining state-action immunity, including its most recent Supreme Court victories in *North Carolina State Board of Dental Examiners*[13] and *Phoebe Putney*.[14] As currently articulated by the Supreme Court, the Sherman Act does not interfere with a state's own anticompetitive policies, but does not shield the anticompetitive conduct of non-sovereign actors unless they "result from procedures that suffice to make it the State's own."[15]

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9 *Penn State Hershey Med. Ctr.*, 838 F.3d at 347.

10 *See id.* at 347-50*; St. Alphonsus Med. Ctr.-Nampa Inc. v. St. Luke's Health Sys., Ltd.*, 778 F.3d 775, 791–92 (9th Cir. 2015) ("But even if we assume that the claimed efficiencies were merger-specific, the defense would nonetheless fail... the Clayton Act does not excuse mergers that lessen competition or create monopolies simply because the merged entity can improve its operations.").

11 *See Penn State Hershey Med. Ctr.*, 838 F.3d at 353.

12 *See, e.g.*, Edith Ramirez, Chairwoman, FTC, Keynote Address at Antitrust in Healthcare Conference in Arlington, VA (May 12, 2016), *available at* https://www.ftc.gov/system/files/documents/public_statements/950143/160519antitrusthealthcarekeynote.pdf; Deborah L. Feinstein, Director, Bureau of Competition, FTC, Antitrust Enforcement in Healthcare: Proscription, no Prescription at the Fifth National Accountable Care Organizations Summit in Washington, D.C. (June 19, 2014), *available at* https://www.ftc.gov/system/files/documents/public_statements/409481/140619_aco_speech.pdf.

13 *N. C. State Bd. of Dental Exam'rs v. F.T.C.*, 135 S. Ct. 1101 (2015).

14 *F.T.C. v. Phoebe Putney Health System Inc.*, 568 U.S. 216 (2013).

15 *N. C. State Board of Dental Exam'rs,* 135 S. Ct. at 1110-11; *Phoebe Putney,* 133 S.Ct. at 1010.

The party seeking immunity must first demonstrate that the challenged collaboration was undertaken pursuant to a "clearly articulated" affirmative state policy to supplant competition with regulation. This first prong ensures that the state has indeed, as a matter of policy, authorized departures from the norm of free market competition. Second, state action immunity requires "active supervision" of the private conduct by the state, such that any restraint on competition is a result of knowing, deliberate, state intervention rather than simply an agreement among private parties.

Phoebe Putney illustrates the first prong of the state action doctrine in a hospital merger case.[16] In that case, a county hospital in Georgia acquired a competing hospital and, essentially, a monopoly on acute-care services in the county. The hospital claimed that the state action doctrine immunized the merger from antitrust review because Georgia law specifically authorized county hospitals to make acquisitions. However, the Supreme Court found that although the state enabling statutes permitted acquisitions, they did not declare that the state had authorized monopolies or exempted county hospital mergers from antitrust law. Thus, the transaction was not immune from the antitrust laws.[17]

The second prong of the state action doctrine was at issue in the FTC's March 2015 victory in the *North Carolina State Dental Board* case. In the *North Carolina Dental Board* case, the Dental Board, consisting of practicing dentists, had excluded non-dentists from the teeth-whitening market, granting practicing dentists a monopoly on teeth-whitening services. The Dental Board invoked the state action doctrine on the grounds that its actions were the actions of the "sovereign." But the Supreme Court concluded that state boards, when controlled by practicing professionals, are not "sovereign" and do not enjoy state action immunity because their actions represent the interests of private parties. The Court held that when state boards or agencies are controlled by practicing professionals, their actions need to be "actively" supervised by the state. The FTC subsequently issued guidance on what is needed to meet the "active supervision" requirement.[18]

IV. HOW DO COPA LAWS WORK?

Certificate of Public Advantage laws seek to utilize the state action doctrine to shield healthcare collaborations and transactions from federal antitrust oversight. The laws typically authorize "cooperative agreements" among providers (usually including mergers) on the grounds that they can improve quality, moderate cost increases, improve access to healthcare services, and help keep smaller hospitals open, particularly in rural

16 568 U.S. at 226-36.

17 Despite this major legal victory, Georgia's Certificate of Need ("CON") laws made the subsequent divestiture order impossible to carry out. State CON laws typically require healthcare providers to obtain state approval before expanding, establishing new facilities or services or making certain large capital expenditures. Here, because the relevant region was deemed "over-bedded" by the Georgia Department of Community Health Hearing Officer, that finding effectively ensured that any prospective divestiture buyer would face a lengthy legal battle with an uncertain outcome. As a result, in March 2015, the FTC dropped its case after four years of litigation, without achieving any remedy.

18 *FTC Staff Guidance on Active Supervision of State Regulatory Boards Controlled by Market Participants* (Oct. 2015), *available at* https://www.ftc.gov/system/files/attachments/competition-policy-guidance/active_supervision_of_state_boards.pdf.

areas. COPA laws typically direct that competition is one issue to be taken into account in considering the grant of a COPA, but not the only issue.

COPA laws are typically expressly drafted to meet the requirements of the state action doctrine. Most include direct language clearly expressing the intention to displace the antitrust laws. For example, New York's COPA law states: "To the extent such arrangements, or the planning and negotiations that precede them, might be anti-competitive within the meaning and intent of the state and federal antitrust laws, *the intent of the state is to supplant competition with such arrangements under the active supervision and related administrative actions of the commissioner* as necessary to accomplish the purposes of this article, *and to provide state action immunity under the state and federal antitrust laws…*"[19] COPA laws typically grant state departments of health and health commissioners the power to review COPA applications, grant COPAs and supervise the merging parties' conduct under COPAs, meeting the active supervision requirement for state-action protection.

Between 1992 and 1995, at least 18 states passed a form of COPA legislation,[20] possibly as an alternative to rate-setting and "all-payer" system experimentation that was taking place in various states around that time. But very few COPAs were actually applied for or issued under those laws. Notable exceptions are the Mission Health COPA in North Carolina issued in 1995 and the Benefis Health System COPA in Montana issued in 1996. There has been limited analysis of the impact of these COPAs on healthcare prices, quality and other public health measures.[21] Notably, on November 1, 2017, the FTC issued a Staff Notice requesting empirical research and public comments on the impact of COPAs.[22]

More recently, new COPA laws have been introduced in some states and more active interest taken in pre-existing laws in others. This activity appears to be in reaction to the FTC's aggressive enforcement approach to healthcare transactions. For example, in 2016,

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19 New York Consolidated Laws, Public Health Law - PBH § 2999-aa (emphasis added).

20 Colorado, Florida, Georgia, Idaho, Iowa, Kansas, Minnesota, Montana, Nebraska, North Carolina, North Dakota, Ohio, Oregon, South Carolina, Tennessee, Texas, Washington, and Wyoming. Since then, several of those statutes, including Colorado, North Carolina, and North Dakota, have been repealed and several other states have enacted COPA laws, including in Alaska, Louisiana, Maine, Mississippi, New York, Virginia, West Virginia, and Wisconsin.

21 Two studies were conducted regarding the Mission Health COPA. One, by the Urban Institute, found that there was no conclusive evidence whether the overall impact of the COPA had been positive or negative. R. R. Bovbjerg and R. A. Berenson, *Certificates of Public Advantage: Can They Address Provider Market Power?* (Feb. 2015), *available at* https://www.urban.org/sites/default/files/publication/42226/2000111-Certificates-of-Public-Advantage.pdf. The other, an economic study commissioned by the state in 2011, recommended modifications of certain COPA conditions, but did not address broader questions of the impact of the COPA on public health or physician incentives to practice in the Asheville NC region. G.S. Vistnes, *An Economic Analysis of the Certificate of Public Advantage (COPA) Agreement Between the State of North Carolina and Mission Health* (Feb. 10, 2011), available at https://mountainx.com/files/copareport.pdf.

22 Press Release, FTC, FTC Staff Notice of COPA Assessment: Request for Emperical Research and Public Comments (Nov. 1, 2017), *available at* https://www.ftc.gov/system/files/attachments/press-releases/ftc-staff-seeks-empirical-research-public-comments-regarding-impact-certificates-public-advantage/p181200_copa_assessment_comment_notice_11-1-17.pdf?utm_source=govdelivery.

the West Virginia legislature passed a COPA law following the FTC's challenge to a local hospital merger, effectively shielding the transaction from FTC enforcement.[23] And in late 2015, Tennessee and Virginia revised their existing COPA laws and introduced detailed regulations for COPA applications in anticipation of the proposed merger of the Wellmont and Mountain States health systems.

V. FTC OPPOSITION TO COPA LAWS

The FTC has repeatedly advocated against the introduction of COPA laws, as well as the granting of COPAs once legislation is in place. The FTC suggests that in passing COPA laws, states fundamentally misunderstand the purpose and scope of federal antitrust laws and that the consumer benefits the antitrust laws seek to preserve are consistent with state public health concerns. Because the federal antitrust laws permit procompetitive joint activity, argues the FTC, proposed laws granting antitrust immunity, or grants of COPAs under such laws, must be designed to shield anticompetitive behavior that would not otherwise pass muster under federal antitrust law. As a result, the FTC contends that state COPA laws pose substantial risk of consumer harm.[24]

In general, the federal antitrust laws prohibit competitors from engaging in conduct that would restrict competition. The laws are founded on the premise that competition among sellers in an open marketplace gives consumers the benefits of lower prices, higher-quality goods and services, greater access to goods and services, and innovation. At one end of the spectrum, the laws summarily prohibit obviously anticompetitive activities, such as price-fixing or market-allocation agreements between competitors. More complex, however, is the treatment of restrictions in the context of activities that otherwise increase efficiency and benefit consumers, such as collaborations of healthcare providers.

The FTC's focus in challenging consolidations or collaborations in the healthcare area has principally been on conduct that may result in collective negotiation of reimbursement rates with commercial providers. The FTC firmly believes that such collective negotiation—particularly where the collaborating providers represent a

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23 W. Va. Code § 16-29B-28 (2017).

24 *See, e.g.,* FTC Staff Submission to the Tenn. Dep't of Health Regarding the Certificate of Pub. Advantage Application of Mountain States Health Alliance & Wellmont Health Sys. (Nov. 21, 2016), *available at* https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-submission-tennessee-department-health-regarding-certificate-public-advantage-application/161122wellmontcommenttenn.pdf; Letter from Marina Lao, Director, FTC Office of Policy Planning, et al. to Hon. Larry C. Stutts, Alabama State Senator (May 2, 2016), *available at* https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-alabama-state-senate-regarding-alabama-house-bill-241-senate-bill-243/160504commentalabama.pdf; Letter from Marina Lao, Director, FTC Office of Policy Planning, et al. to Hon. Mike Pushkin, West Virginia Delegate (Mar. 9, 2016), *available at* https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-west-virginia-house-delegates-regarding-sb-597-competitive-implications-provisions/160310westvirginia.pdf; Letter from Marina Lao, Director, FTC Office of Policy Planning, et al. to Center for Healthcare Policy and Resource Development, Office of Primary Care and Health Systems Management, New York State Department of Health (Apr. 22, 2015), *available at* https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-center-health-care-policy-resource-development-office-primary-care-health-systems/150422newyorkhealth.pdf.

substantial portion of competing providers of a particular service or specialty—is likely to result in increased provider bargaining leverage, increased reimbursement rates, and eventually higher premium and out-of-pocket costs to consumers. The FTC's concerns in this regard are supported by academic literature concerning the impact of provider consolidating on prices.[25]

In addition to questioning the basis and need for COPA laws, the FTC also has raised specific concerns with the effectiveness of state oversight in managing the potential anticompetitive impacts of a competitor collaboration through detailed conditions. For example, with respect to the New York COPA process for DSRIP[26] performing provider systems, the FTC raised concerns about information sharing, joint payor negotiations, and potential spillover effects into commercial healthcare markets (since DSRIP relates only to Medicaid). In the recent Wellmont/Mountain States COPA application review in Tennessee, the FTC cautioned on the difficulty of executing a plan of separation (required as part of the COPA application) should the state later decide that the affiliation is not operating as expected.

VI. POLICY ARGUMENTS IN FAVOR OF COPA LAWS

The impacts of COPA laws are not as black and white as the FTC would have it. Far from rejecting the application of antitrust principles to competitor collaborations, competition principles remain a central element of the analysis for most COPA laws. What the COPA laws effectively do, however, is displace federal antitrust agencies and courts as the decision-makers in assessing the effects of the reduction in competition from a transaction, place greater emphasis on efficiencies and other non-competition factors, and foster a regulated post-merger environment. All three of these effects are at odds with the FTC's traditional policies in reviewing merger transactions.

First, in passing COPA laws, states are not necessarily rejecting the role of antitrust in maintaining the benefits of healthcare competition, but rather the role of the FTC as sole arbiter of whether and how competitor collaborations should go forward. Although the FTC and its Part 3 administrative court have significant expertise and experience in merger analysis—and healthcare merger analysis in particular—many states also have antitrust expertise in state attorneys general antitrust bureaus, and most COPA statutes direct collaboration between the attorney general and the state health department in

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25 *See, e.g.,* Cory Capps & David Dranove, *Hospital Consolidation and Negotiated PPO Prices,* 23 Health Affs. 175, 179 (2004) ("most consolidating hospitals raise prices by more than the median price increase in their markets"); Leemore S. Dafny, *Estimation and Identification of Merger Effects: An Application to Hospital Mergers 26 Nat'l Bureau of Econ. Research,* Working Paper No. 11673 (2005) ("there is conclusive evidence that mergers of independent hospitals can lead to large increases in area prices"); Martin Gaynor & Robert Town, *The Impact of Hospital Consolidation—Update,* Technical Report (Robert Wood Johnson Foundation/The Synthesis Project, Princeton, N.J.) (June 2012), at 2 ("Hospital mergers in concentrated markets generally lead to significant price increases.").

26 New York's Delivery System Reform Incentive Payment (DSRIP) Program is the main mechanism by which New York State is implementing the Medicaid Redesign Team (MRT) Waiver Amendment. DSRIP's purpose is to fundamentally restructure the healthcare delivery system by reinvesting in the Medicaid program, with the primary goal of reducing avoidable hospital use by 25% over 5 years. https://www.health.ny.gov/health_care/medicaid/redesign/dsrip/.

reviewing applications. This regulatory collaboration may make COPA decision-makers better placed to investigate and assess both competitive impact and the contribution of a healthcare transaction to state healthcare policy goals.

Second, COPA laws place greater emphasis on efficiencies and public health benefits than traditional FTC merger analysis. The FTC's *Horizontal Merger Guidelines* set a high bar for the proof of efficiencies in order for them to carry any weight in a merger review. This policy is underscored by judicial skepticism of the efficiencies defense. Many of the efficiencies considered in COPA applications would fail the FTC's tests of merger specificity or verifiability. And public health benefits are likely non-cognizable under FTC standards.

Noneconomic justifications for anticompetitive behavior are regularly rejected by the FTC and courts. As explained by the Supreme Court in *National Society of Professional Engineers v. United States,* 435 U.S. 679, 689 (1978), when rejecting a public health and safety affirmative defense for anticompetitive behavior, the rule of reason standard, under which mergers and other agreements are assessed, "does not open the field of antitrust inquiry to any argument in favor of a challenged restraint that may fall within the realm of reason. Instead, it focuses directly on the challenged restraint's impact on competitive conditions."[27]

COPA laws effectively remove this limitation to merger analysis conducted by state departments of health and allow the consideration of noneconomic benefits that may not be easily quantifiable. In the COPA process, the reviewing agency is expressly directed to take healthcare policy goals and efficiencies into account and to judge the likelihood of achieving claimed benefits of the transaction by a similar standard to that applied to assessing the potential competitive concerns. In the Ballad Health COPA decision, for example, the Tennessee Health Commissioner analyzed each separate claimed benefit and found that benefits would be likely to occur in the areas of: enhancement of hospital and hospital-related care quality; preservation of hospital facilities close to the communities they traditionally service; gains in cost containment and cost-efficiency of hospital services; improvement in the utilization of hospital resources and equipment; population health improvement in the region served; investments in programs and partnerships to address and ameliorate behavioral and addiction problems; and acceleration of risk-based contracts.[28]

Third, the COPAs granted in Idaho, North Carolina, New York, and most recently Tennessee all contained detailed terms and conditions under which the merged entity

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27 *See also Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of Univ. of Okla.,* 468 U.S. 85, 134 (1984) (White, J., dissenting) ("The legitimate noneconomic goals of colleges and universities should not be ignored in analyzing restraints imposed by associations of such institutions on their members, and these noneconomic goals may require that a particular practice, which could properly be viewed as a violation of the Sherman Act in another context, be treated differently. The Court of Appeals, like the District Court, flatly refused to consider what it termed 'noneconomic' justifications advanced by the NCAA in support of the television plan. It was of the view that our decision in *[National Society of Professional Engineers]*, precludes reliance on noneconomic factors in assessing the reasonableness of the television plan. This view was mistaken, and I note that the Court does not in so many words repeat this error.").

28 http://www.tn.gov/assets/entities/health/attachments/Approval_Letter_granting_COPA.pdf

would operate going forward. These terms and conditions provide for regular reporting, requirements to meet predicted cost-saving and quality targets, information firewalls where appropriate, and limitations on future managed care pricing.

In the Ballad Health COPA, for example, the terms and conditions included: restrictions on health plan negotiations and limitations on managed care pricing; prohibitions preventing Ballad Health from restricting suppliers, vendors or other contractors from contracting with competitors; prohibitions preventing Ballad Health from opposing the award of Certificates of Need in the region; prohibitions on restricting non-employed physicians from performing services outside Ballad Health; various aggregate and annual spending commitments tied to specific services, research, education and population health improvement; employee benefits and protections; and quality of care requirements. The conditions also established procedures to ensure access to healthcare services, by requiring certain facilities to remain hospitals; requiring health commissioner approval to remove or repurpose other hospitals, facilities or service lines; requiring discounts for under- or uninsured patients; and implementing a charity care policy.[29]

The FTC has consistently preferred structural remedies over behavioral or conduct remedies in merger cases.[30] One of the key drawbacks of conduct remedies is the need for detailed ongoing oversight and monitoring of compliance by the agency, which has been perceived as difficult to manage and enforce. The FTC has accepted short-term conduct remedies in conjunction with structural remedies, or in cases where a structural remedy was impossible (such as in the *Evanston/Northwestern* transaction, where the FTC's challenge was brought post-closing after the parties had merged), but they remain a rarity. Thus, the premise of a COPA's terms and conditions and ongoing close supervision by the state authority (which also is an essential element for application of the state action doctrine) runs against this policy.

Finally, COPA laws inherently recognize that competition may not be the sole means of addressing public health concerns and that antitrust enforcement alone may not resolve the concerns facing the healthcare industry. The FTC's criticisms of COPA laws ignore the states' broader policy interests in managing healthcare concerns within their own borders—such as access to healthcare for underserved communities—which may supersede antitrust concerns. The FTC itself recognized this in a 2004 study:

> ". . . competition is not a panacea for all of the problems with American healthcare. Competition cannot provide its full benefits to consumers without good information and properly aligned incentives. Moreover, competition cannot eliminate the inherent uncertainties in healthcare, or the informational asymmetries among consumers, providers, and

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29 Ballad Health Terms of Certification, *available at* https://www.tn.gov/assets/entities/health/attachments/Ballad_Health_-_Terms_of_Certification_Governing_the_COPA_-_September_18_2017_-_approved_by_MSHA_Board.pdf.

30 *See, e.g.,* Negotiating Merger Remedies, Statement of the FTC Bureau of Competition (Jan. 2012), available at https://www.ftc.gov/system/files/attachments/negotiating-merger-remedies/merger-remediesstmt.pdf.

payors. Competition also will not shift resources to those who do not have them."[31]

This concern also has been recognized by former Commissioner Julie Brill, who noted:

> "Healthcare policy makers at the state level are faced with difficult issues separate and apart from the strong benefits competition brings to healthcare markets. These include the critically important issue of preserving access to care for the needy, and doing so in a complex market, involving informational asymmetries among patients, providers, and payors. In this context, it is important to understand that competition will not move resources from those that can afford healthcare to those that cannot."[32]

Going forward, the FTC is likely to continue to oppose the grant of antitrust immunity to healthcare collaborations under COPA laws and the expansion of those laws. But for parties considering transactions in states in which COPA laws are already on the books, or where legislators may be interested in introducing such a process, they may be a viable route forward.

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31 FTC and DOJ, IMPROVING HEALTH CARE: A DOSE OF COMPETITION (2004), *available at* https://www.ftc.gov/sites/default/files/documents/reports/improving-health-care-dose-competition-report-federal-trade-commission-and-department-justice/040723healthcarerpt.pdf.

32 Dissenting Statement of Commissioner Julie Brill on the Joint Statement of the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice on Certificate-of-Need Laws and South Carolina House Bill 3250 (Jan. 8, 2016), *available at* https://www.ftc.gov/system/files/documents/public_statements/905323/160111ftc-doj-sclaw-statement.pdf.

DIGITAL HEALTH PRIVACY: OLD LAWS MEET NEW TECHNOLOGIES

By Reece Hirsch and Jenny Harrison[1]

I. INTRODUCTION

When the Health Insurance Portability and Accountability Act ("HIPAA") was enacted in 1996, the smart phone was not even a gleam in Steve Jobs' eye, and mobile health apps and cloud computing did not exist. Even though the primary regulations implementing and amending HIPAA became effective in 2003, 2005, and 2013, regulators and lawmakers continue to play catch-up, striving to apply HIPAA's regulatory framework to an ever-evolving technology landscape.

Recent years have seen the proliferation of devices and applications that permit consumers to create, store and share health information like never before, from activity trackers to personal health records ("PHRs"). This type of information, which exists outside the traditional medical record maintained by healthcare providers, is often referred to as "consumer-generated health information" ("CHI"), and it has caught the attention of the regulators.[2]

The main regulators of the digital health field are the Department of Health and Human Services Office for Civil Rights ("OCR") and the Federal Trade Commission ("FTC"), along with state attorneys general. OCR has jurisdiction under HIPAA to regulate HIPAA-covered entities (*i.e.*, healthcare providers that engage in standard electronic transactions, health plans, or healthcare clearinghouses) and business associates of those entities. The FTC derives its jurisdiction from Section 5 of the Federal Trade Commission Act (the "FTC Act"), which empowers the agency to regulate "unfair or deceptive acts or practices." A business may fall under the FTC's authority if it makes an inaccurate or misleading statement in its website privacy policy (a potentially deceptive practice) or has inadequate security that is inherently unfair or harmful to consumers (a potentially unfair practice).

State attorneys general have the authority to regulate unfair and deceptive practices that are parallel to the FTC's, under the so-called "baby FTC Acts." State AGs also have the authority to enforce HIPAA since enactment in 2009 of the Health Information Technology for Economic and Clinical Health ("HITECH") Act, which amended HIPAA. This article will review (i) how HIPAA privacy and security standards are being applied to new technologies like mobile health apps, activity trackers, personal health records and cloud computing vendors, and (ii) how to determine which agencies have the authority to regulate these new domains, and under what circumstances.

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2 FTC Commissioner Julie Brill has made it clear that CHI is considered sensitive and requires greater protections than other types of consumer data. *See* Fed. Trade Comm'n, Consumer Generated and Controlled Health Data (May 7, 2014 seminar).

II. OCR'S JURISDICTION AND APPLICATION OF HIPAA

HIPAA's privacy and security requirements apply only to a limited group of covered entities: healthcare providers that engage in standard electronic transactions, health plans, healthcare clearinghouses, and business associates of those entities. A mobile app developer that collects health information may be subject to HIPAA's requirements, but only if it is considered a business associate of a covered entity.

A. Who Qualifies as a Business Associate?

Under HIPAA, a business associate is a person or entity acting on behalf of a covered entity that creates, receives, maintains, or transmits PHI for a function or activity regulated by HIPAA (*i.e.*, a covered entity function).[3] If an entity is found to be a business associate, then it must comply with certain security and privacy requirements. The key language for many companies is whether it is "acting on behalf of a covered entity." If a company provides a service directly to the consumer, then it is not a business associate because an individual patient or consumer is not a covered entity. However, a company may be a business associate if it provides the same service to individual patients or health plan members on behalf of a covered entity.

One practical litmus test for the "acting on behalf of" question is who pays for the service. If the consumer is the customer and pays directly for the service, then the company is most likely not a business associate. However, if a covered entity is the customer, then the company is most likely a business associate and would be subject to HIPAA regulation. There is a gray area when a provider only partially pays for the service, for example if the provider only pays for 75% of a fee or provides a partial rebate. OCR has yet to issue sufficient guidance to resolve some of these questions, so it is up to the developer to assess its connection to covered entities and to determine whether it qualifies as a business associate or not.

B. Consequences of Business Associate Status

If a company is a business associate, it is governed by the HIPAA privacy rules and may only use and disclose PHI as provided in the company's business associate agreements with covered-entity customers. If a company is not a business associate, then its privacy policies are governed by FTC privacy principles and the terms of the company's own posted privacy policy. Thus, business associate status has an enormous impact on the business's information collection and disclosure practices. As a business associate, a developer can, with limited exceptions, only use and disclose PHI to provide the contracted services to the covered entity. If the company is not a business associate, it will have greater latitude to use and disclose collected personal information, so long as there is disclosure and appropriate consent obtained through the privacy policy.

Because different privacy and security standards apply depending on the developer's business associate status, it may be necessary to segregate personal information if the developer has both business associate and direct-to-consumer operations.

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3 45 C.F.R. § 160.103 (2014).

III. APPLYING EXISTING LAWS TO NEW TECHNOLOGIES

Each year brings the introduction of new devices and applications that collect, use, and disclose CHI and PHI. Existing privacy regulatory regimes typically do not contemplate, and may be a poor fit for, these new technologies. In the face of this onslaught, federal and state regulators have tried different enforcement strategies to keep pace with new technological advances and societal trends.

A. Mobile Apps

There are thousands of health-related mobile apps that collect and track health information, connect patients with their healthcare providers, or provide other health services. Whether a mobile app developer is considered a business associate is a case-by-case factual determination, often turning on whether the developer is "acting on behalf of a covered entity." In February 2016, OCR issued guidance for mobile health app developers.[4] The guidance provided six examples of how HIPAA applies and does not apply to mobile apps that collect, store, manage, organize, or transmit health information.

Under OCR's guidance, a mobile app is not considered a business associate if it simply allows a consumer to input her own health information and there is no relationship between the mobile app and the consumer's healthcare providers or health plan.[5] In such a scenario, the mobile app is acting on behalf of the consumer, not a covered entity, and, therefore, is not a business associate.

A mobile app developer is still acting on behalf of the consumer, and, therefore, is not considered a business associate, if its app allows a consumer to input personal information or access a healthcare provider's test results, or the app transmits the information to the provider at the consumer's direction.[6] If the developer and healthcare provider have an interoperability arrangement, entered into at the consumer's request to facilitate the secure exchange of health information, the developer is still not a business associate because such an agreement is intended to facilitate access to health information initiated by the consumer. A developer would be considered a business associate if it contracts directly with a healthcare provider for patient management services, such as for remote patient health counseling, monitoring patients' food and exercise, or patient messaging.[7]

To assist mobile app developers in assessing their business associate status, OCR, along with the FTC and FDA, have developed a Mobile Health Apps Interactive Tool. This tool can be used to assist developers in determining whether the app is subject to HIPAA, the FTC Act, the FTC's Health Breach Notification Rule, and/or the Federal Food, Drug and Cosmetic Act.[8]

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4 U.S. Dep't of Health & Human Servs., Office for Civil Rights, Health App Use Scenarios & HIPAA (2016), https://hipaaqsportal.hhs.gov/community-library/accounts/92/925889/OCR-health-app-developer-scenarios-2-2016.pdf.

5 *See id.* at 2 (scenario 1).

6 *See id.* (scenario 2).

7 *See id.* (scenario 3).

8 Fed. Trade Comm'n, Mobile Health Apps Interactive Tool, https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool (last visited Sept. 29, 2017).

1. Recent Actions Involving Mobile Apps

In March 2017, New York Attorney General Eric Schneiderman settled with three health app developers for "misleading claims and irresponsible privacy practices" that violated New York's consumer protection laws. The three health measurement apps purported to measure vital signs without the assistance of any external device. For example, the "My Baby's Beat" app claimed users could monitor a fetus' heartbeat by holding a smartphone running the app to a pregnant woman's stomach. The apps made marketing claims comparing them to traditional medical devices, but they were never submitted to the FDA. The Attorney General found the app privacy policies to be inadequate on a number of grounds, including (i) collecting geolocation data without disclosing that fact, (ii) stating that GPS could be turned off without providing that option, and (iii) presuming consent to the policy through use of the app. The developers also should not have compared their apps to FDA-regulated devices when the app had not been submitted to the FDA. The settlements required the three developers to amend their marketing claims, modify their privacy policies, consent to monitoring, and pay fines ranging from $5,000 to $20,000.[9]

In April 2017, Massachusetts Attorney General Maura Healey entered into a no-fault settlement agreement with a digital advertising company, Copley Advertising, for its geofencing activity. "Geofencing" technology enables a user to create virtual fences and then to "tag" smartphones and other mobile devices as they enter or leave that area. Targeted third-party ads can then be displayed once the phone user opens a mobile app or web browser. The Attorney General alleged that Copley had set virtual fences around reproductive health clinics and methadone clinics in several states, targeting an advertisement about alternatives to abortion to be delivered when GPS data showed that an individual was near a reproductive health clinic. The settlement provides that Copley will not use geofencing technology at or near Massachusetts healthcare facilities to infer the health status, medical condition, or treatment of any individual.[10] If properly disclosed in a privacy policy in accordance with FTC privacy principles, it is possible that geofencing may be permissible, but this is a relatively new practice and the law is still unsettled in this area.

B. Internet of Things

The Internet of Things ("IoT") refers to physical devices or items connected to each other or to the internet, such as smart televisions or home security appliances. In November 2015, Gartner, Inc. estimated that the number of devices connected to the

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9 N.Y. State Attorney Gen., A.G. Schneiderman Announces Settlements with Three Mobile Health Application Developers for Misleading Marketing and Privacy Practices, https://ag.ny.gov/press-release/ag-schneiderman-announces-settlements-three-mobile-health-application-developers (last visited Sept. 29, 2017).

10 Mass. Attorney Gen., AG Reaches Settlement with Advertising Company Prohibiting 'Geofencing' Around Massachusetts Healthcare Facilities, http://www.mass.gov/ago/news-and-updates/press-releases/2017/2017-04-04-copley-advertising-geofencing.html (last visited Sept. 29, 2017).

Internet would exceed 20 billion by 2020. Many of these devices, such as activity trackers and smart medical devices, collect CHI. There is no privacy law that generally regulates IoT data collection and security, but in May 2015, former FTC Commissioner Julie Brill declared that the FTC's enforcement powers extended to privacy and security risks posed by the IoT based on its Section 5 jurisdiction over unfair and deceptive trade practices.[11] Thus, IoT developers must be mindful of what they tell their consumers regarding their data collection and use practices, and what the consumers understand about those practices.

Privacy regulation is based on traditional notions of notice and consent, but these concepts are often difficult to apply to IoT devices. Former FTC Commissioner Brill urged companies to "get creative" about providing privacy transparency and control for consumers to manage their data.[12] For example, a household "command center" could run multiple household devices and describe in simple, consolidated terms how those devices collect and use information. In January 2015, the FTC issued a reported titled "*Internet of Things: Privacy & Security in a Connected World*," which was based on input from technologists, academics, industry representatives, and consumer advocates, at a November 2013 FTC workshop in D.C.[13] The report provided recommended practices and potentially provides insight into future FTC enforcement actions, but it does not have the force of law.

C. Activity Trackers

Activity and fitness trackers are particularly prolific IoT devices that collect and record CHI, such as number of steps per day and heart rate. These devices raise many of the same privacy regulatory issues as health mobile apps. When activity trackers are sold directly to the consumer, the company is not a HIPAA business associate because it is acting on behalf of the consumer, not on behalf of a covered entity. However, a business associate relationship may be triggered if a health plan becomes involved, such as an arrangement in which a health plan purchases activity trackers for its members. In that scenario, business associate status will depend on the specific facts and circumstances of the relationship, such as (1) the degree of control the plan member has over the choice of the device and the sharing of information, and (2) whether the health plan purchases the device or merely recommends it to the member.

The analysis changes when an employer provides activity trackers to its workforce. Such an arrangement probably does not trigger a business associate relationship because the employer is acting in its capacity as an employer, and not a HIPAA-covered entity. However, a business associate relationship may exist if the activity trackers are provided to the employer's group health plan, which is separate and legally distinct from the

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11 Fed. Trade Comm'n, Data Protection & the Internet of Things (2015), https://www.ftc.gov/system/files/documents/public_statements/640741/2015-05-04_euroforum_iot_brill_final.pdf (Federal Trade Commissioner Judy Brill's keynote address at the EuroForum European Data Protection Days).

12 *Id.*

13 Fed. Trade Comm'n, Internet Of Things: Privacy & Security In A Connected World (2015), https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-staff-report-november-2013-workshop-entitled-internet-things-privacy/150127iotrpt.pdf.

employer and plan sponsor. Employer group health plans are almost always health plan covered entities under HIPAA.

Activity trackers face the same issues as IoT devices, generally, regarding traditional notice and consent requirements. Wearable fitness trackers typically do not have a user interface to present consumers with choices about data collection. As with IoT devices, activity trackers must be more inventive in developing approaches to privacy notice and consent.

D. Cloud Computing

Another relatively recent and ubiquitous technology, cloud computing, also raises unique privacy and security issues in the healthcare industry. OCR issued guidance in 2016 on cloud computing and HIPAA, recognizing the proliferation of cloud-based electronic medical records and cloud services offering access to networks, servers, storage, and applications. Prior to the HIPAA Final Rule's 2013 compliance date, cloud service providers ("CSPs") were not business associates if they did not access, use, or disclose PHI. In 2013, the business associate definition was modified to include "maintaining" PHI as a basis for a business associate relationship, which thus encompasses CSPs.[14]

In commentary to the HIPAA regulations, OCR created an exception to the business associate rules known as the "conduit" exception.[15] Under this exception, a transmission-only service for PHI is not a business associate, so long as the transmission service is the only service that the company is providing to the covered entity. This applies to paper transmission providers, such as couriers and the post office, and electronic transmission providers, such as certain telecommunications providers and messaging services. Any access to the PHI by a conduit must be "random and infrequent" and "transient in nature." CSPs would not qualify for this conduit exception.[16]

A CSP is still considered a business associate and must abide by the HIPAA security regulations (the "Security Rule") when the CSP only receives encrypted data and does not have an encryption key for the data. OCR refers to such data and services as "no-view" services. "No-view" data is still considered PHI and encryption of data does not exempt a CSP from Security Rule standards. Thus, the CSP must still be aware of and protect against potential risks, such as corruption of data by malware, physical security risks, or data recovery in emergency or disaster situations.

OCR has acknowledged that, when a CSP provides no-view services, it may be appropriate for the covered entity and the business associate to share Security Rule responsibilities.[17] For example, if the covered entity controls who can view PHI, then it may take responsibility for access controls, like authentication or unique user

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14 45 C.F.R. § 160.103 (2014).

15 *See* 78 Fed. Reg. 5,566, 5,572 (Jan. 25, 2013); *see also* U.S. Dep't of Health and Human Servs., Office for Civil Rights, https://www.hhs.gov/hipaa/for-professionals/faq/245/are-entities-business-associates (last visited Sept. 28, 2017).

16 *See* U.S. Dep't of Health and Human Servs., Office for Civil Rights, https://www.hhs.gov/hipaa/for-professionals/special-topics/cloud-computing/index.html (last visited Sept. 28, 2017).

17 *Id.*

identification, while encryption may be a more appropriate function for the CSP. The parties can divvy up security responsibilities based upon their respective security risk management plans. However, even when the covered-entity customer controls authenticating access to ePHI, the CSP may be responsible for internal controls governing authorized access to the administrative tools that manage the resources, such as storage memory, network interfaces and central processing units. Contracts for cloud services can allocate responsibility for compliance with various Security Rule standards. OCR has indicated that it will take that sort of allocation of duties into account when assessing responsibility in an enforcement action.[18]

A covered entity or business associate may use a CSP that stores ePHI on servers outside the U.S. if applicable HIPAA requirements are satisfied. However, if ePHI is being maintained in a country where there are documented increased attempts at hacking or other malware attacks, those risks should be taken into account in the entity's risk analysis and risk management processes.

E. Personal Health Records

There is no universal definition for a personal health record ("PHR"), but it is generally considered to be an electronic record of an individual's health information by which the individual controls access to the information and may have the ability to manage, track, and participate in his or her own care. PHRs are distinct from an electronic medical record ("EMR"), which must be maintained and largely controlled by a healthcare provider. Depending on the amount and type of CHI collected, a mobile health app or IoT device can take on characteristics of a PHR.

Whether a PHR is subject to HIPAA depends, once again, on whether it is used on behalf of a covered entity or the consumer. For example, a health plan may offer a PHR for its plan members to assist in the management of their health. Such a PHR must abide by the Security Rule safeguards and the limitations on uses and disclosures of PHI imposed by the HIPAA privacy regulations (the "Privacy Rule"). On the other hand, a PHR offered directly to consumers where a plan member can input a copy of his PHI obtained from a healthcare provider or health plan would operate outside HIPAA regulations. Instead of being governed by the HIPAA Privacy Rule, the privacy obligations of such a direct-to-consumer PHR would be primarily defined by the PHR's posted privacy policy and FTC privacy principles.

OCR has issued guidance on "Personal Health Records and the HIPAA Privacy Rule,"[19] which states that consumer-directed PHRs that are not offered by HIPAA-covered entities are not subject to HIPAA. The maintenance of medical records in a PHR by a consumer does not create a business associate relationship, even though the records may have been produced by a physician or other covered entity. Rather, to be covered by HIPAA, a PHR vendor must be acting on behalf of a HIPAA-covered entity.

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18 *Id.*

19 U.S. Dep't of Health and Human Servs., Office for Civil Rights, Pers. Health Records & the HIPAA Privacy Rule, https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/healthit/phrs.pdf.

IV. HEALTH BREACH NOTIFICATION RULE

Recognizing the limits of HIPAA's statutory reach, the FTC issued a Health Breach Notification Rule in 2009, which mirrors HIPAA's Breach Notification Rule and is more prescriptive than state breach notification laws. Entities subject to this rule must notify their customers and others if there is a breach of unsecured, individually identifiable health information. This rule applies to a vendor of PHRs, a PHR-related entity, or to a third-party service provider for a vendor of PHRs or a PHR-related entity. A business is a vendor of personal health records if it "offers or maintains a personal health record."[20] A PHR is defined as an electronic record of "identifiable health information on an individual that can be drawn from multiple sources and is managed, shared, and controlled by or primarily for the individual."[21]

A wide range of mobile health apps, IoT devices, and other digital health services could potentially fall within the definitions of PHR, PHR-related vendor, and third-party service provider. A PHR-related entity is an entity that interacts with a PHR vendor by either offering products or services through the vendor's website or by accessing information in a PHR or sending information to a PHR.

Under the Health Breach Notification Rule, if a breach involves the information of more than 500 people, an entity must notify the FTC as soon as possible, but at least within ten business days after discovering the breach. If the breach involves information of fewer than 500 people, the entity can send the notice on an annual basis within 60 days of the end of the calendar year. If the breach involves more than 500 residents of a particular state, the entity must notify prominent media outlets serving the relevant locale.

V. Conclusion

OCR, FTC, state attorneys general, and other regulators are all trying to protect consumers by applying and adapting existing laws to the new world of digital health privacy. Agency-issued guidance and enforcement actions are excellent sources for navigating this new landscape. Because digital health companies often straddle multiple privacy and security regulatory regimes, it is important to understand which regulatory requirements apply, and to make informed choices when venturing into an area in which applicable law remains unclear.

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20 16 C.F.R. § 318.2(j) (2009).

21 *Id.* at (d).

CAUSATION PRINCIPLES IN PHARMACEUTICAL ANTITRUST LITIGATION

By Steve D. Shadowen[1]

Antitrust plaintiffs bring private claims in the pharmaceutical arena that arise from two recurring sets of facts in which brand-drug manufacturers allegedly delay or impair competition from generic-drug manufacturers. In "exclusion payment" or "pay-for-delay" antitrust cases, plaintiffs allege that the brand manufacturer, in the context of settling patent litigation, paid the generic manufacturer to withdraw its challenge to the patent and delay entry into the market. In "product-hopping" cases, plaintiffs allege that the brand manufacturer reformulated its product and switched the built-up base of prescriptions from the original to the reformulated product, in order to shield the prescription base from automatic generic substitution.

Courts are well along in establishing the rules for liability in exclusion-payment cases.[2] Product-hopping liability rules are currently less well defined, but the broad outlines are coming into view.[3] With liability standards established or on the horizon, the locus of contention in private litigation is increasingly shifting to causation: what evidence must plaintiffs adduce in order to permit a jury to conclude that the antitrust violation caused the injury for which plaintiffs seek recovery?

Borrowing from the common law of torts, courts in antitrust cases apply the familiar rule that plaintiffs must prove that the violation was a "material" or "substantial" cause of the injury. This is a different inquiry than determining the quantum of antitrust damage that the plaintiffs sustained. In determining damages, the plaintiffs compare the price that they actually paid to the price that they would have paid absent the violation—a comparison of the "actual world" to the "but-for world." This requires plaintiffs to offer a reconstruction of what likely would have happened absent the violation. This is not the relevant analytical framework for determining whether the violation likely *caused an injury* to plaintiffs. In determining causation, the jury considers the nature of the violation and the injury that actually occurred, and then makes a common-sense judgment about whether the violation likely caused the injury. For causation, plaintiffs need not offer any reconstructed "but-for world."

In making its judgment about whether the violation likely caused the injury, a jury is aided by a well-settled legal principle, adopted from tort law, that I call the "Causation Inference." Where defendant's conduct is deemed to be anticompetitive because of its

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1 Steve Shadowen, a founder of Hilliard & Shadowen LLP, regularly represents plaintiffs in antitrust litigation in the pharmaceutical and other industries. The views expressed are the author's alone and not necessarily those of his clients, Hilliard & Shadowen LLP, or the institutions with which he is affiliated. Many thanks to Amy Weintraub for excellent research assistance.

2 *See, e.g., FTC v. Actavis, Inc.,* 133 S. Ct. 2223 (2013)*; In re Loestrin 24 Fe Antitrust Litig.,* 814 F.3d 538 (1st Cir. 2016); *King Drug Co. of Florence v. Smithkline Beecham Corp.,* 791 F.3d 388 (3d Cir. 2015); *In re Cipro Cases I & II,* 348 P.3d 845 (2015).

3 *See, e.g., Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co.,* 838 F.3d 421 (3d Cir. 2016); *New York ex rel Schneiderman v. Actavis PLC,* 787 F.3d 638 (2d Cir. 2015). For liability issues that remain to be decided in product-hopping cases, and suggestions for a way forward, *see* Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework,* 92 Notre Dame L. Rev. 167 (2016).

propensity to cause a particular type of injury, and plaintiffs, in fact, suffered that type of injury, the jury is entitled to draw the inference—the Causation Inference—that the violation likely caused the injury. Courts routinely apply the Causation Inference in both tort and antitrust cases, including in pharmaceutical antitrust cases, and hold that it is sufficient to get plaintiffs to a jury on the question of causation.

Two other important consequences flow from the Causation Inference in antitrust cases. First, once the Causation Inference arises, the burden shifts to the defendant to prove that intervening causes would have resulted in the same injury even absent the antitrust violation. In a pharmaceutical exclusion-payment case, for example, once the Causation Inference arises, the defendant has the burden to prove that the generic manufacturer would not have received timely FDA approval or would have lost the patent litigation, or alternatively that, if the patent litigation had been settled, the agreed generic-entry date would not have been any earlier than in the actual agreement.

Second, many antitrust plaintiffs will produce evidence that both supports their but-for world for purposes of proving damages and also rebuts defendant's alleged intervening causes (*e.g.*, evidence that the generic manufacturer would have won the patent litigation). When used to support plaintiffs' damages, this evidence is protected by the lenient evidentiary standard that applies to estimating antitrust damages. That rule does not change because plaintiffs also use the evidence to counter defendants' evidence of intervening causes—an issue on which defendants have the burden of proof.

I. BASIC LAW OF CAUSATION

Section 4 of the Clayton Act permits an antitrust plaintiff to recover damages for injuries that she sustained to her business or property "by reason of" defendant's antitrust violation.[4] Some courts characterize this causation requirement as an element of plaintiff's antitrust standing;[5] others as a stand-alone element of plaintiff's claim for damages.[6] Regardless of how courts frame the issue, the question boils down to whether the defendant's anticompetitive conduct likely caused the injury for which plaintiff seeks recovery.

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4 15 U.S.C. § 15(a).

5 *See, e.g., Sports Racing Servs. v. Sports Car Club of Am.,* 131 F.3d 874, 882 (10th Cir. 1997) ("To maintain standing . . . a plaintiff must show . . . a direct causal connection between that injury and a defendant's violation of the antitrust laws.").

6 *See, e.g., Gerlinger v. Amazon.com*, 526 F.3d 1253, 1255 (9th Cir. 2008) ("For Article III purposes, an antitrust plaintiff establishes injury-in-fact when he 'has suffered an injury which bears a causal connection to the alleged antitrust violation.'") (quoting *Amarel v. Connell*, 102 F.3d 1494, 1507 (9th Cir. 1996)).

Causation in antitrust law generally follows the same principles applicable under the common law of torts.[7] Tort law applies the familiar "substantial factor" test: plaintiff must prove that defendant's wrongful conduct "has been a substantial factor in bringing about the harm [plaintiff] has suffered."[8] Courts therefore require antitrust plaintiffs to prove that the anticompetitive conduct was a "material" or "substantial" part of the causal chain leading to the injury.[9] Causation is a fact-intensive and context-dependent issue usually best left "for the jury to be determined as a fact."[10]

II. CAUSATION FRAMEWORK DIFFERENT FROM DAMAGES FRAMEWORK

Courts could easily go astray in pharmaceutical antitrust cases by confusing the framework for analyzing causation with the framework for analyzing damages. In order to estimate the amount of *damages*, plaintiffs construct a "but-for world," *i.e.*, the hypothetical state of competition that likely would have occurred if defendant had not violated the antitrust law. Purchaser plaintiffs compare the amount they paid for the product in the "actual world," *i.e.*, in the state of competition that they actually experienced, with the amount they would have paid in the but-for world. The difference is their damages.

For example, in an exclusion-payment case, plaintiffs' proffered but-for world might consist of an alternative, hypothetical patent settlement in which the brand manufacturer gave the generic manufacturer a license to enter the market on the expected entry date,[11] say, Year 5 where the patent had a remaining term of 10 years. In the actual world, however, the patent litigants reached a settlement in which the brand manufacturer granted a license to the generic manufacturer to enter the market in Year 7—two years beyond the expected entry date—and also (unlawfully) paid the generic manufacturer $100 million. The generic manufacturer did, in fact, stay out of the market until Year 7. Plaintiffs' damages consist of the savings they would have achieved if generic entry had occurred on the expected entry date, two years earlier.

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7 *See Associated General Contractors of California, Inc. v. California State Council of Carpenters,* 459 U.S. 519, 548–49 (1983) ("Since antitrust violations are essentially 'tortious acts,' *Bigelow v. RKO Radio Pictures,* 327 U.S. 251, 264, (1946), the most apt analogy is to the common law of torts. Although many legal battles have been fought over the extent of tort liability for remote consequences of *negligent* conduct, it has always been assumed that the victim of an *intentional* tort can recover from the tortfeasor if he proves that the tortious conduct was a cause-in-fact of his injuries . . . Indeed, in many situations the common law holds an intentional tortfeasor liable even for the unforeseeable consequences of his conduct. [The court is] not aware of any cases exonerating an intentional tortfeasor from responsibility for the intended consequences of his actions merely because he inflicted harm upon his victim indirectly rather than directly.") (italics in original, internal footnotes omitted)).

8 Restatement (Second) of Torts, § 433b (1979).

9 *See* Herbert Hovenkamp, *Federal Antitrust Policy: The Law Of Competition And Its Practice*, ¶16.3c, at 813 (5th ed. 2016).

10 *Story Parchment Co. v. Paterson Parchment Paper Co.,* 282 U.S. 555, 566 (1931)*; see also Exxon Co., U.S.A. v. Sofec, Inc.,* 517 U.S. 830, 840–41 (1996); *Zenith Radio Corp. v. Hazeltine Research, Inc.,* 395 U.S. 100, 123–24 (1969).

11 The "expected" entry date is the date that, on average, entry is likely to occur as a result of litigating the patent issues. *See In re Cipro Cases I & II,* 348 P.3d at 865, and the legal/economic articles cited therein.

In short, the analytical framework for damages compares competition in the actual world to competition in the but-for world.

That is not the analytical framework for analyzing *causation* in antitrust cases generally, or in pharmaceutical antitrust cases in particular. For causation, antitrust law applies two fundamental, interrelated tort-law precepts. The factfinder decides causation by making a common-sense judgment about whether the defendant's *actual-world* conduct likely contributed to the plaintiff's *actual-world* injury. In this analysis, the factfinder need not compare the actual world to the but-for world.

Further, in making its judgment as to whether defendant's actual-world conduct likely contributed to plaintiffs' injury, the factfinder is aided by the Causation Inference: the inference that, if conduct is unlawful because of a tendency to cause a certain type of injury, and such an injury in fact occurred, the conduct likely caused it.[12] As articulated in the Restatement of Torts, "[i]f, as a matter of ordinary experience, a particular act or omission might be expected to produce a particular result, and if that result has in fact followed, the conclusion may be justified that the causal relation exists."[13]

Returning to the exclusion-payment example above, the plaintiffs' *prima facie* case on causation is incisively simple. Exclusion payments are unlawful because they tend to result in generic manufacturers' delaying entry into the market beyond the expected entry date.[14] So, plaintiffs' principal causation evidence will consist in proving that: (a) the settlement agreement contained an unlawful (*i.e.*, large and unjustified) exclusion payment, and (b) the generic manufacturer did, in fact, stay out of the market until the date to which it agreed in exchange for the payment. Plaintiffs' *prima facie* evidence of *causation* is the compelling inference that (a) caused (b). To collect *damages*, plaintiffs will need to proffer evidence of a but-for world that shows *how much later* than the expected entry date the payment likely caused generic entry to occur. But that is not necessary for causation.

Consider another example. A brand manufacturer's product-hopping is unlawful because it tends to substantially reduce the prescription base available for automatic generic substitution.[15] A plaintiff's principal causation evidence will consist in proving that: (a) the brand manufacturer unlawfully product hopped; and (b) when generic entry occurred, a lower percentage of prescriptions was available for automatic substitution than is typical. Plaintiffs' *prima facie* evidence of *causation* is the compelling inference that (a), which is unlawful because it has a tendency to cause (b), in fact did so in this case. To collect *damages*, plaintiffs will need to proffer evidence of a but-for world that shows *how many fewer* prescriptions the product hop likely caused to be available. But that is not necessary for causation.

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12 These two precepts, in both tort and antitrust law, are discussed further in detail below.

13 Restatement (Second) of Torts, § 433b (1979).

14 *See, e.g., FTC v. Actavis, Inc.,* 133 S. Ct. at 2233; *In re Cipro Cases I & II,* 348 P.3d at 865.

15 *See, e.g., New York ex rel Schneiderman v. Actavis,* 787 F.3d at 654; Carrier & Shadowen, *Product Hopping: A New Framework,* 92 Notre Dame L. Rev. at 171.

III. COURTS' ANALYSIS OF THE CAUSATION INFERENCE

Tort cases routinely announce and apply the Causation Inference—the inference that arises where plaintiff suffered an injury of the type whose tendency to occur rendered defendant's conduct unlawful. A frequently cited case is *BCS Servs., Inc. v. Heartwood 88, LLC,*[16] which held that "once a plaintiff presents evidence that he suffered the sort of injury that would be the expected consequence of the defendant's wrongful conduct, he has done enough to withstand summary judgment on the ground of absence of causation."[17] In *BCS Servs*., a RICO case in which the court applied tort-law causation principles,[18] the rules of tax-lien auctions permitted only one agent per firm to attend and bid. Defendants secretly sent multiple agents, seeking to obtain the bidding advantage that the rule was designed to prevent. Judge Posner explained that the Causation Inference was sufficient for plaintiffs to overcome summary judgment because "[t]he object of their conspiracies was to obtain liens that would otherwise go to one-armed bidders–there could be no other reason. . .The plaintiffs were major bidders. . .How likely is it that they lost *no* bids to [the defendants]?"[19]

Similarly, the plaintiffs in a products liability case established that the defendant's failure to place a warning label on a meat grinder was negligent because it significantly increased the likelihood that someone might accidentally get his hand caught in the grinder.[20] While using the meat grinder, plaintiff, in fact, got his hand caught in it.[21] The confluence of those two circumstances—conduct that was unlawful because of its tendency to cause a certain type of injury, and the plaintiff's having suffered that type of injury—was sufficient to sustain a jury verdict for plaintiff on causation: "When a defendant's negligent act is deemed wrongful precisely because it has a strong propensity to cause the type of injury that ensued, that very causal tendency is evidence enough to establish a *prima facie* case of cause-in-fact."[22]

The same rule applies in antitrust cases. The leading Supreme Court case, *Bigelow v. RKO Radio Pictures, Inc.,*[23] expressly adopted for antitrust law the "well-settled principle" of torts that "the jury [may] conclude as a matter of just and reasonable inference from

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16 637 F.3d 750 (7th Cir. 2011).

17 *Id.* at 758.

18 *Id.*

19 *Id* (italics in original).

20 *Liriano v. Hobart Corp.*, 170 F.3d 264, 271 (2d Cir. 1999).

21 *Id.*

22 *Id. Liriano* cited Judge Cardozo's opinion that, in these circumstances, "[i]f nothing else is shown to break the connection, we have a case, *prima facie* sufficient, of negligence contributing to the result." *Martin v. Herzog,* 126 N.E. 814, 816 (N.Y. 1920).

23 327 U.S. 251 (1946).

the proof of defendants' wrongful acts and their tendency to injure plaintiffs' business . . . that defendants' wrongful acts had caused damage to the plaintiffs."[24]

The Second Circuit's price-fixing decision in *In re Publication Paper Antitrust Litig.*,[25] is especially instructive due to the parallels between price fixing and exclusion-payment agreements. Courts condemn price fixing because of the likelihood that, without the unlawfully agreed price, the price would have been lower; courts condemn exclusion-payment agreements because of the likelihood that, without the exclusion payment, the generic entry date would have been earlier.[26]

Publication Paper reversed a grant of summary judgment to defendants on the issue of causation. The liability evidence was sufficient for a jury to conclude that two competitors in an oligopolistic market agreed to follow a price increase announced by the other. Applying the Causation Inference adopted from tort law, the Court of Appeals held that this evidence also sufficed to get plaintiffs to the jury on whether the unlawful agreement, in fact, caused prices to be higher than they otherwise would have been: "Our analysis is enriched and refined by study of causation principles as developed in the tort law context. . . . [I]f an act is deemed wrongful because it is believed significantly to increase the risk of a particular injury, we are entitled—in the tort context at least—to presume that such an injury, if it occurred, was caused by the act."[27] As applied in the antitrust case, price-fixing agreements are unlawful "precisely because" they "are so likely to result in artificially higher prices being charged to consumers. . . . "[28] Consequently, evidence of the price-fixing agreement "constitutes strong evidence" that the agreement likely caused plaintiffs to pay higher prices than they would have in its absence.[29]

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24 *Id.* at 264; *see also J. Truett Payne Co. v. Chrysler Motors Corp.*, 451 U.S. 557, 565 (1981) (quoting *Bigelow*); *Story Parchment Co.*, 282 U.S. at 566 (jury is entitled to conclude "that the natural and probable effect of the combination and price cutting would be to destroy normal prices"). Especially in antitrust cases, the Causation Inference is supported by policy as well as logic. "The most elementary conceptions of justice and public policy require that the wrongdoer shall bear the risk of the uncertainty which his own wrong has created." *Bigelow*, 327 U.S. at 265. Indeed, "no government seriously concerned about the evil of monopoly" would permit an antitrust violator to avoid liability merely by arguing that what would have happened absent its violation is too speculative; rather, "doubts should be resolved against the person whose behavior created the problem." III P. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶651(c) (2d ed. 2005).

25 690 F.3d 51 (2d Cir. 2012).

26 Plaintiffs in antitrust cases—at least in good antitrust cases—will very often be entitled to the inference of causation that arises when a plaintiff has suffered the type of injury whose tendency to occur makes the defendant's conduct unlawful. That is the *only* type of injury for which an antitrust plaintiff may properly sue. The "antitrust injury" requirement, which is distinct from the causation requirement, provides that plaintiff must show that the injury for which it seeks recovery is "the type that the antitrust laws were intended to prevent and that flows from that which makes the defendants' acts unlawful." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.,* 429 U.S. 477, 489 (1977).

27 690 F.3d at 66.

28 *Id. at 67.*

29 *Id.*

Courts have routinely applied the same principle in pharmaceutical antitrust cases. In *In re Neurontin Mktg. & Sales Practices Litig,*[30] plaintiff Kaiser alleged that Pfizer had fraudulently marketed Neurontin for off-label uses, causing Kaiser to pay more for Neurontin than it otherwise would have.[31] The Court of Appeals for the First Circuit held that, regardless of any inadequacies in plaintiff's regression analyses (which defendant attacked as flawed), the Causation Inference alone supported the jury's verdict. Pfizer devised the fraudulent scheme, it was alleged, specifically to increase Neurontin prescriptions: thus, Kaiser's claimed antitrust injury was the scheme's "foreseeable and natural consequence."[32] Plaintiff satisfied its burden of proof on causation by producing "evidence that he suffered the sort of injury that would be the expected consequence of the defendant's wrongful conduct."[33]

In another Second Circuit case, *In re Actos End-Payor Antitrust Litig.*,[34] plaintiffs alleged that the brand manufacturer unlawfully raised a barrier to generic entry by falsely telling the FDA that the patents claimed the drug product, rather than merely claiming methods of using it. Plaintiffs asserted that falsely describing patents to the FDA is unlawful because it tends to delay generic entry, and that, in fact, generic entry did not occur until the day the entry barrier expired.[35] The Court of Appeals reversed the dismissal of the complaint on causation, ruling that "[a] plaintiff could hardly ask for a clearer causal connection."[36] Plaintiffs' causation allegations were easily sufficient to overcome a motion to dismiss the complaint, and "even at summary judgment, an antitrust plaintiff may be entitled to a presumption of causation where the anticompetitive conduct 'is deemed wrongful because it is believed significantly to increase the risk of a particular injury' and that injury occurred."[37]

The Second Circuit had previously applied the Causation Inference principle in *In re DDAVP Direct Purchaser Antitrust Litig.,*[38] where (a) the brand manufacturer filed a sham Citizen Petition with the FDA—a filing that is unlawful because such petitions tend to delay generic entry—and (b) the FDA, in fact, did not approve any generics for entry until it denied the sham petition. Plaintiffs alleged that (a) caused (b). The court held that the inference that the sham petition "caused a delay in generic competition . . . [is] reinforced by the fact that the FDA approved the generic drug on the same day that it rejected the petition."[39]

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30 712 F.3d 21 (1st Cir. 2013). Although the case involved RICO claims, the court concluded that the RICO proximate cause standard was borrowed directly from the Sherman and Clayton Acts. *Id.* at 35.

31 *Id.* at 28.

32 *Id.* at 37 (quoting *Bridge v. Phoenix Bond & Indem. Co.*, 128 S. Ct. 2131, 2144 (2008)).

33 *Id.* at 45 (quoting *BCS Servs.*, 637 F.3d at 758).

34 848 F.3d 89 (2d Cir. 2017).

35 *Id.* at 100.

36 *Id.*

37 *Id.* at 101 (quoting *Publ'n Paper*, 690 F.3d at 66).

38 585 F.3d 677 (2d Cir. 2009).

39 *Id.* at 694.

Other courts in pharmaceutical antitrust cases have applied the same principle, even when not expressly articulating it. For example, in a pair of appellate cases, the brand manufacturer, HMR, made an exclusion payment to the generic manufacturer, Andrx, to refrain from entering the market "at risk," *i.e.*, while the patent litigation was ongoing and the generic manufacturer was potentially liable for infringing sales. Making such a payment is unlawful because it tends to cause generic manufacturers not to enter the market when they likely would otherwise do so, and Andrx, in exchange for the payment, did, in fact, refrain from entering the market at risk.

Both courts held that these facts created an inference that the payment caused Andrx not to enter the market when it otherwise would have done so. The Court of Appeals for the Sixth Circuit held that, where conduct is unlawful because it tends to delay generic entry, it is "presumed to have the effect of reducing competition in the market for [the brand-name drug] and its generic equivalents to the detriment of consumers," and "a trier of fact may well find that the $89 million payment renders incredible the defendants' claim that Andrx would have refrained from marketing simply because of its fear of infringement damages."[40]

The Court of Appeals for the D.C. Circuit addressed the same anticompetitive agreement, but with a competing generic manufacturer as the plaintiff.[41] Reversing the dismissal of the complaint on causation, the court noted that exclusion payments are anticompetitive because they tend to delay generic entry, and that, as unlawfully agreed, Andrx, in fact, did not enter the market. The causation determination was reduced to a simple calculus: "One can fairly infer from these facts . . . that but for the Agreement, Andrx would have entered the market."[42] The natural inference is that the agreement caused the type of injury whose likelihood of occurring rendered the agreement unlawful: to deny an inference of causation would "contradict[] the very premise of the [unlawful exclusion-payment] Agreement," under which the generic is paid "not to enter the market."[43]

IV. WHY THE CAUSATION INFERENCE MATTERS

As a matter of litigation strategy, antitrust plaintiffs will almost never rely solely on the Causation Inference to satisfy their *prima facie* burden on causation. In exclusion-payment cases, for example, plaintiffs will also proffer evidence that, absent the unlawful agreement, the generic manufacturer would have entered the market at risk,[44] and that both patent litigants would have preferred settling the patent case with earlier generic

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40 *In re Cardizem CD Antitrust Litig.,* 332 F.3d 896, 911 (6th Cir. 2003).

41 *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001). Andrx was the first generic manufacturer to file an ANDA with a Paragraph IV certification, and so was entitled to 180 days of exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv). Its acceptance of an exclusion payment to refrain from entering the market, therefore, prevented other generic manufacturers, including plaintiff in the *Biovail* case, from entering the market.

42 256 F.3d at 809.

43 *Id.* at 806*; see also id.* at 811 ("Andrx's argument that any rational actor would wait for resolution of the patent infringement suit [before entering the market] is belied by the quid of HMRI's quo.").

44 For example: evidence that the generic manufacturer, in anticipation of marketing at risk, had manufactured substantial quantities of the product or solicited orders from customers.

entry rather than litigating,[45] or that, if the parties litigated rather than settled, the generic manufacturer would have won.[46]

But proving, specifically, what would have happened but-for defendant's conduct is difficult. For two interrelated reasons, therefore, it remains vitally important that courts continue to apply the rule that the Causation Inference satisfies plaintiff's *prima facie* burden.

First, applying the Causation Inference shifts the burden to defendant to overcome the inference—to prove, in the exclusion-payment example, that the generic manufacturer would *not* have entered at risk, that the parties would *not* have settled with an earlier entry date, and that the generic manufacturer would *not* have won the patent case. Second, while plaintiff retains the burden of proof on *damages*, on that issue plaintiff benefits from wide latitude and a forgiving standard to reconstruct the but-for world.

A. The Burden Shifts to Defendant to Overcome the Inference

The general rule is that an antitrust plaintiff need only produce a preponderance of evidence that defendant's unlawful conduct materially contributed to the injury; that this burden does not include disproving alternative, allegedly intervening causes; and that the burden then shifts to defendant to prove alternative causes. Once plaintiff shows that the violation was a material cause of the injury, "the defendant must then offer evidence that other forces caused the plaintiff's harm."[47] This follows from the Supreme Court's

45 For example: economic models showing that both litigants would have been better off settling the patent litigation without an exclusion payment and earlier generic entry, at given probabilities of success in the patent litigation, than litigating the case to conclusion.

46 For example: expert testimony from seasoned patent litigators.

47 P. Areeda, H. Hovenkamp, R. Blair & C. Currance, IIA Antitrust Law, ¶ 338a, at 99 (3d ed. 2007).

longstanding rule that "a plaintiff need not exhaust all possible alternative sources of injury in fulfilling [its] burden of proving compensable injury."[48]

This same rule applies when the plaintiff carries her initial burden by relying on the Causation Inference—by showing that she suffered the type of injury whose propensity to occur rendered the defendant's conduct unlawful. Once the Causation Inference arises in favor of plaintiff, the burden of proof shifts to defendant to overcome the inference by convincing the jury that some other event or circumstance would have resulted in the same injury to plaintiff.

Courts so hold in tort and antitrust cases. For example, in the meat grinder tort case discussed earlier in this article, the defendant argued that plaintiff failed to prove that he would have used the machine differently if it had a proper warning label. The court sharply rejected that argument, explaining that it

48 *Zenith Radio Corp.,* 395 U.S. at 114 n.9; *see also Zenith Radio: Callahan v. A.E.V.*, 182 F.3d 237, 257 (3d Cir. 1999) ("Although we recognized that these [alternative] explanations might ultimately prove to be correct, we found that they were issues of fact best left to the jury, not reasons for concluding that the Rockhill Report was insufficient evidence of causation as a matter of law."); *Irvin Indus., Inc. v. Goodyear Aerospace Corp.,* 974 F.2d 241, 245 (2d Cir. 1992) (defendant's alternative plausible cause "cannot in and of itself negate causation as a matter of law"); *Morgan v. Ponder*, 892 F.2d 1355, 1363 (8th Cir. 1989) (although "[o]ther theories might more easily explain what forced plaintiffs out of the newspaper business . . . [w]e need not determine the exact cause. . . Nor must plaintiffs systematically eliminate all possible non-predatory causes."); *Dolphin Tours, Inc. v. Pacifico Creative Service, Inc.*, 773 F.2d 1506, 1509–10 (9th Cir. 1985) (defendant's arguments about alternative causes concern only damages, not causation); *Danny Kresky Enterprises Corp. v. Magid*, 716 F.2d 206, 209, 212 (3d Cir. 1983) (where defendant conspired with artists for concert promotion, excluded plaintiff that lost profits was not required to disprove other possible causes of the loss); *Litton Systems, Inc. v. American Tel. & Tel. Co.*, 700 F.2d 785, 823 n.49 (2d Cir. 1983) (rejecting defendant's argument that plaintiff needed to "prove a negative"—that plaintiff's injuries were not the result of other companies' opposition to certification standards that would have allowed plaintiff to compete); *Bohack Corp. v. Iowa Beef Processor*, 715 F.2d 703, 711 (2d Cir. 1982) (plaintiff must establish by a preponderance of evidence that the antitrust violation was a material cause of its injury, but need not disprove alternative causes); *Rea v. Ford Motor Co.*, 497 F.2d 577, 591–92 (3d Cir. 1974) (where plaintiff provided sufficient proof of injury resulting from Ford's price-fixing agreement, plaintiff was not required to prove that it would have purchased new cars for a different price absent the agreement); *Fontana Aviation, Inc. v. Beech Aircraft Corp.*, 432 F.2d 1080, 1087 (7th Cir. 1970) (plaintiff need not "exhaust every possible avenue to avoid the effects of defendant's alleged illegal activity but could maintain an action for an injury which flows naturally and expectedly from such activity"); *Hasbrouck v. Texaco, Inc.*, 842 F.2d 1034, 1042 (9th Cir. 1987) ("While a defendant may introduce evidence of alternative causes of the injury, such evidence constitutes only a part of the information the jury may consider in determining whether price discrimination was or was not a material cause.").

> "rests on a false premise. It assumes that the burden was on [the plaintiff] to introduce additional evidence showing that the failure to warn was a but-for cause of his injury . . . but [the plaintiff] does not bear that burden. When a defendant's negligent act is deemed wrongful precisely because it has a strong propensity to cause the type of injury that ensued, that very causal tendency is evidence enough to establish a *prima facie* case of cause-in-fact. The burden then shifts to the defendant to come forward with evidence that its negligence was not such a but-for cause. . . . The law presumes normality and requires the defendant to adduce evidence that the case is an exception."[49]

Similarly, in the *BCS Services* bid-rigging case discussed earlier, Judge Posner rejected the district court's conclusion that conduct other than the defendants' fraud, such as the auctioneer's perception of the bids and the plaintiffs' own lack of speed, may have caused them to lose the bids.[50] Plaintiffs were not required to prove the "nonexistence of potential superseding causes"; rather, the court held, once the Causation Inference arises "the burden of proving an 'intervening cause' . . . is on the defendant."[51] In contending otherwise, Judge Posner declared, "the defendants were throwing sand in the district judge's eyes."[52]

Similarly, in the *Publication Paper* price-fixing case, defendants argued that, even absent the unlawful agreement, one of the conspirators had already *independently* decided that it would match any price increase that the other initiated. The court concluded that "[a]lthough defendants' argument has some force, and might well persuade a jury," it could not justify summary judgment.[53] Once the plaintiff establishes the Causation Inference, the court concluded, "the burden then shifts to the defendant 'to bring in evidence tending to rebut the strong inference, arising from the [injury], that the [act] was in fact a but-for cause of the plaintiff's injury.'"[54]

In the *Actos* pharmaceutical antitrust case, the Court of Appeals for the Second Circuit likewise concluded that, after the Causation Inference arises, the burden shifts to the defendant to rebut it. There the district court had dismissed the complaint because plaintiffs had "failed to rule out a litany of alternative possible causes of Teva's delayed market entry."[55] Teva's timely entry might have been prevented by its losing the patent litigation; by a pending Citizens Petition; or by failure to get FDA approval.[56] The Court of Appeals reversed because plaintiffs had alleged that they suffered the type of

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49 *Liriano v. Hobart Corp.,* 170 F.3d at 271.

50 *BCS Servs.,* 637 F.3d at 757–58.

51 *Id.* at 757.

52 *Id.* at 758.

53 *Publication Paper,* 690 F.3d at 67.

54 Id. (quoting *Liriano*, 170 F.3d at 271); *see generally Story Parchment Co.*, 282 U.S. at 566 (defense contentions regarding intervening or alternate cause should be left "for the jury to be determined as a fact").

55 *In re Actos,* 848 F.3d at 100.

56 *Id.* at 100-01.

injury whose likelihood of occurring made defendant's conduct unlawful. Whether on a motion to dismiss, on summary judgment, or at trial, once plaintiffs make that showing "then it would be *Takeda's* [defendant's] burden to show that some other factors, such as the ones identified above, are the 'true' cause of the delay, and, therefore, the 'true' cause of the artificially high drug prices plaintiffs paid."[57]

The *Actos* decision echoed that of the First Circuit in *Neurontin Mktg. & Sales Practices*. In *Neurontin*, the First Circuit succinctly held that, once the Causation Inference arises, "the burden shifts to the defendant to rebut this causal inference" and plaintiffs "need not prove a series of negatives."[58]

One recent case, *In re Wellbutrin XL Antitrust Litig.,*[59] considered causation where the brand manufacturer, GSK, made an exclusion payment to Anchen to secure its delayed entry. Atypically for exclusion-payment cases, however, a patent held by a third party, Andrx (whom GSK did not pay), may have prevented Anchen's entry in any event. In these unique circumstances, the Court of Appeals affirmed summary judgment against plaintiffs, holding that they never adduced *prima facie* evidence of causation and, therefore, the burden of proof never shifted to GSK as to whether the Andrx patent was an intervening cause.[60] The court did not discuss the Causation Inference, or its implications for shifting the burden of proof on intervening causes, because the plaintiffs there never asserted the Causation Inference.[61]

If the *Wellbutrin XL* court had considered the Causation Inference, it might well have concluded that such an inference had not arisen, because the court apparently did not believe that the exclusion payment was anticompetitive. The court concluded that,

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57 *Id.* at 101 (emphasis in original).

58 712 F.3d at 45; *see also In re Aggrenox Antitrust Litig.*, No. 14-md-2516, 2015 WL 4459607, *10 (D. Conn. 2015) ("The defendants can certainly defend themselves in this case by arguing that generic entry for one reason or another would have been impossible at any particular time even in the absence of the agreement."). That defendant has the burden to prove alternative causes has a number of subsidiary procedural consequences. For example, on a motion to dismiss the complaint, an antitrust plaintiff need not plead the absence of alternative possible causes of the delayed generic entry. *See, e.g., In re Skelaxin (Metaxalone) Antitrust Litig.,* No. 12-md- 2343, 2013 WL 2181185, at *16 (E.D. Tenn. May 20, 2013)*; In re Neurontin Antitrust Litig.,* MDL No. 1479, 2009 WL 2751029, at *12 (D.N.J. Aug. 28, 2009); *In re Wellbutrin SR/Zyban Antitrust Litig.,* 281 F. Supp. 2d 751, 757 (E.D. Pa. 2003).

59 868 F.3d 132 (3d Cir. 2017).

60 *Id.* at 166.

61 Plaintiffs alluded to the Causation Inference on appeal only by way of a notice of supplemental authority (the Second Circuit's *Actos* decision) under Fed. R. App. P. 28(j). *See In re: Wellbutrin XL Antitrust Litigation:* Nos. 15-3559, 15-3591, 15-3681 & 15-3682, Document No. 003112535892 filed February 9, 2017 (3d Cir.).

Plaintiffs argued that, under the usual rules related to "supervening causes," GSK had the burden of proving that the Andrx patent would have blocked Anchen's entry. But the burden would have shifted to GSK only if plaintiffs had first made a *prima facie* case on causation. Plaintiffs did not argue the Causation Inference or that it satisfied their initial burden. They adduced much *other* evidence to meet their initial burden, but the Court of Appeals discounted all of it. 868 F.3d at 166-68. Whether the court *properly* discounted that other evidence is not this article's subject; what matters here is that the plaintiffs did not argue for the Causation Inference and the court did not address it.

where the potentially blocking patent is held by a third party, courts have little reason to believe that the brand manufacturer's payment reflects its belief that the patent is weak, *i.e.*, little reason to believe *that the payment is anticompetitive*.[62] And the court accepted an argument from an *amicus curiae* brief that payments *are not anticompetitive* because brand manufacturers might be risk averse.[63]

Ignoring the unique facts of *Wellbutrin XL*—that the blocking patent was held by a third party rather than the brand manufacturer that made the exclusion payment—some defense counsel have argued that the case supports the proposition that, in order to prove causation, plaintiffs in exclusion-payment cases must prove that *the brand manufacturer's patent* was invalid or not infringed.[64] As applied to exclusion payments where the brand manufacturer itself holds the blocking patent, however, *Actavis* precludes the arguments that *Wellbutrin XL* accepted. *Actavis* held that large payments do reflect the brand manufacturer's view that its patent is weak, and the Supreme Court thus necessarily rejected the "risk aversion" hypothesis.[65]

More broadly, *Actavis* held that large and unexplained payments are unlawful because they tend to result in generic entry later than the expected, *i.e.*, probability-adjusted,

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62 868 F.3d at 168.

63 *Id.* at 168-69.

64 *See, e.g.,* David Kully & Charles Weiss, *Recent Cases Provide Hope for Reverse-Payment Defendants,* Law 360 Competition (Sept. 21, 2017).

65 *Actavis* concluded that the existence of an exclusion payment is "a workable surrogate for a patent's weakness." 133 S. Ct. at 2236. The necessary predicate for that conclusion is that brand manufacturers are not risk averse—if the Court believed that manufacturers, generally, were risk averse it could not have concluded that a payment is a surrogate for patent weakness because the payment might instead result from risk aversion. The Court rejected the risk-aversion premise despite its having been vigorously argued by the defendant (Brief for Respondent Solvay Pharms., Inc., No. 12-416 (S. Ct.), at 33, filed Feb. 21, 2013), and various amici (*e.g.*, Brief of Antitrust Economists as Amici Curiae In Support of Respondents, No. 12-416 (S. Ct.), at 19-21, filed Feb. 28, 2013; Brief for Shire PLC as *Amicus Curiae* Supporting Respondents, No. 12-416 (S. Ct.), at 11, filed Feb. 28, 2013) and accepted by the dissent (*e.g.*, 133 S. Ct. at 2244 (Roberts, C.J., dissenting)). Even the argument's proponents admit that the Supreme Court "consider[ed] the possible implications of risk aversion" and "brushed the concern aside." Addanki & H. Butler, *Activating Actavis: Economic Issues in Applying the Rule of Reason to Reverse Payment Settlements,* 15 Minn. J.L. Sci. & Tech. 77, 83 n.37 (2014). On the merits, the risk-aversion hypothesis, in the context of exclusion payments, makes little theoretical or economic sense. Some individual persons are risk-averse, "preferring a sure thing to uncertain levels of consumption." Paul A. Samuelson & William D. Nordhaus, Economics 193 (16th ed. 1998). But publicly traded corporations avoid risk-aversion because stock ownership is a "form of risk sharing," which allows "the financial ownership of physical capital [to] be spread among many owners." *Id.* at 194. Nor does standard economics assume that individual managers usurp corporate risk neutrality. "Various forces keep managers from deviating from profit-maximizing behavior." Dennis W. Carlton & Jeffrey M. Perloff, Modern Industrial Organization 13 (4th ed. 2005). These include "[i]ncentives, such as stock ownership and other bonuses," not to mention the threat of being "fired for inefficiency." *Id.* Accordingly, in standard economics "[c]orporations are generally assumed to be risk neutral since any riskiness involved in the corporation's business can be eliminated by the shareholders, each of whom can combine his shares in the corporation with other shares . . . to create a portfolio that will be as risky or as risk free as he desires." Richard A. Posner, Antitrust Law 269 n.2 (2d ed. 1976). The standard economic assumption of corporate risk-neutrality applies when evaluating exclusion payments. *See, e.g.*, Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 Tex. L. Rev. 283, 312 (2012); Jeremy Bulow, *The Gaming of Pharmaceutical Patents*, in Innovation Policy and the Economy 145, 162 (2004).

entry date.[66] The *Actavis* Court's realistic view of patents is that the rights they grant are probabilistic—a patent's actual ability to preclude competition depends on all of the evidence in the patent case, all of the relevant patent law, the interaction of that evidence and law with the Hatch-Waxman Act, etc.[67] Defense arguments that plaintiffs cannot prove causation without proving invalidity/non-infringement, whether the patent is held by the brand manufacturer or a third party, are founded on a radically different, formalistic view of patents (they're either valid/infringed or not) that *Actavis* rejected.[68] It is true that *Actavis* considered only whether exclusion payments are unlawful, and did not consider causation, but courts considering the causation element should not use a formalistic view of patents that the Supreme Court rejected.

More specifically, to gain entry into the market before patent expiry the generic manufacturer need not prove the patent invalid or not infringed. The generic can instead use the threat of a finding of invalidity or non-infringement to negotiate an early-entry license. Therefore, after-the-fact proof of patent invalidity/non-infringement would not suffice to prove an intervening cause in the antitrust case, because the generic manufacturer need not have proved invalidity/infringement in order to have entered the market earlier.[69]

Let me end the discussion with what is important here: *Wellbutrin XL* did not address the Causation Inference. The causation issues it did address arose in the unique circumstance where the potentially-blocking patent was held by a third party, not the brand manufacturer who made the large and unjustified payment.

B. Plaintiffs Benefit From Leniency on Damage Evidence

The Causation Inference satisfies plaintiff's *prima facie* case for causation, so plaintiffs will be adducing evidence of the but-for world principally in order to prove damages. In an exclusion-payment case, for example, plaintiffs might offer evidence that the generic manufacturer would have entered the market at risk, that the patent litigants

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66 133 S. Ct. at 2233.

67 *Id.* at 2231 ("[t]he patent here may or may not be valid, and may or may not be infringed," and "[t]he paragraph IV litigation in this case put the patent's validity at issue, as well as its actual preclusive scope").

68 In *In re Nexium Antitrust Litig.,* 842 F.3d 34, 63 (1st Cir. 2016), the defendants produced evidence "that AstraZeneca's patents, not its reverse payment to Ranbaxy, were the bar to a generic launch." In those circumstances, the court required plaintiffs to produce "some evidence" of the patent's invalidity in order to reach the jury on whether the generic manufacturer would have marketed the product at risk. *Id.* Neither the district court nor the Court of Appeals required plaintiffs to produce any such evidence in order to pursue the causation theory that the generic manufacturer would have used the threat of invalidity/noninfringement to get a license for earlier entry. Moreover, the court did not address the Causation Inference, what evidence satisfies plaintiff's initial burden of proof, whether or when the burden shifts, the quantum of evidence required, or any other details that would illuminate its views, if any, on the Causation Inference.

69 Consider a false-imprisonment tort case where a court found that defendant improperly prevented plaintiff from exiting a room that had two doors—Door A and Door B. We would scratch our heads in wonder at a defendant who insisted that plaintiff could prove causation only by showing that she would have exited through Door A rather than Door B. Defense arguments that proof of validity/infringement breaks the causal chain—where the generic could instead have entered earlier by negotiating an earlier-entry license—are no less head-scratch-inducing.

would have negotiated an earlier generic-entry date, or that the generic manufacturer would have won the patent litigation (or some or all of these three possible earlier-entry scenarios). Plaintiffs will offer this evidence in order to prove *how much earlier* generic entry would have occurred in the but-for world, and, therefore, how large the damages are. This evidence also responds to defendants' attempts to carry their burden of proof on alternative causes, but plaintiffs use it *affirmatively* on the issue of damages.

Plaintiffs' proffered damage evidence is sheltered by the well-established rule that courts cannot insist on unduly rigorous proof of the quantum of damage. "[T]he wrongdoer may not object to the plaintiff's reasonable estimate of the cause of injury and its amount, supported by the evidence, because [the estimate] is not based on more accurate data which the wrongdoer's misconduct has rendered unavailable."[70] The "traditional rule excus[es] antitrust plaintiffs from an unduly rigorous standard of proving" damages.[71]

The Supreme Court has indicated that this protective standard applies to plaintiff's evidence of both causation and damages.[72] Some lower courts have, nevertheless, asserted that the forgiving standard applies only to damages, not causation,[73] while others

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70 *Bigelow,* 327 U.S. at 265 (internal citation omitted)*; see also In re Neurontin Mktg. & Sales Practices Litig.,* 712 F.3d at 49-50 ("[T]he factfinder is afforded a greater deal of freedom to estimate damages where the defendant, as here, has created the risk of uncertainty.").

71 *J. Truett Payne Co.*, 451 U.S. at 565.

72 *Bigelow,* 327 U.S. at 265 (protective standard applies to "the cause of injury and its amount"). Several courts follow *Bigelow* in this regard. *See, e.g., DDAVP Direct Purchaser Antitrust Litig.,* 585 F.3d at 689 (applying *Bigelow* to the question of "speculativeness," a subtest within the antitrust standing inquiry that considers the quality of evidence linking the defendant's conduct to the injury); *Schwartz v. Sun Co.,* 276 F.2d 900, 904 (6th Cir. 2002) (quoting *Bigelow* to show that "[i]t is wellestablished that proving antitrust injury should not be unduly rigorous"); *Stelwagon Mfg. Co. v. Tarmac Roofing Sys.,* 63 F.3d 1267, 1273 (3d Cir. 1995) (quoting *Bigelow* to show that "a plaintiff must prove a causal connection . . . Traditionally, however, antitrust plaintiffs have not been held to an unduly rigorous standard of proving antitrust injury" (internal citation omitted)); *Danny Kresky Enterprises Corp. v. Magid,* 716 F.2d 206, 212 (3d Cir. 1983) (rejecting district court's addition of a causation requirement that the plaintiff be entitled to only damages that were "certain" to be "directly flow[ing]" from defendant's unlawful conduct and quoting *Bigelow* to discredit that idea); *In re E.J. Delaney Corp. v. Bonne Bell, Inc.,* 525 F.2d 296, 303–05 (10th Cir. 1975) (*Bigelow* establishes "liberal rules . . . relating to the evidence requisite to establish a cause for anti-trust damage award"); *Haverhill Gazette Co. v. Union Leader Corp.,* 333 F.2d 798, 806–07 (1st Cir. 1964) (rejecting lower court's conclusion that the difficulties of proof needed to be the result of the defendant's unlawful acts in order to lessen plaintiff's burden on proof of causation); *Momand v. Universal Film Exchanges, Inc.,* 172 F.2d 37, 42 (1st Cir. 1948) (*Bigelow* determines "the degree of certainty required of a plaintiff in proving causation of damage").

73 *See, e.g., MCI Communications Corp. v. American Tel. & Tel. Co.,* 708 F.2d 1081, 1161 (7th Cir. 1983) (asserting that *Bigelow's* holding concerned only "proof of the *amount* of damages," not "proof of causation of damages"); *Moore v. Boating Indus. Assocs.,* 754 F.2d 698, 718 (7th Cir. 1985) (asserting that *Bigelow's* lenient standard applies only after plaintiff establishes causation); *National Farmers' Org., Inc. v. Associated Milk Producers, Inc.,* 850 F.2d 1286, 1293 (8th Cir. 1988) (asserting that *Bigelow* lowers the standard for proving only the amount of damage).

have hedged.[74] Until the courts clarify that the lenient standard applies to both causation and damages, it is especially important that courts treat leniently plaintiff's evidence of the but-for world, to the extent that it relates to damages.

V. CONCLUSION

Causation issues will play an increasingly important role in private pharmaceutical antitrust cases. Courts should continue to apply the longstanding principle that plaintiffs make a *prima facie* case on causation by proving that they suffered the type of injury whose likelihood of occurring prompted courts to conclude that defendant's conduct was anticompetitive. The burden then shifts to defendant to prove that an intervening cause—*e.g.*, that the generic manufacturer would not have obtained timely FDA approval, would have lost the patent litigation, or would not have obtained a license for earlier entry—broke the causation chain. When plaintiffs offer a reconstruction of the but-for world in order to both rebut the defendant's intervening causes and prove damages, they benefit from a lenient evidentiary burden with respect to the latter, and do not have the burden of proof as to the former.

74 *See, e.g., United States Football League v. National Football League,* 842 F.2d 1335, 1378 (2d Cir. 1988) (the "latitude [afforded to antitrust plaintiffs as to proof of damages] is thus circumscribed by the need for proof of causation"); *Flintkote Co. v. Lysfjord,* 246 F.2d 368, 392 (9th Cir. 1957) (asserting that there is a "distinction between the quantum of proof necessary to show the fact as distinguished from the amount of damage; the burden as to the former is the more stringent one").

ANTITRUST'S HIDDEN HOOK IN DRUG PRICE INCREASES

By Michael A. Carrier[1]

High drug prices have recently been in the news. The media, public, and politicians have lamented significant price increases. At the same time, such developments have been met with explanations that antitrust cannot address price hikes. Critics contend that U.S. courts do not regulate price and that antitrust law is ill-equipped to referee these disputes.

But what if antitrust could address price hikes? What if the price increases were a result of anticompetitive conduct? In that case, antitrust could play a role, addressing the anticompetitive behavior that resulted in high prices. This article focuses on two price hikes that received significant attention, showing how conduct such as settlements, government petitions, exclusive dealing, and restricted distribution systems contributed to the increases.[2]

The article first introduces Daraprim, which witnessed a 5000-percent price increase shortly after its distribution system was significantly restricted. It then analyzes the EpiPen, which underwent sustained price increases at the same time the company engaged in a patent settlement, citizen petition, and exclusive dealing.

I. DARAPRIM: RESTRICTED DISTRIBUTION SYSTEM

Daraprim received attention for its 5000-percent price increase but not for its restricted distribution system. This section shows how the adoption of this system could constitute monopolization, with the two elements of monopoly power and exclusionary conduct satisfied.

A. Background

Notorious pharmaceutical entrepreneur Martin Shkreli made worldwide headlines in 2015. As CEO of Turing Pharmaceuticals, Shkreli obtained U.S. marketing rights to pyrimethamine (Daraprim) and quickly increased the price 5000 percent, from $13.50 to $750 per pill.[3] Pyrimethamine is a decades-old drug used primarily to treat toxoplasmosis, a fatal parasitic brain infection that usually occurs in patients with weakened immune systems, such as those with end-stage HIV infection.[4]

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1 Distinguished Professor, Rutgers Law School. Parts of this article are adapted from Michael A. Carrier, Nicole Levidow & Aaron S. Kesselheim, *Using Antitrust Law to Challenge Turing's Daraprim Price Increase*, 31 BERK. TECH. L. J. 1379 (2017) and Michael A. Carrier & Carl J. Minniti III, *The Untold EpiPen Story: How Mylan Hiked Prices by Blocking Rivals*, 102 CORNELL L. REV. ONLINE 53 (2017).

2 Antitrust also plays a role when price remains elevated longer than it should, for example, when a brand pays a generic to settle patent litigation and delay entering the market. *See, e.g.*, FTC v. Actavis, 133 S. Ct. 2223 (2013).

3 Andrew Pollack, *Drug Goes From $13.50 a Tablet to $750, Overnight*, N.Y. Times, Sept. 21, 2015, at B1.

4 Sara Fazio, *Toxoplasmosis*, NEW ENG. J. MED. BLOG (Feb. 23, 2012), http://blogs.nejm.org/now/index.php/toxoplasmosis/2012/02/23/.

Turing's price hike was met with widespread outrage among the public and in the medical and public health communities, with the episode leading to censure by other drug companies, congressional hearings seeking ways to address the problem, and policy proposals from presidential candidates. Despite the fact that there were no patents or other forms of market exclusivity protecting the drug, Turing was able to raise the price because the relatively small market in the United States for pyrimethamine had attracted no other generic manufacturers. Indeed, Shkreli later lamented that he did not raise the price even higher.[5]

In addition to increasing price, Turing initiated another less widely understood move—it changed the distribution scheme for the drug. Before its acquisition by Turing, pyrimethamine was available without restriction to patients seeking to fill prescriptions at local pharmacies and to hospitals seeking to stock the product for inpatient use. But in the months before the price hike, apparently as a condition of the sale to Turing, pyrimethamine was switched to a controlled distribution system called Daraprim Direct, in which prescriptions or supplies of the product could be obtained only from a single source: Walgreen's Specialty Pharmacy.[6] As a result, hospitals could no longer obtain the drug from a general wholesaler, and patients could no longer find it at a local pharmacy.

Instead, Turing required institutions and individuals to set up accounts through Daraprim Direct, and outpatients were only able to receive the drug by mail order.[7] Comments from Turing executives suggested that a primary goal of the Daraprim Direct system was to make it impossible for anyone other than registered clients to obtain the drug, including generic manufacturers wishing to obtain samples for use in bioequivalence studies needed to obtain Food and Drug Administration (FDA) approval. This behavior could demonstrate monopolization, with the next two sections analyzing evidence of monopoly power and exclusionary conduct.

B. Monopoly Power

Monopoly power has been defined as "the power to control prices or exclude competition."[8] It can be shown in one of two ways, each of which appeared to be satisfied in the case of Daraprim. First, monopoly power can be proved indirectly by examining a defendant's market share along with barriers to entry that could entrench that market position.[9] Courts regularly hold that a 90 percent market share supports market power, with several courts finding a 75 percent share to be sufficient.[10]

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5 Kate Gibson, *Martin Shkreli: "I Should've Raised Prices Higher,"* CBS News (Dec. 4, 2015), http://www.cbsnews.com/news/martin-shkreli-i-shouldve-raised-prices-higher/.

6 Andrew Pollack & Julie Creswell, *The Mercurial Man Behind the Drug Price Increase that Went Viral*, N.Y. Times, Sept. 23, 2015, at B1.

7 Monica V. Mahoney, *New Pyrimethamine Dispensing Program: What Pharmacists Should Know*, Pharm. Times (July 17, 2015), http://www.pharmacytimes.com/contributor/monica-v-golik-mahoney-pharmd-bcps-aq-id/2015/07/new-pyrimethane-disprogram-what-pharmacists-should-know.

8 United States v. E.I. duPont de Nemours & Co., 351 U.S. 377, 391 (1956).

9 Herbert Hovenkamp, Federal Antitrust Policy: The Law of Competition and its Practice ¶ 6.2b, at 359-60 (5th ed. 2016).

10 *Id.* ¶ 6.2a, at 357.

Evidence that Turing has 100 percent of the relevant market is provided by the lack of effective, FDA-approved substitutes. Pyrimethamine is part of all widely accepted first-line therapeutic regimens for toxoplasmosis.[11] In fact, the American Society of Microbiology warned that the 5000 percent price increase would "negatively impact both healthcare costs and individual patient treatments."[12] Regulatory barriers to entry cement the effect of this high market share as generics can enter the U.S. market only after receiving FDA approval.

Second, monopoly power can be proved directly,[13] such as through observable effects on the market, for example, a price increase or output reduction.[14] Turing's conduct has revealed both types of direct evidence.

To begin, Turing significantly increased price. Even though there was not an increase in the costs of producing pyrimethamine (which costs pennies per pill to manufacture[15]), Turing increased the price 5000 percent. In addition, it was able to maintain this increase despite public outrage and substantial attention from the press and politicians.[16] Given the barriers to entry imposed by obtaining FDA review, the high prices likely will be maintained for an extended period of time.[17]

Documents provided to a congressional committee offer examples of price increases including patient copays in the thousands of dollars. Just to pick one example, one presentation reported that "[p]atients with commercial/private insurance [are] experiencing increased co-pays, delays in claims approval[,] and rejections," with one facing a copay of $16,830.[18]

Output reductions are another direct indicator of monopoly power. After pyrimethamine's price increase, hospitals complained that they were not able to obtain

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11 Sara Fazio, *Toxoplasmosis*, New Eng. J. Med. Blog (Feb. 23, 2012), http://blogs.nejm.org//index.php/toxoplasmosis/2012/02/23/.

12 Memorandum from the Democratic Staff to Democratic Members of the Full House Comm. on Oversight and Gov't Relations, at 5 (Feb. 2, 2016), https://democrats-oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/Memo%20on%20Turing%20Documents.pdf.

13 ABA Section of Antitrust Law, Antitrust Law Developments 69–70 (7th ed. 2012) (noting that "direct proof has provided the basis for findings of substantial anticompetitive effects in some prominent cases").

14 *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir. 2007).

15 *See* Karthick Arvinth, *Daraprim: Generic Version of Drug Costs Less than £0.07 in India*, International Business Times (Sept. 25, 2015), http://www.ibtimes.co.uk/like-drug-costs-less-0-07-india-1521144.

16 Pollack, *supra* note 2.

17 See, e.g., Star Fuel Marts, LLC v. Sam's E., Inc., 362 F.3d 639, 654 (10th Cir. 2004).

18 Comm. Memorandum, *supra* note 11, at 5.

the drug,[19] with Turing's own press release conceding that hospitals and clinics "were having trouble accessing the product."[20]

In short, Turing appears to have monopoly power in engineering and maintaining a 5000 percent price increase, preventing hospitals from obtaining pyrimethamine, and ensuring the absence of FDA-approved substitutes for the drug.

C. Exclusionary Conduct

To bring a successful monopolization claim, a plaintiff must show not only monopoly power but also exclusionary conduct. Courts often distinguish between the "willful acquisition or maintenance of [monopoly] power" and "growth or development as a consequence of a superior product, business acumen, or historic accident."[21] Such a test is easier to state than apply.

In determining whether Turing's refusal to provide samples constitutes exclusionary conduct, consideration of the regulatory background is essential. The Supreme Court in *Verizon Communications v. Trinko*[22] explained that "antitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue."[23] In particular, courts must take "careful account" of "the pervasive federal and state regulation characteristic of the industry," and the analysis must "recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies."[24]

A central objective of the Hatch-Waxman Act is to encourage generic entry.[25] Congress sought to achieve this goal through several mechanisms, including formalizing the expedited pathway and allowing generics to experiment on brand drugs before the end of the patent term.[26] Most relevant for our purposes, the scheme allows generics to earn abbreviated approvals if they can show that their drugs are bioequivalent to the

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19 Letter from Stephen B. Calderwood & Adaora Adimora to Tom Evegan & Kevin Bernier (Sept. 8, 2015), http://www.hivma.org//HIVMA/HomePageContent/PyrimethamineLetterFINAL.pdf.

20 *Press Release: Important News about Daraprim (pyrimethamine)*, Turing Pharmaceuticals (Sept. 18, 2015), http://www.turingpharma.com/media/press-release?=important-news-about-daraprim%25c2%25ae-%28pyrimethamine%29.

21 *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966).

22 540 U.S. 398 (2004).

23 *Id.* at 411.

24 *Id.*

25 See, e.g., Michael A. Carrier, Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality, 108 Mich. L. Rev. 37, 41-43 (2009).

26 *See* 35 U.S.C. § 271(e)(1) (2012); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669-70 (1990) (allowing experimentation before end of patent term would prevent "unintended distortion" of patent laws that would extend "de facto monopoly"); FTC, Generic Drug Entry Prior to Patent Expiration: An FTC Study 5 (2002), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf.

brand's drug.[27] But this crucial element of competition is possible only if the generic has access to the brand firm's samples.[28] Restricted distribution systems threaten this access.

Most prescription drugs are available through a standard pharmaceutical distribution chain: from manufacturer to wholesaler, then to retail or mail-order pharmacy, and then to consumer.[29] The goal is to distribute the drug as widely as possible, as widespread distribution tends to increase manufacturers' revenues by making drugs available to be prescribed to as many people as possible.

Drugs with limited distribution schemes, by contrast, are not available through standard retail or mail-order pharmacies. Instead, the manufacturer eliminates the wholesaler and distributes the drug only through specialty pharmacies selected by the manufacturer. Funneling sales through one wholesaler gives the manufacturer complete control over the distribution chain, which could prevent generics from having the access to samples they need to conduct bioequivalence studies and reach the market.

Restricting the typical expansive distribution scheme also tends to involve conduct that makes no sense, other than stifling generic entry. The no-economic-sense analysis asks whether conduct allegedly maintaining a monopoly by excluding nascent competition "likely would have been profitable if the nascent competition flourished and the monopoly was not maintained."[30] The test focuses on the conduct's "reasonably anticipated impact" (according to "objective economic considerations for a reasonable person") when undertaken rather than its actual impact.[31] Such conduct provides a simple way to determine whether a company's sole motive is to impair competition. If a firm undertakes conduct that makes no economic sense, then its "anticompetitive intent" can be "unambiguously . . . inferred."[32]

In the regulatory context, and considering behavior that does not make business sense, the leading monopolization cases foreshadow liability. For example, in *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*,[33] the owner of three downhill skiing facilities failed to offer a justification for withdrawing from a joint ticketing arrangement with the owner of the only other facility in the area.[34] Just as the Supreme Court found liability

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27 *See* Generic Drug Study, *supra* note 25, at 5; Lauren Battaglia, *Risky Conduct with Risk Mitigation Strategies? The Potential Antitrust Issues Associated with REMS*, Antitrust Health Care Chronicle 26, 28 (Mar. 2013).

28 Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need a Re-designed Approach for the Modern Era?*, 15 Yale J. Health Pol'y L. & Ethics 293, 340-41 (2015).

29 Kaiser Family Foundation, Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain (2005), http://avalere.com/research/docs/Follow_the_Pill.pdf.

30 Gregory J. Werden, *Identifying Exclusionary Conduct Under Section 2: The "No Economic Sense" Test*, 73 Antitrust L.J. 413, 415 (2006). For conduct allegedly creating a monopoly, the test asks "whether the conduct likely would have been profitable if the existing competitors were not excluded and monopoly was not created." *Id.*

31 *Id.* at 416.

32 A. Douglas Melamed, Exclusive Dealing Agreements and Other Exclusionary Conduct—Are There Unifying Principles?, 73 Antitrust L.J. 375, 393 (2006).

33 472 U.S. 585 (1985).

34 *Id.*

where the defendant was "willing to sacrifice short-run benefits and consumer goodwill in exchange for a perceived long-run impact on its smaller rival,"[35] a generic that offers to purchase samples at the full retail price can claim that a brand refuses sales that would have been profitable.

In a second example, *Otter Tail Power Co. v. United States,*[36] the Supreme Court required a company to share electric power transmission with rivals. Similar to the facts in that case, in which the defendant was able to "sell[] power at wholesale to those towns that wanted municipal plants" but refused to sell "solely to prevent municipal power systems from eroding its monopolistic position," the brand in this context already is voluntarily selling the drug but restricting its distribution system so that it would not need to sell to others.[37]

In addition, the concerns the Court raised in *Trinko* are less relevant because the brand already sells at retail (reducing problems with "forced sharing" and differing from the "brand new" service Verizon was required to create) and makes only a one-time sale (limiting judicial involvement).[38] At the same time, Turing's change to the distribution scheme did not resemble the setting in *Trinko*, where "[t]he complaint d[id] not allege that Verizon voluntarily engaged in a course of dealing with its rivals," but instead was similar to that in *Aspen Skiing*, where "[t]he unilateral termination of a voluntary (*and thus presumably profitable*) course of dealing suggested a willingness to forsake short-term profits to achieve an anticompetitive end."[39]

The 2015 switch of pyrimethamine to a restricted distribution scheme as a condition of its sale to Turing threatened to result in fewer sales. Drug manufacturers typically have expansive distribution systems. Absent medical necessity, there is no reason to voluntarily restrict these systems. In this case in particular, there was no apparent rationale for limiting distribution 62 years after the FDA approved pyrimethamine and with no recent safety concerns.

If there were any doubt as to the reason for the change in the distribution system, it was dispelled by Turing itself. Jon Haas, the director of patient access, admitted that he "would block [a] purchase" of pyrimethamine if a generic manufacturer sought to order the pill and conceded that Turing "would like to do our best to avoid generic competition" and was "certainly not going to make it easier" for the generics.[40] Turing's insistence on behavior that lacks rational business sense provides strong evidence of blocking generic rivals. This is a powerful illustration of exclusionary conduct that appears to violate the antitrust laws.

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35 *Id.* at 610-11.

36 410 U.S. 366 (1973).

37 *Id.* at 378.

38 540 U.S. at 408-09.

39 *Id.* at 409.

40 Ed Silverman, *How Martin Shkreli Prevents Generic Versions of his Pricey Pill*, Pharmalot (Oct. 5, 2015), http://pharmalot.com/how-martin-shkreli-prevents-generic-versions-of-his-pricey-pill/.

Nor, finally, are these the only examples of potentially anticompetitive restrictive-distribution systems. Two precursors arose with Shkreli's previous start-up company, Retrophin. In the first case, the company made rare genetic disorder-treating Chenodal available only through a restricted system that allowed it to increase the drug's price from $9,460 to $47,300 per 100 pills[41] and to prevent generics from "access[ing] product for bioequivalence study."[42] In the second, it restricted distribution for cystinuria-treating (predisposing patients to kidney stones) Thiola, which allowed it to raise the price from $1.50 per pill to $30 per pill,[43] recognizing that "[e]xclusivity (closed distribution) creates a barrier and pricing power."[44] In short, Turing's Daraprim-related behavior provides evidence of monopoly power and exclusionary conduct, which could satisfy the requirements of a monopolization case.

II. EpiPen: Settlement, Petition, Exclusive Contracts

Conduct related to the EpiPen also threatens anticompetitive behavior, albeit through a different combination of activity: settlements, citizen petitions, and exclusive contracts.

A. Background

In the summer of 2016, Mylan found itself under fire for high EpiPen prices. Between 2009 and 2016, Mylan raised the price of this life-saving device, which delivers epinephrine to treat anaphylactic shock, 15 times, resulting in an increase of more than 400%.[45] The medicine in an EpiPen costs only pennies per dose.[46] But a pack of two, which needs to be replaced each year and which families buy multiples of for various locations, costs more than $600.[47] The consequences of these prices are felt in all corners,

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41 *Retrophin, Inc. Report*, U.S. Sec. Exch. Comm'n (Apr. 3, 2014), http://ir.retrophin.com/.cfm?filingID=1193805-14-689&CIK=1438533.

42 Derek Lowe, *The Most Unconscionable Drug Price Hike I Have Yet Seen*, In the Pipeline (Sept. 11, 2014), http://blogs.sciencemag.org/pipeline/archives//09/11/__unconscionable_drug_price_hike_i_have_yet_seen.

43 *Id.; see also* Lydia Ramsey, *The CEO Who Jacked up the Price of a Drug by 5,000% Has Done This Before*, Business Insider (Sept. 23, 2015), http://www.business.com/shkreli-history-of-price-hikes-2015-9.

44 Memorandum from the Democratic Staff to Democratic Members of the Full House Comm. on Oversight and Gov't Relations, at 3 (Feb. 2, 2016), https://democratsoversight.house.gov/sites/democrats.oversight.house.gov/files/documents/Memo%20on%C20Turing%20Documents.pdf. *See also* Carrier, Levidow & Kesselheim, *supra* note *, at 1407-08 (discussing Namenda drug at heart of New York Attorney General's product-hopping case, for which manufacturer imposed restricted distribution system for original, but not reformulated, version).

45 Sy Mukherjee, *How Mylan Got Away With Its Enormous Price Hike for the EpiPen*, Fortune, Aug. 22, 2016, http://fortune.com/2016/08/22/mylan-epipen-price-hike-monopoly/; Matt Egan, *How EpiPen Came to Symbolize Corporate Greed*, CNN Money, Aug. 29, 2016, http://money.cnn.com/2016/08/29/investing/epipen-price-rise-history/; Anna Edney & Cynthia Koons, *Mylan Plans Generic EpiPen to Quell Outcry Over $600 Cost*, Bloomberg, Aug. 29, 2016, http://www.bloomberg.com/news/articles/2016-08-29/mylan-to-sell-generic-epipen-to-quell-outcry-over-600-cost.

46 Letter from Jason Chaffetz (R-UT) & Elijah E. Cummings (D-MD) to Heather Bresch, Aug. 29, 2016, http://democrats.oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/2016-08-29%20JC%20and%20EEC%20%20to%20Bresch-Mylan%20EpiPen%20Pricing.pdf (questioning price increase and commencing congressional investigation).

47 *Id.*

as life-threatening allergies from peanuts, shellfish, and other substances affect fifteen million Americans and one in thirteen children.[48]

In the summer and fall of 2016, the uproar over the price increases thundered across the spectrum. Politicians from both parties expressed concern,[49] including through vigorous criticism at a September 2016 hearing.[50] The company was accused of "corporate greed,"[51] with particular ire directed towards CEO Heather Bresch.[52]

Many reasons were offered for the price hike. Some blamed the FDA for a slow-moving generic approval process.[53] Others lamented a broken healthcare system.[54] Bresch indicted a convoluted distribution chain, with multiple parties each taking a portion of the profits.[55]

Little attention was paid, however, to *Mylan's* role in clearing the field of competitors through potentially anticompetitive actions. The next three sections show how Mylan engaged in an expansive and aggressive array of actions that exploited (1) the litigation process through settlement, (2) the administrative process through FDA citizen petitions, and (3) the laws requiring auto-injectors in schools through exclusive contracts.

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48 Mukherjee, *supra* note 44, at 1.

49 Chaffetz & Cummings Letter, *supra* note 45; Letter from Charles E. Grassley (R-IA) to Heather Bresch, Aug. 22, 2016, http://www.grassley.senate.gov/sites/default/files/constituents/upload/2016-08-22%20CEG%20to%20Mylan%20(EpiPen).pdf.

50 Full House Comm. on Oversight & Gov't Reform, *Hearing on Reviewing the Rising Price of EpiPens* (Sept. 21, 2016), *available at* https://oversight.house.gov/hearing/reviewing-rising-price-epipens-2/; Anna Edney & Robert Langreth, *Mylan Blasted for Raising EpiPen Prices to Get "Filthy Rich,"* Bloomberg (Sept. 21, 2016), http://www.bloomberg.com/news/articles/2016-09-21/mylan-criticized-on-profits-and-pay-at-house-oversight-hearing.

51 Egan, *supra* note 44.

52 Andrew B. Polumbo, *To the EpiPen CEO: My Daughters Will Be Nothing Like You*, Huffington Post, Aug. 31, 2016, http://www.huffingtonpost.com/entry/father-to-epipen-ceo-my-daughters-will-be-nothing_us_57c48b04e4b024fca58c9367.

53 Rand Paul, *Sen. Rand Paul: EpiPen Scandal Is a Perfect Example of Crony Capitalism*, Time (Sept. 7, 2016), http://time.com/4482179/sen-rand-paul-epipen-scandal/; *A Drug Cartel at the FDA*, Wall St. J. (Sept. 26, 2016) (criticizing FDA's generic label regulations and commenting that "next time you hear a political sermon on the scandalous expense of treatments, remember this government collusion to keep drug prices high"), http://www.wsj.com/articles/a-drug-cartel-at-the-fda-1474931423.

54 *E.g.*, Charley Grant, *The EpiPen Controversy Isn't About Mylan*, Wall St. J., Aug. 25, 2016, http://www.wsj.com/articles/the-epipen-controversy-isnt-about-mylan-1472145456; Aaron E. Carroll, *The EpiPen, a Case Study in Health System Dysfunction*, N.Y. Times, Aug. 23, 2016, http://www.nytimes.com/2016/08/24/upshot/the-epipen-a-case-study-in-health-care-system-dysfunction.html?_r=0.

55 Dan Mangan & Anita Balakrishnan, *Mylan CEO Bresch: 'No One's More Frustrated Than Me' About EpiPen Price Furor,* CNBC, Aug. 25, 2016, http://www.cnbc.com/2016/08/25/mylan-expands-epipen-cost-cutting-programs-after-charges-of-price-gouging.html.

B. Settlement

The first activity involved settlement. In August 2009, Meridian Medical Technologies (a Pfizer subsidiary that manufactures the EpiPen) and King Pharmaceuticals (which acquired Meridian) sued Teva for patent infringement.[56] After a four-day bench trial in early 2012,[57] the parties settled in April 2012,[58] only weeks before post-trial briefings were due in late May 2012.[59] While the terms of the settlement are confidential, a Mylan press release confirms that Teva agreed to delay entering the market for more than three years, until June 2015.[60] During the period in which Teva could not enter the market, EpiPen prices more than doubled, from (roughly) $220 to $460.[61]

One cannot know with certainty how the court would have decided the patent litigation. But ominous tea leaves on the patents' validity are revealed by the court's *Markman*[62] claim construction hearing, which signaled greater success for Teva than for the patent owners.[63] The settlement also was concerning not just because it delayed a successful generic from the market but also because of its effects on other, later-filing generics. The Hatch-Waxman Act awards 180 days of exclusivity to the first generic to challenge a brand firm's patent claiming that it is invalid or not infringed.[64] This period does not begin until the first-filing generic enters the market, in this case three years in the future. Because Teva was the first filer,[65] as a result of delaying Teva's entry into the

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56 Complaint, *King Pharm., Inc. v. Teva Parenteral Med. Inc.*, Case No. 09-652-GMS (D. Del. Aug. 28, 2009). At the time of this suit, the 2009 Orange Book listed Meridian as EpiPen's sponsor. Mylan Specialty took over as EpiPen's sponsor in the 2014 Orange Book. Even though Meridian and King formally filed the lawsuit, this article connects the conduct to Mylan given (1) its wholly-aligned interests as exclusive marketer and distributor, (2) the division of responsibility by which Meridian/King filed lawsuits and Mylan listed patents in the Orange Book, and (3) Mylan's announcement of the settlement, which quotes executives not from Meridian or Pfizer but only from Mylan. *See infra* note 57 and accompanying text (quoting CEO Heather Bresch: "We are pleased with this settlement, and are confident that the EpiPen® Auto-Injector will continue to be a market leader.").

57 Case No. 09-652, D.I. 150–54 (D. Del. July 25, 2012) (transcript of trial held on Feb. 16, 2012 and Mar. 7-9, 2012).

58 *See* Mylan and Pfizer Announce Epinephrine Auto-injector Settlement Agreement with Teva, Mylan (Apr. 26, 2012), http://newsroom.mylan.com/pressreleases?item=123144.

59 Case No. 09-652-GMS, D.I. 146 (D. Del. Apr. 12, 2012).

60 *Id.* The West Virginia Attorney General has opened an antitrust investigation of the settlement. Chris Morran, *West Virginia Investigating EpiPen Maker Mylan For Alleged Medicaid Fraud, Antitrust Violations,* Consumerist, Sept. 20, 2016, https://consumerist.com/2016/09/20/west-virginia-investigating-epipen-maker-mylan-for-medicaid-fraud-antitrust-violations/.

61 *See* Dan Mangan, *This Chart Shows Why Everyone's Angry About Soaring Price of Lifesaving EpiPen*, CNBC, Aug. 23, 2016, http://www.cnbc.com/2016/08/23/this-chart-shows-you-why-a-lot-of-people-are-angry-about-the-price-of-epipen.html (providing figures from July 2012 and May 2015).

62 S*ee generally Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996) (holding that claim construction is a matter of law and that judges are to construe the meaning of patent claims).

63 *See* Carrier & Minniti, *supra* note *, at 61-62.

64 21 U.S.C. §355(j)(5)(B)(iv) (2012).

65 *Update: Teva and Antares's Generic Challenge to Epi-Pen*, SeekingAlpha, Feb. 23, 2012, http://seekingalpha.com/article/388681-update-teva-and-antaress-generic-challenge-to-epipen.

market, Mylan and its partners delayed *all generics* that sought to file applications based on the EpiPen.[66]

Settlements of patent litigation threaten potential landmines of anticompetitive effects. The Supreme Court made clear in *FTC v. Actavis*[67] that a settlement by which a brand pays a generic to delay entering the market could have "significant adverse effects on competition" and violate the antitrust laws.[68]

Although the *Actavis* decision post-dated the settlement, the parties could not have been unaware at the time they settled in April 2012 that potentially rigorous scrutiny was on the horizon. Any appeal of the Delaware court's decision would be heard by the Third Circuit. And the settlement was signed shortly after that court's December 2011 oral argument in *In re K-Dur Antitrust Litigation*, in which the judges expressed skepticism of arguments for minimal antitrust scrutiny.[69] In July 2012, the court adopted a test of presumptive illegality.[70] Because the terms of the settlement are confidential, it is not possible to know whether there was a transfer of consideration to Teva.[71] But the generic-friendly claim construction bolstering Teva's leverage, together with the vast

66 *See* Michael A. Carrier, *Payment After Actavis*, 100 Iowa L. Rev. 7, 15 (2014) (noting that the 2003 Medicare Amendments, which were designed to encourage expedited entry by specifying events that led to a forfeiture of the exclusivity period, were ineffective).

67 133 S. Ct. 2233 (2013).

68 *Id.* at 2231.

69 Oral Argument, *In re K-Dur Antitrust Litig.*, Nos. 10-2077, 10-2078, 10-2079, & 10-4571, at 25, 36, 37 (3d Cir. Dec. 12, 2011) (noting that "Senator Hatch himself has said that he thinks these reverse payments are anti-competitive" and questioning arrangement by which brand purchased generic product on grounds that it "le[]d to the presumption that [it] could have been buying off the generic from entering the market earlier" and that "what [the parties] ended up [with] was an allocation of the market—which violates the antitrust laws").

70 *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012), *cert. granted and judgment vacated by* Upsher-Smith Lab., Inc. v. La. Wholesale Drug Co., 133 S. Ct. 2849 (2013).

71 *See* Notice of Removal of Action from State Court Pursuant to 28 U.S.C. §§ 1331, 1332, 1338, 1367, 1441, 1446 & 1454 at Exhibit A at ¶¶ 34–35, *Teamsters v. King Pharms.*, No. 1:15-cv-04666-LAK (N.Y. filed June 16, 2015) (requesting access to settlement agreement and stating that "[u]pon information and belief, Teva received unjustifiable consideration, incentives, and benefits in exchange for their collusion" since "[n]o rational economic actor with a viable product would refrain from entering a lucrative 'blockbuster' market unless they received some form of valuable consideration").

scale of the market,[72] increased the likelihood that Meridian delayed Teva's entry through payment.[73]

C. Citizen Petition

In addition to delayed-entry settlements, Mylan sought to forestall Teva's entry by employing a "citizen petition," which is meant to raise safety concerns with the FDA but which has been used by brand firms to delay generic entry. As I have shown, "citizen" petitions are filed mostly by brand firms, and are almost always (92%) denied.[74]

Mylan filed its citizen petition against Teva's Abbreviated New Drug Application (ANDA or generic application) in January 2015.[75] A response from the FDA was anticipated no later than June 2015[76]—only weeks before Teva was permitted to enter the market pursuant to its settlement. As my study revealed, Mylan's petition appears to have been filed as a delay tactic to avoid generic approval and the loss of its overwhelming share of the market.[77]

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72 One analyst anticipated that a Teva victory could have resulted in it "captur[ing] 40% of the Epi-Pen unit market and roughly 20% of current sales, or about $54 million, in the first year of introduction." Larry Smith, *The Promise of the Antares Pipeline is the Basis of My Buy Recommendation*, Smith On Stocks, Jan. 25, 2012, https://smithonstocks.com/the-promise-of-the-antares-pipeline-is-the-basis-of-my-buy-recommendation-ais-2-40/.

73 In the midst of the EpiPen price-hike saga, Teva has declined to comment on whether payment was made in exchange for the settlement. Chris Glorioso & Evan Stulberger, *I-Team: Company Behind EpiPen Fought to Keep Cheaper Generic off Market*, NBC New York, Aug. 30, 2016, http://www.nbcnewyork.com/news/local/EpiPen-Cheap-Generic-Teva-Product-Mylan-Investigation-Drug-Cost-391758871.html. As of this writing, Teva has not received FDA approval. But that is the result of a history in which it delayed entering for several years, and which conceivably lessened its incentives to enter the market.

Nor was this the only settlement. In January 2011, King commenced litigation against Intelliject (now Kaleo) for infringement after the company sought approval for Auvi-Q. Complaint, *King Pharm., Inc. v. Intelliject Inc.*, Case No. 1:11-cv-00065-UNA (D. Del. Jan. 19, 2011). In February 2012, the parties settled on terms allowing Auvi-Q to enter the market in November 2012 (three months after receiving FDA approval). *Mylan and Pfizer Announce Epinephrine Auto-Injector Settlement Agreement*, FiercePharma, Feb. 16, 2012, http://www.fiercepharma.com/pharma/mylan-and-pfizer-announce-epinephrine-auto-injector-settlement-agreement; Phil Milford, *Pfizer, Mylan Settle With Sanofi Over Epinephrine Injector*, Bloomberg, Feb. 16, 2012, http://www.bloomberg.com/news/articles/2012-02-16/pfizer-mylan-settle-with-sanofi-over-device-for-severe-allergic-reactions; NDA 201739, Drugs@FDA: FDA Approved Drug Products, http://www.accessdata.fda.gov/scripts/cder/daf/ (enter 201739 into the Search by Drug Name, Active Ingredient, or Application Number field).).

74 Michael A. Carrier & Carl Minniti, *Citizen Petitions: Long, Late-Filed and At-Last Denied,* 66 Am. U. L. Rev 305, 333 (2016) (examining all 505(q) petitions (which ask the FDA to take action against a pending generic application) filed between 2011 and 2015); *see also* Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 Cardozo L. Rev. 249, 274 (2012) (finding that the FDA denied 81% of petitions filed between 2001 and 2010).

75 Citizen Petition from Mylan Specialty, L.P., Docket No. FDA-2015-P-0181-0001 at *1 (posted on Jan. 16, 2015).

76 *See* 21 U.S.C. § 355(q)(F) (2012) ("The Secretary shall take final agency action on a petition not later than 150 days after the date on which the petition is submitted.").

77 *See* Carrier & Minniti, *supra* note 73, at 350-51.

Just as concerning, in May 2015, four months after filing the petition, Mylan filed a supplemental study asserting that patients would not be able to operate Teva's proposed device without retraining.[78] Experts explained, however, that Mylan's supplemental study "had a lot of problems" as it "lacked a control group; did not study the actual generic but a prototype instead; used a small number of participants; failed to provide them with proper instructions for use; and told participants to watch a video rather than actually use the Teva device."[79]

Shedding even more light on the questionable petition and supplemental study is its timing. In a development of which the industry would be keenly aware, Teva filed its ANDA against the Epi-Pen in 2008.[80] And court documents show that Teva produced its ANDA filing in the course of litigation in September 2010.[81] This material included "detailed product descriptions, drawings, and instructions for use" for Teva's proposed generic.[82]

At the time (and to this day), Mylan was working hand-in-hand with Meridian/King, with the former taking over Orange Book sponsorship of the drug application and the latter targeting rivals in litigation.[83] It thus seems exceedingly likely that Mylan would have been aware of Teva's ANDA in 2008 and aware of documents explaining Teva's product in 2010. In fact, it was *Mylan* that announced the settlement of the litigation, confirming its close connection to the case.[84] This connection raises significant concerns that Mylan waited more than four years to file its citizen petition in 2015.

Even though Teva's ANDA was ultimately denied in February 2016,[85] Mylan would not have known this when it filed its petition in January 2015. And my comprehensive study of citizen petitions found that in 2015, the FDA approved three ANDAs on the *same day* it denied a petition, suggesting that generic approval was at least partially delayed until the petition was resolved.[86]

It is reasonable to conclude that Mylan's (1) filing of a petition years after invariably knowing about Teva's generic; (2) filing of a petition calculated to delay entry after

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78 Supplement from Mylan Specialty, L.P., Docket No. FDA-2015-P-0181-0007 at *10 (posted on May 5, 2015).

79 Ed Silverman, *How Mylan Tried to Keep Teva from Selling a Generic EpiPen*, Stat, Aug. 31, 2016, https://www.statnews.com/pharmalot/2016/08/31/mylan-teva-generic-epipen/. The petition also included a statement from Dr. Eli Meltzer—who received roughly $95,000 from Mylan between 2014 and 2015—that users trained on the EpiPen would not "be able to reliably use a different operational platform in an emergency situation as safely and effectively." *Id.*

80 Smith, *supra* note 71.

81 Defendants' Brief in Support of their Motion to Dismiss at 6, *King Pharm., Inc. v. Teva Parenteral Med. Inc.*, Case No. 09-652-GMS at *6 (D. Del., filed Dec. 13, 2010).

82 *Id.*

83 *See supra* note 57.

84 *See supra* note 57.

85 Carly Helfand, *FDA Swats Down Teva's EpiPen Copy, Putting Mylan in Cruise Control*, FiercePharma (Mar. 1, 2016), http://www.fiercepharma.com/sales-and-marketing/fda-swats-down-teva-s-epipen-copy-putting-mylan-cruise-control.

86 *See* Carrier & Minniti, *supra* note 73, at 341-44.

settlement; and (3) late-filing of a supplemental study together comprised a strategy to delay Teva's ANDA approval *beyond* the *already-delayed* agreed entry date of June 2015. Although the FDA is required to respond to petitions within 150 days, on numerous occasions the agency offers only an interim response explaining that it requires more time due to "complex issues raised" in the petition.[87] As a result, a strategy similar to the one Mylan used easily could have pushed a petition's disposition (and thus generic approval) past 150 days. For a billion-dollar drug product like the EpiPen, each day of delay meant an extra $3 million.

Parties filing petitions with government agencies often can rely on the immunity from the antitrust laws provided by the *Noerr-Pennington* doctrine, as "[t]hose who petition [the] government for redress are generally immune from antitrust liability."[88] But this defense is not absolute. In particular, there is a well-established "sham" exception, whose requirements of subjective motivation and objective baselessness could conceivably be satisfied in this case from Mylan's likely longstanding knowledge of Teva's generic, the timing of the petition in relation to the settlement, and the questionable nature of the supplemental study.[89] On a broader level, the petition could be viewed as an integral part of an overall scheme of monopolization, together with settlement and (as discussed immediately below) exclusive dealing.[90]

D. Exclusive Dealing

In addition to delaying *future* generic entry from Teva (and others waiting in line behind it) through settlement and petition, Mylan blocked *present* competitors through its program for distributing the EpiPen to schools.[91]

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87 *E.g.*, Interim Response Letter from FDA CDER to Cubist Pharm., Inc., Docket No. FDA-2015-P-1595-0004 (posted on Oct. 26, 2015) (interim response from FDA, 173 days after petition filing, stating that "FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials").

88 Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., 508 U.S. 49, 56 (1993).

89 E.g., Tyco Healthcare Group v. Mutual Pharm., 762 F.3d 1338, 1348 (Fed. Cir. 2014); In re DDAVP Direct Purchaser Antitrust Litig., 585 F.3d 677, 694 (2d Cir. 2009); In re Flonase Antitrust Litig., 795 F. Supp. 2d 300, 317 (E.D. Pa. 2011); In re Prograf Antitrust Litig., 2012 WL 293850, at *5 (D. Mass. Feb. 1, 2012); *see also* Tyco Healthcare Group v. Mutual Pharm., 2015 WL 3460790, at *9 (D.N.J. May 29, 2015) (denying summary judgment because generic offered evidence that petition delayed entry).

90 *See, e.g., In re* Neurontin Antitrust Litig., 2009 WL 2751029, at *15 (D.N.J. Aug. 28, 2009) ("Courts have routinely upheld the validity of 'overall monopolization scheme' claims in the patent context, even in the absence of allegations that any one of the scheme's predicate actions was independently violative of antitrust laws." (quoting *Abbott Labs v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 428 (D. Del 2006))).

91 The New York Attorney General launched an antitrust investigation of this conduct. Press Release, *N.Y. Attorney General, A.G. Schneiderman Launches Antitrust Investigation into Mylan Pharmaceuticals Inc., Maker of EpiPen*, Sept. 6, 2016, http://www.ag.ny.gov/press-release/ag-schneiderman-launches-antitrust-investigation-mylan-pharmaceuticals-inc-maker.

In November 2013, in response to a seven-year-old girl at a Virginia school dying from an allergic reaction to peanuts,[92] Congress passed the School Access to Emergency Epinephrine Act.[93] Under this law, the Secretary of Health and Human Services is authorized to give preferential funding to states with schools that maintain an emergency supply of epinephrine for students.[94] The law has had a significant effect: 11 states require[95] and 38 encourage[96] schools to stock epinephrine.[97] This federal legislation has been supplemented by state laws that mandate that public schools obtain auto-injectors.[98]

On one hand, such an arrangement could increase access to a life-saving device. But on the other, it could exclude competitors. As a condition of receiving discounted EpiPens,[99] schools were required to agree that they would "not in the next twelve (12) months purchase any products that are competitive to EpiPen® Auto-Injectors."[100] The language appeared in order forms in August 2014, June 2015, and April 2016,[101] and Mylan has admitted such a practice.[102]

In antitrust terms, this conduct offers a discount price based on exclusivity. As the leading treatise explains, such an arrangement "should generally be treated as no different from an orthodox exclusive-dealing arrangement."[103] Exclusive dealing case law stems from Section 3 of the Clayton Act, which prohibits a "discount . . . or rebate . . . on the condition, agreement, or understanding that the . . . purchaser . . . shall not use or deal in the goods . . . of a competitor" where there is an adverse effect on competition.[104]

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92 Cynthia Koons & Robert Langreth, *How Marketing Turned the EpiPen into a Billion-Dollar Business*, BloombergBusinessweek, Sept. 23, 2015, http://www.bloomberg.com/news/articles/2015-09-23/how-marketing-turnedthe-epipen-into-a-billion-dollar-business.

93 Pub. L. No. 113-48, 127 Stat. 575 (2013) (codified at 42 U.S.C. § 280g(d)(1)(F)–(G)).

94 *Id.*

95 *School Access to Epinephrine Map*, Food Allergy Res. & Educ. https://www.foodallergy.org/advocacy/epinephrine/map (last updated July 6, 2016).

96 *Id.* Hawaii is the only state that does not require or allow schools to stock epinephrine.

97 Koons & Langreth, *supra* note 91.

98 *See* Aimee Nienstadt, *Comment, The Insufficiency of the Law Surrounding Food Allergies*, 36 Pace L. Rev. 595, 611 (2016) (providing analysis on state epinephrine auto-injector laws). For a discussion of Mylan's role in the enactment of the 2013 Act, *see* Carrier & Minniti, *supra* note *, at 67-68.

99 Ike Swetlitz & Ed Silverman, *Mylan May Have Violated Antitrust Law in its EpiPen Sales to Schools, Legal Experts Say,* Stat, Aug. 25, 2016, https://www.statnews.com/2016/08/25/mylan-antitrust-epipen-schools/ (noting that the "discounted price was $112.10," roughly "a quarter of the cost charged to pharmacies at the time").

100 *Id.*

101 *Id.*

102 Full House Comm., *supra* note 49 (pt. 1, at 1:44:00) (in testimony to House Committee, Bresch responded to Representative Duckworth's question about whether "schools purchasing discounted EpiPens had to make any representations or warranties to Mylan that they would adhere to certain conditions in order to access the discount price by conceding: "For people that wanted to buy it at the discounted rate, yes").

103 XI Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application ¶ 1807b, at 133 (3d ed. 2006).

104 15 U.S.C. § 14 (2012); see id.

Exclusive dealing also can constitute monopolization under Section 2 of the Sherman Act if the defendant has monopoly power.[105] The general concern with exclusive dealing arrangements is that they block competitors from the market and result in higher prices and lower output.

In evaluating the antitrust aspects of such arrangements, courts have historically focused on the share of the market foreclosed by the arrangement, requiring plaintiffs to show roughly 30% to 40% foreclosure.[106] Assuming this threshold is cleared, courts then analyze other factors, such as the duration of the contracts, prevalence in the industry, existence of entry barriers, distribution alternatives, and other competitive effects.[107]

Recent cases have shifted the emphasis away from foreclosure. One commentator has found that courts "have looked beyond foreclosure to focus instead on the effect of exclusive dealing in creating, enhancing, or preserving the defendant's market power."[108] Recent cases "have . . . found exclusive dealing and similar arrangements unlawful despite minimal, or even zero, levels of percentage foreclosure from access to the ultimate consumer."[109]

Applying antitrust law to Mylan's EpiPen contracts, the first question is whether distribution through schools constitutes its own market. An expansive view would treat together distribution in varied settings including schools, hospitals, amusement parks, and families. According to such an interpretation, the share distributed to schools would likely be a modest subset of the total number of devices.

But a more justified interpretation is that schools constitute their own separate market. While each state law differs on the particular age through which students are required to attend school, it is generally accepted that children up to the age of eighteen must do so.[110] After the passage of the 2013 legislation, schools are either required, or receive significant incentives, to stock epinephrine auto-injectors. Schools' decisions on which devices to purchase are not tied to those of parents and hospitals. And given the number of children that do not carry EpiPens with them, school nurses play an irreplaceable role during school hours on the front lines of treating anaphylactic shock, buttressing the conclusion of a market for distribution through schools.[111]

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105 15 U.S.C. § 2.

106 Herbert Hovenkamp, Federal Antitrust Policy: The Law of Competition and its Practice 596 (5th ed. 2016).

107 *Id.* at 597.

108 *See* Jonathan M. Jacobson, *Exclusive Dealing, "Foreclosure," and Consumer Harm,* 70 Antitrust L.J. 311, 311 (2002).

109 *Id.* at 363; *see also id.* ("precise percentage of the market asserted to be foreclosed . . . appears to be a wasteful exercise" as "[f]ew serious cases today are based on assertions that foreclosure alone is the source of the asserted competitive harm").

110 *See* 78A C.J.S. School and School Districts § 988 (2016).

111 *See* David Stukus, *New Epinephrine Study Shows Alarming Results*, Kids With Food Allergies: KFA Medical Advisory Team (July 14, 2014), http://community.kidswithfoodallergies.org/blog/new-epinephrine-study-shows-alarming-results (study showed that only 40% of families carried self-injectable epinephrine with them).

In the market of school distribution for epinephrine auto-injectors, the precise extent of foreclosure is unclear.[112] There are roughly 129,000 elementary, middle, and high schools in the U.S. today: 98,000 public[113] and 31,000 private.[114] While more than half of these schools, over 65,000, receive free EpiPens, the number of schools that have bought EpiPens at a discount is less clear, which prevents definitive conclusions on foreclosure.[115]

Regardless of the percentage of the market foreclosed, other factors favor antitrust liability.[116] For competitors not yet on the market, there are high entry barriers in the form of FDA approval. It is particularly difficult for companies to obtain approval of epinephrine auto-injectors as the FDA is cautious given the potentially fatal consequences from misapplication.[117] Barriers also applied to alternatives on the market like Adrenaclick and Auvi-Q, as the Mylan contracts made it more difficult to gain a foothold. Nurses would be trained on the EpiPen, and caregivers whose children's lives were saved by a nurse using an EpiPen—or even who merely knew that the devices were present at the school—would tend to purchase (and tell relatives and others to buy) EpiPens.

In addition, the competitive effects are as clear as they ever are in these cases: a 400% surge from 15 price increases between 2009 and 2016. For each of those increases, Mylan hiked the EpiPen's price at least 9%, and as much as 15%.[118] In short, Mylan's exclusive dealing agreements appeared to block competitors from the market and to increase price.

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112 *E.g., EpiPen4Schools Program*, Mich. Ass'n of Intermediate Sch. Admins., http://www.gomaisa.org/epipens-4-schools-program (last visited Oct. 20, 2016) (covering "qualifying public and private kindergarten, elementary, middle and high schools in the U.S.").

113 Jill Barshay, The Hechinger Report, *Number of U.S. Charter Schools Up 7 Percent, Report Shows*, U.S. News & World Rep. (Nov. 3, 2014), http://www.usnews.com/news/articles/2014/11/03/number-of-us-charter-schools-up-7-percent-report-shows.

114 *Facts and Studies*, Council for Am. Priv. Educ., http://www.capenet.org/facts.html.

115 Swetlitz & Silverman, *supra* note 98; Mylan Letter to Sen. Elizabeth Warren et al., Sept. 12, 2016, at 7-8 (noting that 1,348 schools purchased EpiPens at a discount between September 2015 and September 2016 but not explaining whether restrictive contracts were in place for entire period or whether such figures were representative of earlier periods); Ed Silverman, *Lawmakers Call for FTC Probe into Potential Antitrust Violations in EpiPen School Program*, Stat, Nov. 8, 2016, https://www.statnews.com/pharmalot/2016/11/08/ftc-mylan-epipen-antitrust/ (noting that "700,000 free pens have been distributed to schools" and that "another 45,000 pens" were distributed at a discount).

116 The 12-month duration of the contract would present the sole factor that would counsel against liability, but would likely be significantly outweighed by the other factors.

117 *See* Helfand, *supra* note 84 ("regulators flagged 'certain major deficiencies'"); *see generally* Pauline Bartolone, *EpiPen's Dominance Driven by Competitors' Stumbles and Tragic Deaths*, NPR: Shots Health News from NPR (Sept. 7, 2016), http://www.npr.org/sections/health-shots/2016/09/07/492964464/epipen-s-dominance-driven-by-competitors-stumbles-and-tragic-deaths.

118 Jayne O'Donnell et al., *EpiPen's Steady Price Increases Masked Until Deductibles Rose*, USA Today, Aug. 25, 2016, http://www.usatoday.com/story/news/politics/2016/08/23/epipens-steady-price-increases-masked-until-deductibles-rose/89123786.

Depending on Mylan's market share (which was 94% in August 2016[119] but 71% in March 2017[120]), this analysis may form the basis for not only a Clayton Act Section 3 claim but also a monopolization claim.[121]

III. Conclusion

A greater number of price increases than is commonly recognized can be explained by anticompetitive behavior like that outlined in this article. As the Daraprim and EpiPen examples showed, in these cases antitrust can address price hikes. In the years ahead, antitrust enforcers and observers should carefully scrutinize price increases to determine if they are accompanied by anticompetitive behavior.

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119 *E.g.*, Matt Egan, *EpiPen Outrage May Fuel Cheap Generic in 2017*, CNNMoney: The Buzz (Aug. 26, 2016), http://money.cnn.com/2016/08/26/investing/epipen-price-hike-generic-alternative/.

120 Sy Mukherjee, *Mylan's EpiPen Is Bleeding Market Share to Its Rivals*, Fortune, Mar 6, 2017, http://fortune.com/2017/03/06/mylan-epipen-competitors-surge/.

121 In fact, courts have accepted lower foreclosure figures in the context of monopolization. *See United States v. Microsoft Corp.*, 253 F.3d 34, 70 (D.C. Cir. 2001) ("[A] monopolist's use of exclusive contracts, in certain circumstances, may give rise to a § 2 violation even though the contracts foreclose less than the roughly 40% or 50% share usually required in order to establish a § 1 violation.").

EMPIRICAL EVIDENCE OF DRUG COMPANIES USING CITIZEN PETITIONS TO HOLD OFF COMPETITION

By Robin Feldman,[1] John Gray,[2] & Giora Ashkenazi[3]

I. INTRODUCTION

The United States patent system is designed to reward innovation and spur new technological growth. While this is incredibly effective in most fields, it can be especially problematic in the pharmaceutical industry where the inelasticity of demand for products has allowed for exorbitant drug prices. This is most clearly seen in the effect that the entry of generic drugs has on the market. Since 1984, more than 10,000 generics have entered the market,[4] and the percentage of prescriptions filled with generics rose from just 13 percent in 1980[5] to around 86 percent by 2013.[6] Notably, the dramatic rise of generics has saved the public inordinate amounts of money. The Food and Drug Administration (FDA) estimates that consumers saved more than $217 billion through the use of generics in 2012 alone, with total savings of $1.68 trillion from 2005 to 2014.[7] It is, therefore, of the utmost importance to ensure that generic drugs enter the market properly as patents expire. Brand-name pharmaceutical companies have long been known to play a myriad of games to delay generic entry for as long as possible.

In a recently published book and article,[8] co-authored by team members at the UC Hastings Institute for Innovation Law, we expose troubling behavior in which

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3 Research Fellow, Institute for Innovation Law, University of California Hastings College of the Law. This piece summarizes a study published in the following works: Robin Feldman & Evan Frondorf, Drug Wars: How Big Pharma Raises Prices and Keeps Generics Off the Market (Cambridge 2017); Robin Feldman, Evan Frondorf, Andrew Cordova, & Connie Wang, *Empirical Evidence of Drug Pricing Games: A Citizen's Pathway Gone Astray,* 20 Stan. Tech. L. Rev. 39 (2017). It is published with the permission of Cambridge University Press and the Stanford Technology Law Journal.

4 *See* Wendy H. Schacht & John R. Thomas, Cong. Res. Serv., Report R41114, The Hatch-Waxman Act: A Quarter Century Later 5, at Summary (2011), https://digital.library.unt.edu/ark:/67531/metadc816414/m2/1/high_res_d/R41114_2012Mar13.pdf.; *see also Medicare Prescription Drug, Improvement, and Modernization Act: Hearing on H.R. 1 Before S. Comm. on the Judiciary,* 108th Cong. (2003) (statement of Jon W. Dudas, Deputy under Secretary of Commerce for Intellectual Property and Deputy Director, U.S. Patent and Trademark Office), https://www.gpo.gov/fdsys/pkg/CHRG-108shrg91832/html/CHRG-108shrg91832.htm.

5 Cong. Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry 37* (1998).

6 *See Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013,* IMS Inst. for Healthcare Informatics at 51 (Apr. 2014), https://democrats-oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/IMS-Medicine%20use%20and%20shifting%20cost%20of%20healthcare.pdf.

7 *Implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA): Hearing before the H. Comm. on Oversight & Gov't Reform,* 114th Cong. 1 (2016) (statement of Janet Woodcock, Director, Ctr. for Drug Evaluation & Res., U.S. Food & Drug Admin.).

8 *See* Feldman & Frondorf, *supra* note 3.

pharmaceutical companies use the FDA's citizen petition process to delay entry of generic competitors. Examining more than a decade of FDA data related to citizen petitions, along with data related to generic drug approvals, the study provides broad empirical evidence that citizen petitions at the FDA have become an important pathway for strategic behavior by pharmaceutical companies.

Improper citizen petition behavior arises against the backdrop of soaring drug prices in the United States, a problem exacerbated by the lack of effective competition in pharmaceutical markets.[9] Although citizen petitions provide only one pathway for delaying competition, the study examines this essential piece of the puzzle. Key results from the study include the following:

- The FDA's citizen petition process is one of the critical pathways involved in the modern generation of generic drug delay, playing a role in various game-playing strategies.
- Citizen petitions from brand name and generic companies seeking to delay competitors have effectively doubled since 2003.
- Of all citizen petitions at the FDA (including those concerning tobacco, food, dietary supplements, medical devices, etc.), nearly 15 percent have the potential to delay generics, climbing to 20 percent in some years.
- Many citizen petitions from competitor companies appear to be an eleventh-hour effort to hold off generic competition. In fact, the most common category of delay-related petitions was that of petitions filed within six months of generic approval. This is particularly noteworthy given that the overwhelming majority of citizen petitions are denied.[10]
- In short, the results suggest that many competitor petitions are filed late in the game, as a last-ditch attempt to delay competition just a little longer, even though the petitions are unlikely to be successful.
- Congressional reforms enacted in 2007 have not stemmed the tide.

II. BACKGROUND

The Hatch-Waxman Act of 1984 revolutionized the pharmaceutical industry, creating a streamlined pathway for approval of generic drugs. The goal was to frontload the approval process of generics during the patent term to allow them to enter the market as soon as the patent on the original drug expired, thereby increasing competition and driving down prices for patients and the healthcare system as a whole. The Act

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9 *See generally id.*

10 *See* Michael A. Carrier & Carl J. Minniti, *Citizen Petitions: Long, Late-Filed, and At-Last Denied,* 66 Am. U. L. Rev. 305, 333 tbl. 4 (2016), *available at* http://ssrn.com/abstract=2832319 (finding that between 2011 and 2015, the FDA denied 92 percent of section 505(q) citizen petitions, the type most often employed to oppose generic entry); Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study,* 34 Cardozo L. Rev. 249, 274 (2012) (finding that the FDA denied 81 percent of all citizen petitions filed by competitors against drug companies between 2001 and 2010).

introduced the concept of an Abbreviated New Drug Application ("ANDA"), allowing prospective generics to use clinical data from approval of the original, brand-name drug to demonstrate safety and efficacy. Rather than repeating the lengthy and costly clinical trials, a generic hopeful need only demonstrate that its own product is bioequivalent to the brand-name drug. Hatch-Waxman also provides a complex process for generic applicants to initiate and resolve patent issues prior to bringing the drug to market. Complexity breeds opportunity,[11] however, and Hatch-Waxman's complicated language opened the door to strategic behaviors that drug companies have deployed to maintain competition-free zones for as long as possible. The tactics have evolved over time, and the modern generation of strategic behaviors frequently involves obstruction tactics to prevent or delay approval of generic competitors. One such method involves filing citizen petitions with the FDA.

Citizen petitions were designed as a mechanism for independent scientists and citizens to raise concerns about a food product or a drug. The process, however, has been hijacked by pharmaceutical companies to challenge and delay drug applications from potential competitors. Drug companies use a variety of approaches in their citizen petitions, including asking the FDA to require of the generic what it already requires for any generic application, raising safety concerns, and asking the FDA to preserve or add new exclusivities for the brand-name drug. Although the FDA eventually rejects the vast majority of these demands, it spends time and resources to review them; time and resources that are diverted from considering the generic competitor's application. In addition, although the FDA must respond to a citizen petition within five months, a delay of such time period can be worth hundreds of millions of dollars in revenue for a blockbuster drug. Significantly, those five months can be added onto other delay tactics, which the branded company strings out, one after the other. While competitors languish on the sidelines, the brand-name company remains free to charge sky-high prices.

Anecdotal evidence has suggested that drug companies abuse the citizen petition process, but little empirical evidence had existed. This leaves the pharmaceutical industry free to suggest that the behavior is limited to a few bad apples. For example, in testifying before a U.S. House Judiciary Subcommittee this summer, one witness sympathetic to the pharmaceutical industry argued emphatically that suggestions of improper citizen petition behavior were no more than "anecdote and rhetoric."[12]

III. Method

To examine whether widespread abuse of the citizen petition process exists, we set out to assemble a database of all citizen petitions filed with the FDA between the years 2000 and 2012, which could potentially delay generic entry. This task was tremendously difficult, to say the least. Some of the most important information about citizen petitions must be pieced together or estimated; at other times, it simply does not exist. For

11 Robin Feldman, Rethinking Patent Law 160 (2012) ("As so often is the case, complexity breeds opportunity, and clever lawyers have been exploiting the details of the act since its inception.").

12 *See* House Judiciary Subcommittee on Antitrust Concerns and the FDA Approval Process (July 27, 2017) (statement of witness Lietzan, starting at 2:03:45, suggesting that claims rest on "anecdote and rhetoric, not evidence"), *available* at https://www.youtube.com/watch?v=dt2yOVCMFdA&feature=youtu.be&t=2h49m17s.

example, the FDA does not expressly reveal the date on which the generic application for a drug was filed, making it difficult to determine the timing relationship between a generic application's filing date and the date upon which a potentially delaying citizen petition was filed. Selected details of the methodology include the following:

- We compiled all FDA citizen petitions and related documents filed between 2000 and 2012.
- We identified citizen petitions related to pharmaceuticals, with a particular focus on generic drugs.
- We read each remaining citizen petition and determined which of these petitions were related to generic drugs or had the power to delay generic approval, regardless of the merits or circumstances of the petition.
- We constructed a data set of all generic applications approved between 2006 and 2015, recording the approval date for each application.
- We compiled filing dates for the generic applications, pulling them when available from PDFs of letters within the FDA's databases. When filing information was not publicly available, we were able to estimate a filing date down to the quarter-year for most drugs.
- We matched each citizen petition with the generic application most relevant to the requests made in the petition.
- Using these citizen petition-generic application pairs, we constructed metrics with the goal of isolating the timing of petitions during the generic drug approval process.

The final pool of citizen petitions with the potential to delay the introduction of generic drugs consisted of 249 citizen petitions filed between 2000 and 2012. We then matched these petitions with the generic application that would be most directly affected. At the end of this process, 164 citizen petitions of the original 249 originally identified were linked to generic applications that had data available: either a filing date, an approval date, or both.[13] Out of those 164 petitions, 152 (or 61 percent of the total 249 petitions) were linked to generic applications with both the filing date and approval date.[14]

IV. RESULTS

The results of the study provide empirical evidence that the citizen petition process at the FDA has become a key avenue for strategic behavior by pharmaceutical companies to delay entry of generic competition.

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13 In rare circumstances, a filing date was available, but not an approval date. This occurred when a drug had only been tentatively approved, but was still posted on the FDA's website with an attached letter noting the filing date.

14 There were a total of 157 delay-related citizen petitions with filing information (including those with only a filing date and those with both a filing and approval date) and 159 delay-related citizen petitions with approval information (including those with only an approval date and those with both a filing and approval date).

A. Rise in Citizen Petitions with the Potential to Delay

As seen in Table I below, a notable percent of citizen petitions seems to have the potential to delay generic entry. Looking at the overall number of citizen petitions filed at the FDA on any topic, fourteen percent have the potential to delay a generic drug application, climbing to roughly twenty percent in some years. That means one in five of *all* citizen petitions to the FDA—not just those concerning pharmaceuticals—have the potential to delay generic competition in some years. This table also shows that starting around 2003 and 2004, petitions rose in popularity as a way to delay generics or raise issues about generics. Not only did the number of citizen petitions rise noticeably after 2002, but the number of delay-related petitions also sharply increased as a proportion of all petitions.

TABLE I — ALL DELAY-RELATED PETITIONS, BY YEAR

YEAR	NUMBER OF DELAY-RELATED PETITIONS	PERCENTAGE OF YEARLY TOTAL PETITIONS
2000	2	2/47 = **4.3%**
2001	4	4/63 = **6.3%**
2002	5	5/106 = **4.7%**
2003	12	12/120 = **10.0%**
2004	26	26/178 = **14.6%**
2005	15	15/148 = **10.1%**
2006	24	24/184 = **13.0%**
2007	25	25/160 = **15.6%**
2008	23	23/166 = **13.9%**
2009	32	32/171 = **18.7%**
2010	31	31/149 = **20.8%**
2011	22	22/157 = **14.0%**
2012	28	28/141 = **19.9%**
TOTAL	**249**	**249/1,790 = 13.9%**

B. When Are Citizen Petitions Filed in Relation to Final Approval?

The results also demonstrate that many drug companies are filing citizen petitions as a last-ditch effort in the period immediately before generic approval. Moreover, the timing suggests that many of these citizen petitions appear to be the very last barriers standing in the way of final generic approval. These implications emerged when we graphed the amount of time between when a citizen petition was filed and when the generic application was approved.

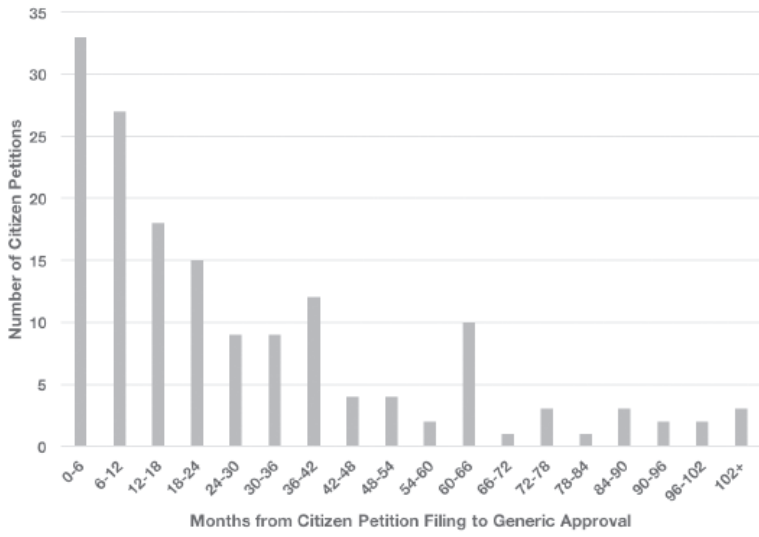
In particular, our original hypothesis was that if citizen petitions are being used systematically to delay the approval of generics, petitions might be deployed most effectively for that purpose near the end of a generic approval cycle. If filed earlier, the petition could merely introduce a review process running parallel to the rest of the generic approval process.

The data confirm this hypothesis. As seen in Figure I below, there is a clear trend in favor of citizen petitions filed shortly before the FDA approves a generic. In fact, the

most common category was "0–6 months," with 33 petitions, or 21 percent of the total,[15] filed with up to six months or less remaining before the FDA approved the generic. Considering that the average length of time from generic filing to approval is roughly four years, this category occurs most often during the last leg of the approval process.

In other words, the trend is toward an increasing number of petitions as one moves closer to the final approval date. Thus, this histogram suggests that delay-related citizen petitions are often filed in the final stages of generic approval to raise concerns at the last minute, rather than early or midway through the process. This pattern potentially extends the length of the generic application approval process, thus delaying the market entry of generic competition.

Figure I – Generic Drug Application Pendency



15 The number of citizen petitions filed within six months before generic drug approval was 33 out of a total of 158 petitions (21 percent).

C. How Did the 2007 Amendments Affect Citizen Petition Timing?

After years of hearings and debate on numerous FDA issues, Congress passed a large package of amendments in 2007, which included the largest reform of the citizen petition process in the petition program's thirty-year history.[16] These changes attempted to address concerns with citizen petitioning at the FDA, ranging from growing petition backlogs to signs that the process was being used inappropriately.[17]

Specifically, the 2007 Amendments added a subsection, 505(q), applying a new set of regulations to all citizen petitions that ask the FDA to take action related to a pending generic application. The section requires that the FDA respond to such petitions within 180 days, a period that was shortened to 150 days in 2012.[18] If a petition falls under section 505(q), the person filing the petition must certify that 1) the petition is not frivolous, 2) all information favorable and unfavorable has been provided, and 3) the petitioner did not intentionally delay filing the petition. The petition must also provide the date when the filer first became aware of the concerns and the names of those who are funding the petition.[19] Finally, section 505(q) grants the FDA the power to summarily deny any petition that the Agency believes was filed with the "primary purpose" of delaying generic approval, if the petition also does not "on its face raise valid scientific or regulatory issues."[20] Together, the provisions of section 505(q) were meant to speed the process and end any abuse of citizen petitions by pharmaceutical companies.

To test the impact of the 2007 Amendments, we compared the periods before and after 2007. Figure II below, which looks specifically at the period before the 2007 Amendments, shows that 41 percent of petitions were filed within a year and a half of approval.[21] In the period after the 2007 Amendments, the existence of last-minute petitions with the potential to delay has not abated. In fact, the trend is even more dramatic (see Figure III). Fifty-six percent of the petitions were filed within a year and a half of generic approval.[22]

Moreover, in the post-2007 period, a remarkable 46 percent of petitions were filed within a year of generic approval. The "0–6 months" and "6–12 months" categories were

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16 FDA Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007) (codified as amended in scattered sections of 21 U.S.C.).

17 *See* Carrier & Wander, *Citizen Petitions, supra* note 10, at 263 (quoting 153 Cong. Rec. 25,047 (2007)) (discussing testimony of Senator Edward Kennedy that "[t]he citizen petition provision is designed to address attempts to derail generic drug approvals. Those attempts, when successful, hurt consumers and the public health").

18 21 U.S.C. § 355(q)(1)(F) (2015); Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, 126 Stat. 993 (2012) (codified as amended in scattered sections of 21 U.S.C.).

19 *See id.*

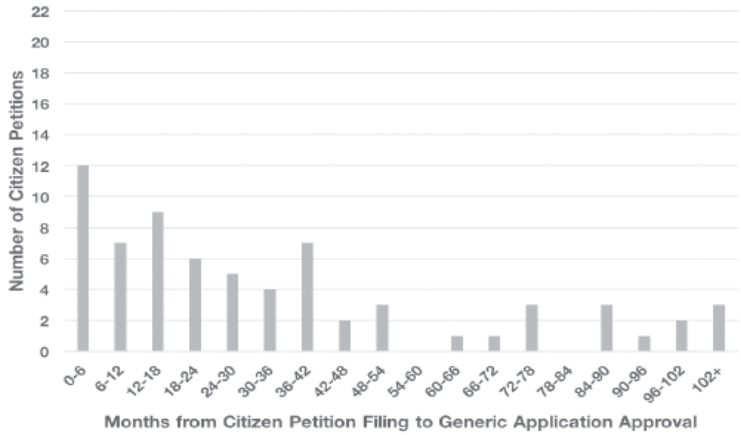
20 *See id.*

21 A total of 69 citizen petitions were filed in the period before the 2007 Amendments. Twenty-eight of them (41 percent) were filed within eighteen months of generic drug approval.

22 In the post-2007 Amendments period, we measured a total of 89 citizen petitions relating to generic drug applications with approval dates available. Of those 89 petitions, 50 were filed (56 percent) within eighteen months of generic drug approval.

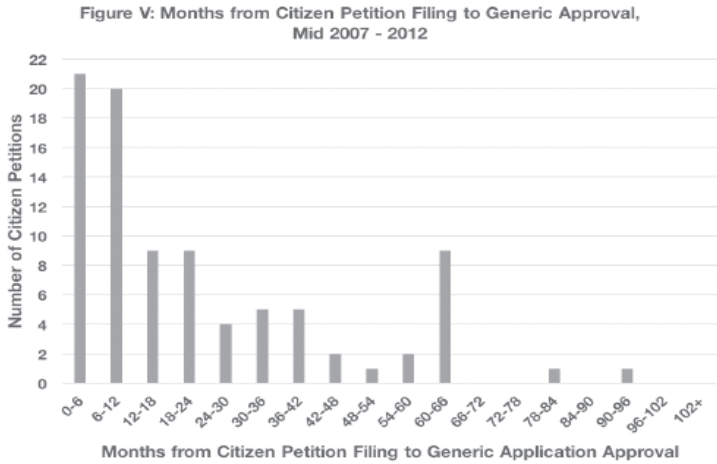
by far the most popular, garnering 24 percent and 22 percent of the total, respectively.[23] The biggest exogenous shift between the 2000 to mid-2007 histogram (Figure II) and the mid-2007 to 2012 histogram (Figure III) is, of course, the enactment of the 2007 Amendments. Its most notable change—requiring that the FDA respond to citizen petitions within 180 days—may explain why the post-2007 graph (Figure III) paints such a dramatic picture of citizen petition timing.

Figure II – Months from Citizen Petition to Generic Approval, 2000–2007



23 In the post-2007 Amendments period, the number of citizen petitions filed within six months of generic approval was 21 out of a total of 89 petitions (24 percent). The number of citizen petitions filed between six and twelve months of generic approval was 20 out of a total of 89 petitions (22 percent). Our findings are consistent with another study using a different methodology and a smaller sample set of the five years of citizen petitions filed between 2001 and 2015. *See* Carrier & Minniti, *Citizen Petitions, supra* note 10, at 338, 339 & Table 8. Ninety-eight percent of these "late-filed" petitions were denied. *Id.* at 341 & Table 8.

Figure III – Months from Citizen Petition to Generic Approval, 2007–2012



The FDA's 180-day time limit for responding to citizen petitions equates to six months, which aligns with our smallest category of 0–6 months. This has two implications: first, many drug companies are filing citizen petitions as a last-ditch effort just months before generic approval; and, second, many of these citizen petitions may be the last barrier in the way of final generic approval. Put another way, when so many generic applications are approved within six months—the equivalent of 180 days—of when a citizen petition is filed, and the FDA had 180 days to respond to a citizen petition, the relationship does not seem to be mere coincidence. This may also explain why the trend toward late citizen petitions is not as pronounced in the period before the 2007 Amendments: citizen petitions still may have been filed during the late stages of the FDA's consideration of generic applications, but since the FDA was not held to a specific deadline for responding to citizen petitions, lengthy petition reviews could have pushed back the horizon for final generic approval by more than six months. Delving deeper into this striking correlation between the FDA's deadline of 180 days and the plurality of citizen petitions filed within 180 days of generic approval would be an interesting avenue for future research.

V. THE ROAD AHEAD

As the results demonstrate, pharmaceutical companies have hijacked the citizen petition process as a route to frustrate generic approvals. We found evidence that many citizen petitions are not filed as soon as potentially worrisome information about a drug is discovered, but are instead filed near the later stages of the generic approval process. Nearly half of potentially delay-related citizen petitions between 2000 and 2012 were filed within a year and a half of approval, with numbers even higher when the data are restricted to the period after the 2007 Amendments. In fact, 46 percent of the post-2007 Amendment citizen petitions were filed within a year of final approval of the generic drug, and 24 percent were filed within six months. These findings suggest that the citizen petitions were some of the last barriers to approval for some generics.

Looking at the nature of the problem, one could imagine three types of approaches to curb the behavior of filing citizen petitions to delay generic entry. These might include (1) a simple prohibition on competitors filing citizen petitions related to generic entry, if one were to conclude that most behavior represented by this type of petition is likely to be inappropriate; (2) procedural blocks to ensure that the behavior cannot create suboptimal results; or (3) punitive measures as a deterrent. The details of the mechanism are less important, however, than choosing among the pathways and identifying the proper incentive structures and the optimal institutional actors.

No approach is a perfect or permanent solution. Fixing abuse of the citizen petition pathway may require a combination of these approaches. Moreover, in our book "*Drug Wars,*" my colleague and I show that when the legal system closes off one pathway, pharmaceutical companies will search for others. Thus, whatever paths and approaches are chosen to curb citizen petition abuse, it will be critical to ensure that regulators, legislators, and courts can see new techniques as they emerge. A little sunshine goes a long way.

In particular, greater transparency from the FDA could be tremendously effective in exposing new drug pricing schemes early on. Although the FDA makes a wealth of information publicly available, there are significant gaps in the system. For example, as described earlier, there is no systematic way to find the date on which a generic application was filed. Perhaps all generic applications should be posted when filed, along with the date of their filing, and the public should not have to wait until the generic is approved to find that information, if it even appears in the approval letter. As it stands now, the more effective a drug company is at blocking generic competition, the longer that company has before anyone outside the FDA can see what is being done. At the very least, once a generic application has been approved, the public should be able to tell easily when the application was filed. Specifically, all approval letters should be posted on the FDA website, and the FDA website should always list filing and approval dates for every generic, and not only in those letters.

Unfortunately, the FDA appears to be moving in the opposite direction and lessening transparency. For our study, we were able to extract filing dates from some of the approval letters that the FDA posted and backfill many others through our estimation technique when the FDA approval letters did not mention the filing date. The FDA recently changed its protocols, however, so that the public will no longer be able to do even that. According to one report, the FDA has initiated a new protocol in which it will omit from approval letters any mention of the filing date of the original generic application.[24]

Other basic information could improve transparency as well, including more complete labeling of citizen petitions themselves, and full information on generic application numbers and how they are assigned. Finally, the massive Freedom of Information Act (FOIA) backlog at the FDA also operates to mask improper behavior.

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24 *See* Bob Pollock, *Do You Notice Something Missing? What the Heck!,* Lachman Consultants (Mar. 31, 2016), www.lachmanconsultants.com/2016/03/do-you-notice-something-missing-what-the-heck/.

When we inquired for our research, Agency personnel were wonderfully helpful, but noted that FOIA requests would require approximately two years for a response.

Making full data on generic applications quickly and clearly available to the public is essential for curbing inappropriate behavior. Particularly if the FDA is not assigned the full task of policing competition, other actors—including state and federal regulators, legislators, academic researchers, public interest groups, and generics companies themselves—must have easy access to the relevant information. Transparency efforts such as these, along with the types of approaches described here for curbing attempts to delay generic competition through citizen petitions, are essential for addressing the problems. Without such endeavors, we will continue to see a citizen's process diverted to the service of pharmaceutical companies playing games to hold off generic entry as long as possible. Consumers, of course, would end up paying the price.

THE EFFICIENCIES DEFENESTRATION: ARE REGULATORS THROWING VALID HEALTHCARE EFFICIENCIES OUT THE WINDOW?

By Jacob Snow, Ronnie Solomon, Kyle Quackenbush[1]

I. INTRODUCTION

Assessing efficiencies is an important part of any regulatory merger review. Efficiencies that are merger-specific and verifiable can, under the Merger Guidelines, save an otherwise anticompetitive merger. The presentation by merging parties of pro-competitive efficiencies is often referred to as an efficiencies "defense."

Healthcare in the United States is changing. Recent years have brought a significant increase in healthcare mergers, and provisions in the Patient Protection and Affordable Care Act ("Affordable Care Act") encourage integration and coordination of healthcare services. In light of these changes, some argue that regulators put too little weight on efficiencies in the healthcare context, and that the high bar set by the Merger Guidelines—requiring that efficiencies be verifiable and merger specific—is an unnecessary hindrance to healthcare mergers that will benefit the public. Does it make sense to continue to hold efficiencies to such a high bar, in the face of technological developments and pressure on healthcare entities to integrate?

This article argues that the Merger Guidelines' (relatively) strict standards should be maintained. Federal regulators have challenged relatively few of the thousands of healthcare combinations announced in recent years. Under the Merger Guidelines, antitrust regulators give careful consideration to efficiency claims, despite lingering uncertainty in the courts about the role of efficiencies under the law. Nor does the Affordable Care Act *require* that companies pursue a merger or acquisition. There is also much the parties can do to present real efficiencies that are more likely to pass regulatory muster. Finally, state laws that provide antitrust immunity to entities seeking to integrate are not the answer. And there is little support for the notion that these laws are a direct consequence of overly-stringent enforcement by antitrust regulators.

A. The Role of Merger Efficiencies Under the Law is Uncertain

There is lingering uncertainty over whether claimed efficiencies can overcome a merger's anticompetitive effects. For starters, an efficiency defense has no clear statutory basis. Section 7 of the Clayton Act does not mention efficiencies.[2] Neither does case law provide clear guidance on the application or scope of an efficiency defense. The Supreme

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2 Section 7 of the Clayton Act prohibits mergers and acquisitions where the effect "may be to lessen competition, or to tend to create a monopoly." 15 U.S.C. § 18.

Court has never officially recognized an efficiency defense,[3] and instead has "cast doubt on its availability."[4] And no court has ever held that the claimed economic efficiencies were sufficient to overcome an otherwise unlawful merger.

Lower courts are split. Several circuit courts have recently cast doubt on whether an efficiencies defense exists and on its scope.[5] In *St. Luke's,* the Ninth Circuit affirmed a district court ruling that plaintiffs' economic efficiencies were not merger-specific and were insufficient to rebut a *prima facie* case of Section 7 illegality. While the Ninth Circuit decision assumed the availability of an efficiency defense, it also noted its uncertain status: "we remain skeptical about the efficiencies defense in general and about its scope in particular."[6] More recently, the D.C. Circuit addressed in *United States v. Anthem* whether an efficiency defense exists. In *Anthem,* the D.C. Circuit affirmed a lower court finding that the claimed efficiencies of a merger between two large health insurance providers were neither merger-specific nor verifiable.[7] As in *St. Luke's,* the court assumed the availability of the defense, but cautioned that "it is not at all clear that [efficiencies] offer a viable legal defense to illegality under Section 7," citing the Supreme Court's "clear holding" in *Procter & Gamble.*[8] Moreover, *Anthem* noted that while some courts recognized efficiencies as a means to rebut a *prima facie* case, the question of whether efficiencies can serve as an ultimate defense under Section 7 remains unresolved.[9]

Other circuits have recognized the availability of efficiencies, at least to rebut a *prima facie* case of illegality; but none of those decisions found that the claimed efficiencies

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3 Because the Supreme Court has not definitively addressed the issue of whether a pro-competitive efficiency can serve as a "defense" to an otherwise anticompetitive merger, there is some argument that the issue is one still open for determination. *See FTC v. Penn State Hershey Medical Center,* 838 F.3d 327, n. 8 (3rd Cir. 2016) ("Some commentators have argued that, because the efficiencies defense has never been squarely presented to the Supreme Court, the issue has never been definitively decided."). Others have argued that the modern approach to reviewing mergers must consider efficiencies. In *U.S. v. Anthem,* Judge Kavanaugh argued in a dissenting opinion that the "modern approach" to antitrust law recognizes that courts "must take account of the efficiencies and consumer benefits that would result from this merger. Any suggestion to the contrary is not the law." *See United States v. Anthem,* 855 F.3d 345, 376–77 (D.C. Cir. 2017). Judge Kavanaugh relied on a line of cases, including *U.S. v. General Dynamics,* 415 U.S. 486 (1974) and *United States v. Baker Hughes, Inc.,* 908 F.2d 981 (D.C. Cir. 1990). *Id.*

4 *See FTC v. Procter & Gamble,* 386 U.S. 568, 580 (1967) ("Congress was aware that some mergers which lessen competition may also result in economies but it struck the balance in favor of protecting competition."); *Brown Shoe Co. v. United States,* 370 U.S. 294 (1962) (casting doubt on the economic efficiency defense and stating "we cannot fail to recognize Congress' desire to promote competition through the protection of viable, small, locally owned business.").

5 *See Anthem,* 855 F.3d 345; *FTC v. Penn State Hershey Medical Center,* 838 F.3d 327, 348 (3rd Cir. 2016) (declining to recognize efficiency defense and noting: "we have never formally adopted the efficiencies defense . . . we are skeptical that such an efficiencies defense even exists."); *Saint Alphonsus Medical Center Nampa, Inc. v. St. Luke's Health System, LTD.,* 778 F.3d 775, 790 (9th Cir. 2015) ("we remain skeptical about the efficiencies defense in general and about its scope in particular.").

6 *St. Luke's,* 778 F.3d at 790.

7 *United States v. Anthem,* 855 F.3d at 348–49.

8 *Id.* at 353 (citing *FTC v. Procter & Gamble*).

9 *Id.* at 355 ("In this expedited appeal, prudence counsels that the court should leave for another day whether efficiencies can be an ultimate defense to Section 7 illegality.").

actually rebutted the presumption.[10] Courts that have recognized economic efficiencies have limited their scope. In *University Health,* the Eleventh Circuit noted that efficiencies are "an important consideration in predicting whether the acquisition would substantially lessen competition," but that once a court determines that a merger would substantially lessen competition, "expected economies, however great, will not insulate the merger from a section 7 challenge." [11] Where recognized, the focus of an efficiencies defense is whether they will enhance or heighten competition, rather than lessen it, and whether the *prima facie* case inaccurately portrays the merger's probable effects on competition.[12]

B. Whatever Their Status Under the Law, the Merger Guidelines and Antitrust Regulators Recognize Economic Efficiencies

Despite this case law, efficiencies are nonetheless important. Antitrust regulators take efficiency arguments presented by parties seriously in reviewing a merger. The 2010 Horizontal Merger Guidelines ("Merger Guidelines"), issued by the Federal Trade Commission ("FTC") and the Department of Justice ("DOJ"), specifically recognize efficiencies in reviewing mergers. Section 10 of the Merger Guidelines sets out the framework for assessing efficiencies. Under the Merger Guidelines, efficiencies are weighed against anticompetitive effects provided that those efficiencies are cognizable—that is, the claimed efficiencies must be "merger-specific" and "verifiable."[13] More precisely, federal antitrust regulators will not challenge a merger "if cognizable efficiencies are of a character and magnitude such that the merger is not likely to be anticompetitive."[14] In other words, regulators consider whether cognizable efficiencies are likely to "reverse" potential harm to consumers. While the Merger Guidelines are neither precedential nor binding on courts, they inform regulators' analysis and may serve as a "helpful tool" to courts in merger cases.[15] Thus, efficiencies can and do play an important role in analyzing the anticompetitive effects of a merger at the agency level. A former Director of the FTC's Bureau of Competition has emphasized that the agencies review efficiencies closely, noting that "studying only litigated cases for guidance on efficiencies presents a skewed sample set, given the very high levels of concentration

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10 *See Pro Medica Health Sys., Inc. v. FTC,* 749 F.3d 559, 568 (6th Cir. 2014); *H.J. Heinz Co.,* 246 F.3d 708, 716 (D.C. Cir. 2001); *FTC v. Tenet Health Care Corp.,* 186 F.3d 1045 (8th Cir. 1999); *FTC v. Univ. Health, Inc.,* 938 F.2d 1206, 1219-20 & n.27 (11th Cir. 1991).

11 *University Health,* 938 F.3d 1222, n.29. The Eleventh Circuit in *Univ. Health* stated "it may further the goals of antitrust law to limit the availability of an efficiency defense."

12 *St. Luke's,* 778 F.3d at 790.

13 The standard that applies to efficiencies, well known among the antitrust bar, is that efficiencies are creditable, or cognizable, where they are merger-specific (unlikely to be achieved absent the merger), verifiable (not vague, speculative, or otherwise cannot be verified by reasonable means), and do not arise from anticompetitive reductions in output. *See* Merger Guidelines, Section 10.

14 Merger Guidelines, Section 10.

15 *Anthem,* at 349: The *Anthem* court noted that the Merger Guidelines are a "helpful tool, in view of the many years of thoughtful analysis they represent, for analyzing proposed mergers."

involved in most litigated cases, and lingering doubts by some courts about the legal basis for an 'efficiencies defense.' "[16]

II. ARGUMENT

Market trends and changes in the law should be taken into account by antitrust authorities in reviewing mergers. Today, the law of healthcare is undergoing changes and healthcare providers and insurers likely have opportunities to improve their operations by operating more efficiently and delivering higher quality care to their customers.

These opportunities have been the recent focus of policymakers. President Obama's opening remarks at the White House Health Care Summit on March 5, 2009, focused on "the exploding costs of healthcare in America," and characterized healthcare reform as "no longer just a moral imperative, it's a fiscal imperative."[17] This sentiment echoed concern that the United States healthcare outcomes were worse than international peers while its costs were significantly higher.[18] The ACA's structure was motivated in part by this triad of concerns: coverage, cost, and quality.[19] And the ACA's proposed means of improving healthcare along these dimensions were numerous and ambitious. A five-year review of the ACA called the law "one of the most aggressive efforts in the history of the nation to address the problems of the delivery system."[20]

Among the primary efforts in that regard were the ACA's provisions directed at moving payment for healthcare services away from volume-based fee-for-service reimbursement and towards linking provider payments to better patient outcomes.[21] Those provisions include modifications that aim to create additional incentives for providers to reduce both: 1) patients being admitted to the hospital after discharge and 2) the rate of conditions acquired in the hospital during treatment.[22] Other provisions in the ACA encourage providers and insurers to form new organizations called Accountable Care Organizations ("ACOs") that enable "integration and coordination of ambulatory, inpatient, and post-acute care services."[23] Some see ACOs as "a bridge from fragmented fee-for-service care to integrated, coordinated delivery systems that resemble the tightly

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16 *FTC v. Sysco: Old-School Antitrust With Modern Economic Tools,* Remarks of Deborah L. Feinstein, Director, Bureau of Competition, September 18, 2015 (available at https://www.ftc.gov/public-statements/2015/09/ftc-v-sysco-old-school-antitrust-modern-economic-tools).

17 Transcript of President Obama's Opening Remarks White House Health Care Summit, March 5, 2009 (https://www.c-span.org/video/transcript/?id=1117).

18 For recent data, *see* U.S. Health Care from a Global Perspective: Spending, Use of Services, Prices, and Health in 13 Countries, Commonwealth Fund pub. 1819 Vol. 15 ("On several measures of population health, Americans had worse outcomes than their international peers."), available at http://www.commonwealthfund.org/~/media/files/publications/issue-brief/2015/oct/1819_squires_us_hlt_care_global_perspective_oecd_intl_brief_v3.pdf.

19 *The Affordable Care Act at 5 Years,* David Blumenthal, M.D., M.P.P., Melinda Abrams, M.S., and Rachel Nuzum, M.P.H., N. Engl. J. Med. 372;25 (June 18, 2015).

20 *Id.*

21 *Id.*

22 *Id.* at 2453.

23 *Id.* at 2454.

organized Medicare Advantage plans."[24] Participants in the healthcare market can be forgiven for interpreting the ACA—as well as market trends more broadly—as pointing to integration and consolidation as the path towards a healthcare system that delivers higher quality care at lower cost to more people.

A widely read article from The New Yorker in 2009 similarly described the challenge policy-makers seeking healthcare reform face as a choice between fee-for-service medicine, in which doctors care is compensated in proportion to the procedures they perform, and structures in which providers "adopt[] measures to blunt harmful financial incentives" and "[take] collective responsibility for improving the sum total of patient care."[25] The article concluded memorably as follows:[26]

> *As America struggles to extend healthcare coverage while curbing healthcare costs, we face a decision that is more important than whether we have a public-insurance option, more important than whether we will have a single-payer system in the long run or a mixture of public and private insurance, as we do now. The decision is whether we are going to reward the leaders who are trying to build a new generation of Mayos and Grand Junctions. If we don't, McAllen won't be an outlier. It will be our future.* ♦

In the wake of the Affordable Care Act's passage in 2010 and the wave of consolidation that followed, some merging parties have taken on the mantle of "leaders . . . trying to build a new generation of Mayos and Grand Junctions." And the "reward" sought was the close of an investigation into a proposed healthcare merger. Given the importance of healthcare and the potential benefits of improving quality and reducing cost on a large scale, it is a fair question whether these benefits are (or should be) cognizable efficiencies under the Merger Guidelines.

Those guidelines require that efficiencies be verifiable and merger-specific in order to offset the anticompetitive effects of a transaction. These restrictions ensure that purported efficiencies are not used to offset the anticompetitive effects of a transaction unless completing the transaction is likely to achieve the efficiency (the verifiable requirement) and the efficiency is not achievable without the merger (the merger-specificity requirement).

A. The Economic Literature Casts Doubt on Whether Cost and Quality Benefits of Consolidation Are Verifiable

Over the last two decades, there has been significant consolidation in healthcare, including a notable increase in mergers and acquisitions in the wake of—though not

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24 *Id.*

25 *The Cost Conundrum,* The New Yorker, June 1, 2009 (available at http://www.newyorker.com/ magazine/2009/06/01/the-cost-conundrum) ("The lesson of the high-quality, low-cost communities is that someone has to be accountable for the totality of care. Otherwise, you get a system that has no brakes. You get McAllen.").

26 *The Cost Conundrum,* The New Yorker, June 1, 2009 (available at http://www.newyorker.com/magazine/2009/06/01/the-cost-conundrum).

necessarily as a result of—the ACA.[27] Between 1998-2015, over 1,400 hospital mergers were announced.[28] And there has been a significant increase since 2011, with five of the top seven most active years (by announced mergers) occurring in the last five years.[29] Many of those mergers involve the purchase of multiple hospitals.[30] And the number of hospitals that operate as part of a larger health system has also increased in the last decade, from approximately 2,700 in 2004 to 3,200 in 2014.[31]

Consolidation is not necessarily bad for consumers. Mergers between competitors have the potential to benefit consumers by enabling the merged entity to, for example, take advantage of economies of scale and scope and to purchase inputs at lower prices by gaining leverage over suppliers.[32] Consumers can also benefit if merging parties lower prices to consumers as a result of these efficiencies.[33] The Merger Guidelines balance the potential benefits of an acquisition against the likely competitive harm. But those guidelines also take the practical realities of the legal process into account, where the challenging agency must prove that a transaction is likely to substantially lessen competition.[34] An "ephemeral possibility" of anticompetitive effects is not sufficient to establish that a merger is unlawful.[35]

It is not appropriate, however, to presume that clinical and operational integration in the healthcare field is likely to result in lower costs or better care. Economic research indicates that neither hospital mergers nor the formation of integrated delivery systems reliably produce the efficiency or quality improvements that would be required to justify an otherwise anticompetitive transaction.

1. Mergers Between Competitor Hospitals Generally (Though Not Always) Result in Increased Prices

When hospitals merge, the concern for antitrust regulators is a simple one. Before the merger, competition between the two firms may be effective at restraining prices. But after the merger, a hospital's customers may have no (or fewer) alternatives, allowing the merged firm to charge higher prices.[36]

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27 American Hospital Association, Trendwatch Chartbook, 2015, Chart 2.9; *see also* Martin Gaynor, New Health Care Symposium: Consolidation And Competition In US Health Care (available at http://healthaffairs.org/blog/2016/03/01/new-health-care-symposium-consolidation-and-competition-in-us-health-care/).

28 American Hospital Association, Trendwatch Chartbook, 2015, Chart 2.9.

29 *Id.*

30 *See id.* (showing that the number of hospitals acquired per year is larger (often by greater than a factor of 2) than the number of hospital-acquisition deals).

31 American Hospital Association, Trendwatch Chartbook, 2015, Chart 2.4.

32 *Effects of hospital mergers and acquisitions on prices,* Ranjani A. Krishnana, Hema Krishnan, 56 Journal of Business Research 647–656, 647 (2003).

33 *Id.*

34 *Brown Shoe Co. v. United States,* 370 U.S. 294, 323 (1962).

35 *United States v. Marine Bancorp., Inc.,* 418 U.S. 602, 623 (1962).

36 *See Do hospital mergers reduce costs?,* Matt Schmitt, Journal of Health Economics 52 (2017) 74–94.

Economic literature going back to the 1990s indicates that, generally, hospital consolidation results in higher prices. A 2006 synthesis of research on the impact of hospital mergers on price, costs, and quality of care concluded that "hospital consolidation in the 1990s raised prices by at least five percent, and likely by significantly more."[37] The same review noted that while the "great weight of the literature shows that hospital consolidation leads to price increases," "a few studies reach the opposite conclusion."[38] Studies examining consolidation among hospitals that are geographically close to one another found that "consolidation leads to price increases of 40 percent or more."[39] A 2012 update to the 2006 review came to similar conclusions, noting that hospital consolidation generally increases prices and that competition (not consolidation) between hospitals increases quality of care.[40]

A more recent analysis of hospital mergers undertook a broader assessment of whether cost reductions followed mergers between hospitals in the same and in different markets.[41] That study found an average cost reduction between 4 and 7% in the years following the acquisition.[42] The overall result indicates that cost reductions are possible (and even likely) when the merging hospitals are *not* competitors. But in that survey, the results for mergers between hospitals in the same market were not generally statistically significant, and the author cautions against applying the results to in-market acquisitions.[43]

2. The Potential Benefits of Integrated Healthcare Delivery Systems Are Not Apparent in the Literature

An "integrated delivery system" refers generally to an organization that both serves as a provider of healthcare services and bears some measure of financial risk for the health outcomes of the covered patient population.[44] That financial risk can come in many forms, from Accountable Care Organizations, to providers that contract on a capitated basis with health plans, to fully integrated provider systems with premiums as a sole source of income.[45] The idea that vertically integrated healthcare delivery systems might

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37 Wiliam B. Vogt, Ph.D. and Robert Town, Ph.D., *How has hospital consolidation affected the price and quality of hospital care?,* The Synthesis Project, Robert Wood Johnson Foundation (February 2006) (available at https://www.rwjf.org/en/library/research/2006/02/how-has-hospital-consolidation-affected-the-price-and-quality-of.html).

38 Vogt and Town at 4.

39 Vogt and Town at 4.

40 Martin Gaynor, PhD1 and Robert Town, PhD, *The Impact of Hospital Consolidation,* The Synthesis Project, Robert Wood Johnson Foundation (available at https://www.rwjf.org/en/library/research/2012/06/the-impact-of-hospital-consolidation.html)

41 *Do hospital mergers reduce costs?,* Matt Schmitt, Journal of Health Economics 52 (2017) 74–94.

42 *Id.*

43 *Id.* at 84 ("From an antitrust perspective, out-of-market acquisitions—for which cost savings appear to be more prominent—are likely not as relevant as in-market acquisitions.").

44 *See Integrated Delivery Networks: In Search of Benefits and Market Effects,* Jeff Goldsmith, Lawton R. Burns, Aditi Sen, Trevor Goldsmith (National Academy of Social Insurance, February 2015) (available at https://www.nasi.org/research/2015/integrated-delivery-networks-search-benefits-market-effects).

45 *Id.* at 5.

have incentives to control costs while increasing quality is not a new one. Advocates of moving healthcare towards an integrated model argue that it improves quality and reduces cost, first, by improving coordination among providers.[46] An integrated system, they argue, will be better able to share information between providers through a centralized medical records system.[47] A second benefit of integrated care is that financial risk taken by the integrated system will encourage the management of care across healthcare providers.[48] Integrated systems, in this way, have the potential to eliminate the incentive to perform unnecessary tests and treatment that is inherent in fee-for-service medicine.[49]

A study by the National Academy of Social Insurance (NASI) analyzed a sample of integrated delivery networks (referred to as "IDNs") to understand how those organizations performed compared with non-integrated alternatives.[50] That study concluded that "the likelihood that IDNs are producing *neither cost nor quality advantages* over dispersed networks of caregivers assembled by health plans raises serious policy questions regarding the reliance upon ACOs as a contracting model by Medicare or private insurers."[51] But the study also noted that its conclusions were preliminary, and encouraged policy-makers to seek "a more solid evidentiary foundation" before assuming that integrated care generally yields the cost and quality benefits many have hoped for.[52] A particular limitation of the NASI study was that its performance assessment was based on publicly available information about the subject integrated systems.[53]

The empirical work in this area should not be interpreted as an insurmountable barrier to asserted efficiencies. Quite the contrary, some integrated systems achieve impressive results and can serve as an operational model for delivering higher-value care. But regulators should expect merging parties to offer compelling evidence to show that efficiencies are likely based on the particular facts of the merger under review. It is not enough to rely on the possibility of efficiencies resulting from a transaction's structural characteristics that have a mixed record of practical success.

B. A Response to Fendall and Maas

In a companion article, Kaley Fendall and David Maas levy two criticisms of regulator's consideration of efficiencies.[54] First, they argue, regulator's assessment of efficiencies should be more transparent, offering merging parties guidance that will allow them to more reliably ascertain the outcome of a particular merger review.[55] And

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46 *Id.* at 7.

47 *Id.* at 7 (citing supporting literature).

48 *See id.* at 8 (citing supporting literature).

49 *See id.* at 8 (citing supporting literature).

50 *See Integrated Delivery Networks: In Search of Benefits and Market Effects* at 5.

51 *See id.* at 29 (emphasis added).

52 *Id.* at 29.

53 *See id.* at 1, 29.

54 Kaley Fendall & David Maas, *Where Art Thou, Efficiencies? The Uncertain Role of Efficiencies in Merger Review,* Competition, Winter 2017–2018, pp. 7–11.

55 *Id.* at 7–9.

second, the authors argue that the burden of demonstrating creditable efficiencies is too high, likely dooming beneficial combinations.[56]

With respect to the transparency criticism, it may be true that regulators can improve the guidance to industry, but significant efforts to be transparent have been made in the past. In 2006, the FTC and the DOJ released the Commentary on the Horizontal Merger Guidelines, which offered additional guidance describing how regulators view the review process.[57] That commentary also included high-level discussion of how the reviewing agency viewed particular transactions. Assessing the Nucor-Birmingham Steel transaction in 2002, for example, the commentary noted that "the Department concluded that plausible merger-specific reductions in variable costs were significant relative to the worst case scenario of anticompetitive effects from the acquisition, and the Department granted early termination under HSR."[58] This kind of analysis appears to be what Kendall and Maas are looking for, and we agree that the FTC and DOJ should consider an updated commentary based on the 2010 Merger Guidelines.

Kendall and Maas's argument for giving more weight to efficiency claims is, in our view, less persuasive. The authors' point to integrated value-based care and the application of technology to healthcare as justifications for giving more weight to efficiency claims.[59] As we explain above, the trend towards integrated care may be real, but the economic literature indicates that integration does not necessarily yield efficiency gains. For that reason, a case-by-case assessment is necessary, and a case-by-case assessment is what the Merger Guidelines require.

Similarly, recent developments in machine learning and medical technology may well yield efficiency and quality improvements that benefit patients and providers alike.[60] But exuberance about the promise of new technologies is no substitute for concrete evidence that a transaction is necessary to achieve particular efficiency gains. If that evidence exists, the Merger Guidelines provide an adequate framework for regulators to consider it. It is neither necessary nor wise for the FTC and DOJ to give more weight, across the board, to efficiency claims when technological developments merely have the potential to transform an industry. If that transformation is coming, consolidation may not be necessary to achieve it.

Kendall and Maas also point to unintended, negative consequences of excessive scrutiny, including state laws providing antitrust immunity to healthcare combinations. These include Certificate of Public Advantage ("COPA") statutes, which permit hospitals and other qualifying entities to merge, affiliate, and conduct other activities that would

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56 *Id.* at 9–11.

57 Commentary on the Horizontal Merger Guidelines, U.S. Department of Justice and the Federal Trade Commission, March 2006.

58 *Id.* at 50.

59 Kendall & Maas, p. 9 ("As we are seeing drastic changes in the way healthcare is delivered—more integrated value-based care, the introduction of machine learning and artificial intelligence, the rapid development of new medical technology—it seems that we are in or entering another era when efficiency arguments for provider mergers should be given more credit.").

60 *See, e.g.,* How Big Tech Is Going After Your Healthare, https://www.nytimes.com/2017/12/26/technology/big-tech-health-care.html?_r=0.

otherwise be subject to federal antitrust regulation. COPA laws expressly permit these combinations and affiliations, and provide corresponding antitrust immunity, where they further a state's expressed public policy.

But Federal antitrust agencies should not apply a lower standard to efficiency claims in response to oft-misguided state laws that may seek to circumvent the antitrust laws. COPA laws may result in negative outcomes for consumers and competition, and such a move would only further harm consumers and competition. Moreover, there is no evidence that such laws are a result of overly strict federal antitrust enforcement and policies.

1. How Can Merging Parties Present Creditable Economic Efficiencies?

In assessing how parties can present successful efficiencies claims, it is first worth considering when efficiency claims are likely to matter. Even where efficiencies are cognizable, they must still outweigh the likely competitive harms. In general, efficiencies will not tip the scale where a merger is highly anticompetitive and is likely to result in significantly lessened competition and consumer harm. "Possible economies cannot be used as a defense to illegality,"[61] and efficiencies "almost never justify a merger to monopoly or near-monopoly."[62] The Merger Guidelines recognize that the more anticompetitive a merger is likely to be, the greater the cognizable efficiencies and the consumer pass-through there must be.[63] This balance makes sense, given that it is competition and consumers, not competitors, which antitrust law aims to protect.

While every case is fact-specific, the following may promote a successful efficiency claim:

First, parties should present honest and realistic efficiency claims while avoiding claims that are aspirational or for which they offer no support.[64] Such claims are not likely to be verifiable. Presenting unsubstantiated claims may also affect credibility and cause regulators to cast doubt on other efficiency claims.

Second, merger review most often occurs outside the purview of a court and involves federal agency review. In this context, merging parties must convince a federal agency that claimed efficiencies are creditable. This has some benefit for merging parties. At the agency level, as opposed to in the context of litigation, parties are not faced with a legal standard or rebutting a *prima facie* case of illegality. It may therefore be easier to convince regulators to accept efficiencies than it would be to persuade a court. Of course, parties must still demonstrate that efficiencies are merger-specific, verifiable, and do not arise from anticompetitive reductions in output.

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61 *St. Luke's*, 778 F.3d 775, 789 (2015).

62 Merger Guidelines, Section 10.

63 *Id.*

64 In *St. Luke's*, for instance, the court did not credit claims that the merger would likely lead to an integrated health delivery system, noting that the parties merely desired to move in that direction. And in *Anthem*, the court found that the claimed $2.5 billion in cost savings was inflated and unsubstantiated.

Third, parties must present efficiencies that benefit consumers. For instance, merging hospitals often present claims of improved quality of care, avoidance of capital expenditures, job consolidation and operational cost reductions.[65] Efficiencies that result in pro-consumer cost savings, quality improvements, and increased product offerings are critically important. By contrast, operational and cost efficiencies that will only increase a company's profits, and that will not be passed-through to consumers, are less likely to be persuasive.

Fourth, parties should endeavor to present economic efficiencies that are real, achievable, and that have demonstrable support. This includes, for example, where an efficiency is based on ordinary-course business documents, executive testimony, or on a company's past business experience,[66] as opposed to claims that are designed for litigation. Past experience might include a track record of achieving cost savings and consumer pass-through, or successfully achieving quality-of-care improvements in prior acquisitions. Mergers that are efficiency-driven combinations, and where efficiencies are a key part of the deal rather than an afterthought, are more likely to be successful. As two commentators note: "FTC staff place great weight on evidence that executives evaluated likely cost-savings of a merger as part of the deal analysis and did so identifying the sources of cost savings in a concrete, specific way."[67]

Fifth, parties must be specific regarding the claimed efficiencies. The Merger Guidelines recognize that information is often "uniquely" in the possession of merging firms, and courts have noted the difficulty in predicting future outcomes in merger cases. Parties should therefore provide as much specific information as possible to regulators in assessing claims. A former FTC Bureau Director summarized this point aptly: "[t]he parties must explain more than just the processes and practices that the acquiring hospital system can transfer to an additional hospital; they need to address the specifics of how those processes and practices will benefit patients through improved care."[68] And, with respect to some quality efficiencies, there is an argument that "the more specific the efficiency, the less justified is an assumption that it would be realized with an alternative partner."[69]

Specifics can take the form of detailed plans for achieving efficiencies, independent verification of the claimed efficiencies, and concrete explanations why the efficiency is likely to succeed or otherwise could not happen absent the merger. For instance, if

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65 *See* Feinstein (2015) for a discussion of how efficiencies are evaluated. (Feinstein, *"FTC v. Sysco: Old-School Antitrust With Modern Economic Tools,"* remarks at GCR Live, New York, NY, September 18, 2015).

66 *See* Merger Guidelines, Section 10: "Projections of efficiencies may be viewed with skepticism, particularly when generated outside of the usual business planning process. By contrast, efficiency claims substantiated by analogous past experience are those most likely to be credited."

67 Perry & Cunningham, *Effective Defenses of Hospital Mergers in Concentrated Markets*, Antitrust, Vol. 27, No. 2, Spring 2013.

68 *See* Feinstein (2015) for a discussion of how efficiencies are evaluated. (Feinstein, *"FTC v. Sysco: Old-School Antitrust With Modern Economic Tools,"* remarks at GCR Live, New York, NY, September 18, 2015).

69 David J. Balan, *Merger-Specificity of Quality and Cost Efficiencies in Hospital Merger Cases,* Competition Policy International Antitrust Chronicle, July, 2017.

infection control is a quality improvement, a party could offer evidence that it has achieved these types of improvements in prior acquisitions. Where parties plan to incentivize physicians to improve quality, parties should be explicit about what those incentives are. Suppose merging parties identified the formation of an integrated healthcare delivery system ("IDS") as a merger-specific efficiency. This is a laudable goal, but integrated healthcare delivery systems vary widely. To promote it as a successful efficiency, merging parties could present specific information to show that the integration is likely to be achieved and successful. This could include details regarding how integration will be achieved, rewards and incentives systems, coordination and alignment objectives, plans for system monitoring and information sharing technologies, ideas for performance management and outcome measurement, and implementation timelines.[70] And, in the event that the parties do not move forward or are unsuccessful in implementing an IDS, are there any penalties or failures for doing so? Some of these details could come in the form of a study or a report undertaken by the parties.

Sixth, specifics may not always be feasible. Nor can parties predict the future with certainty. Yet the more investment parties can make in planning to achieve efficiencies in the future, the more specific plans and projections might be.

Parties should also be aware of when courts have rejected claimed efficiencies. While most efficiency claims never make it before a court and litigated cases are a somewhat skewed sample, they nonetheless offer useful guidance as to why specifics are important. In *Anthem*, the court highlighted Anthem's uncertain projections, the contingent nature of claimed price reductions, a lack of evidence to show how long it would take to develop an improved insurance product, and "woefully insufficient" evidence regarding why it had not previously succeeded in improving its products and services on its own (i.e., why the claimed efficiencies could only be achieved through a merger). The court also noted Anthem's failure to show how it would achieve consumer pass-through and the unreliability of its expert projections. In *St. Luke's,* the Ninth Circuit similarly refused to credit an integrated healthcare reimbursement system, because the parties merely noted a desire to move in that direction, without offering specifics.

2. COPA Laws, and other State Laws that Provide Antitrust Immunity, are Harmful to Consumers and Competition

COPA statutes are state laws that shield a non-sovereign private actor from state and federal antitrust enforcement. These laws are subject to the state action doctrine and must further: (1) "a clearly articulated and affirmatively expressed [] state policy" that is (2) "actively supervised by the state."[71] In exchange for state regulation, COPA laws allow healthcare entities to integrate, merge, affiliate, and engage in other conduct that would otherwise raise antitrust concerns, with the hope that such integration will improve quality or achieve efficiencies. COPA laws are currently on the books in

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70 *See* Suter et. al., *Ten Key Principles for Successful Health Systems Integration,* Healthcare Q. 2009 Oct. 13 (Spec No): 16–23, available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3004930/.

71 *California Retail Liquor Dealers Ass'n v. Midcal Aluminum, Inc.,* 445 U.S. 97, 105 (1980) (summarizing standards for antitrust immunity under the "state action" doctrine).

sixteen states.[72] Some states, such as New York, have passed COPA laws to promote greater integration and coordination of health services to meet the goals of the Affordable Care Act, believing that consolidation among healthcare providers may otherwise be unachievable under state and federal antitrust laws.[73]

COPA laws are often not a good thing. Some anticompetitive healthcare mergers have sought to escape federal scrutiny by petitioning state legislatures for an antitrust exemption. For example, in response to a pending FTC complaint against the consolidation of two hospitals, the West Virginia legislature amended its law to exempt the hospitals from antitrust enforcement.[74]

Some view the proliferation of state COPA statutes as an unintended, negative consequence of excessive antitrust scrutiny and the high burden by which efficiencies claims are tested. But there is little support for this assertion. As the FTC has stated in response to the passage of COPA laws, COPA regulations are based on a "fundamentally flawed" premise that procompetitive healthcare combinations are otherwise prohibited under the antitrust laws.[75] And in recent years, federal antitrust agencies have challenged very few of the thousands of healthcare mergers, joint ventures, and other collaborations.[76] When they have, it was only "after [a] rigorous analysis of market conditions showed that the acquisition was likely to substantially lessen competition."[77] And since "procompetitive healthcare collaborations already are permissible under the antitrust laws, the main effect of the COPA regulations is to immunize conduct that would *not* generate efficiencies and therefore would *not* pass muster under the antitrust laws."[78] Nor are COPA statutes a trend in response to healthcare entities buckling under the weight of the antitrust laws and failed efficiencies claims. COPA statutes are not a new phenomenon, as these laws have been around since the 1990s. The number of states with COPA laws has remained relatively stable since then, at just 16.

Moreover, COPA laws require active supervision by the state, in lieu of antitrust enforcement, and can be burdensome for the covered healthcare providers, capping

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72 Fla. Stat. § 381.0406-.0465 (rural hospitals only); Idaho Code § 39-4903; Kan. Stat. § 65-6801 to -6809; Me. Rev. Stat. tit. 22, § 1844; Miss. Code § 41-9-307; Mont. Code § 50-4-603; Neb. Rev. Stat. § 71-7701 to -7711; N.Y. Pub. Health Law § 2999-aa to -bb (proposed); Ohio Rev. Code § 3727.21 to .24; Tenn. Code § 68-11-1303; Tex. Health & Safety Code § 314.002; Va. Code § 15.2-5384.1; Wash. Rev. Code § 43.72.300 to 3.10; Wis. Stat. § 150.85; W. Va. Code § 16-29B1 to -29B26; Wyo. Stat. § 35-24-101 to -116 (all statutes current through date of publication).

73 https://www.nysenate.gov/legislation/bills/2011/S2809/amendment/D

74 *See* Brendan Pierson, *FTC drops challenge to West Virginia hospital merger*, Reuters (Jul. 7, 2016) available at https://1.next.westlaw.com/Document/I54268cd0446f11e6b6f98b2c0bdde6ed/View/FullText.html?transitionType=SearchItem&contextData=(sc.Category); Spencer Weber Waller, *How Much of Health Care Antitrust Is Really Antitrust?*, 48 Loy. U. Chi. L.J. 643, 660 (2017).

75 FTC Public Comment Re: Certificate of Public Advantage Applications Filed Pursuant to New York Public Health Law, 10 NYCRR Subpart 83-1, FTC, pg. 3, available at: https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-center-health-care-policy-resource-development-office-primary-care-health-systems/150422newyorkhealth.pdf.

76 *Id.*

77 *Id.*

78 *Id.*

profit margins and the number of doctors that may be employed. This in itself can be burdensome for parties, but also risks harming competition in a market. "Economists have long recognized the difficulties of regulating monopolists and how regulation, no matter how carefully crafted and implemented, can inadvertently create undesirable incentive."[79]

COPA statutes overall can be harmful to consumers and competition. COPA laws require active supervision by the states, but consumers may be left at the mercy of lax or inadequate oversight by state enforcement authorities.[80] There is also the prospect that covered entities will abuse the system by failing to comply with self-reporting requirements. Moreover, where a state repeals its COPA laws or ends regulation,[81] it may be left with monopolist healthcare systems that are no longer subject to supervision, thereby harming consumers. For instance, North Carolina repealed a COPA exemption in 2015 that had allowed two hospitals to merge. This ultimately left North Carolina with a monopolist hospital that increased its prices and threatened to exclude insurance companies from the market.[82] In another instance, the Montana Department of Justice granted antitrust immunity using a COPA to a merger that created a healthcare monopoly in Great Falls, Montana.[83] Montana eventually rescinded the law and ended regulation. Since then, prices have soared by as much as 38% in three years and no competitor exists in the region.[84]

For these reasons, even if COPA laws could be viewed as a consequence of antitrust enforcement policies, regulators should not change current practice. Rather, even if state legislatures offer an (ill-advised) path to immunity, regulators should remain committed to their mission of protecting consumers and promoting competition in the marketplace.

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79 Gregory S. Vistnes, *An Economic Analysis of the Certificate of Public Advantage (COPA) Agreement Between the State of North Carolina and Mission Health*, pg. 11 (Feb. 10, 2011).

80 Roger McCredie, The Kingdom of Mission: Private practice vs. Asheville's imperial healthcare system, The Tribune Papers (April 21, 2013) http://www.thetribunepapers.com/2013/04/21/the-kingdom-of-mission-private-practice-vs-ashevilles-imperial-healthcare-system/.

81 *NC Dissolves anti-Monopoly Rules on Mission Health,* Citizen Times Newspaper (September 29, 2015), available at: http://www.citizen-times.com/story/news/2015/09/29/nc-dissolves-anti-monopoly-rules-mission-health/73042066/.

82 *Patients Caught in the Cross Hairs of Mission Heath, Blue Cross Battle,* The Mountaineer (July 12, 2017), available at: http://www.themountaineer.com/news/patients-caught-in-the-cross-hairs-of-mission-health-blue/article_a23d4dcc-6643-11e7-8e2d-3f46aa69bfa4.html.

83 Jimmy Tobias, *Costly Care,* Missoula Independent (Mar. 26, 2014).

84 *Id.*

WHAT PAST AGENCY ACTIONS SAY ABOUT COMPLEXITY IN MERGER REMEDIES, WITH AN APPLICATION TO GENERIC DRUG DIVESTITURES

By Eric Emch, Thomas D. Jeitschko, and Arthur Zhou[1]

I. INTRODUCTION

Traditionally, antitrust agencies have drawn a hard line between "structural remedies" for merger harm, which are favored when available, and "behavioral remedies," which generally are not. A recent speech from the Assistant Attorney General Makan Delrahim echoed this longtime stance, and arguably drew an even harder line between the two approaches

> . . . at times antitrust enforcers have experimented with allowing illegal mergers to proceed subject to certain behavioral commitments. That approach is fundamentally regulatory, imposing ongoing government oversight on what should preferably be a free market. And, as 11 Senators wrote to the Attorney General earlier this year, the "lack of enforceability and reliability of such conditions [can] render them insufficient" to protect consumers. As we reduce regulation across the government, I expect to cut back on the number of long-term consent decrees we have in place and to return to the preferred focus on structural relief to remedy mergers that violate the law and harm the American consumer.[2]

In the antitrust context, "structural remedies" refers to remedies involving the sale of key assets[3] by the merging firms to a third firm in order to create a new competitor to replace the competition lost by the merger.[4] "Behavioral remedies," also known as "conduct remedies," refers to restrictions on the post-merger conduct of the merged firm designed to prevent the exercise of market power.[5] Behavioral remedies have historically been seen as more difficult to design, implement and monitor, and ultimately as less likely

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2 Keynote Address by Makan Delrahim at the American Bar Association's Antitrust Fall Forum, Nov. 16, 2017, *available at* https://www.justice.gov/opa/speech/assistant-attorney-general-makan-delrahim-delivers-keynote-address-american-bar

3 Key assets can include, for example, manufacturing facilities, intellectual property, or inventories.

4 U.S. Department of Justice, Antitrust Division, "Antitrust Division Policy Guide to Merger Remedies," Oct. 2004, 7.

5 *See, e.g.,* John E. Kwoka and Diana L. Moss, "Behavioral Merger Remedies: Evaluation and Implications for Antitrust Enforcement," The American Antitrust Institute, 2011, *available at* https://www.antitrustinstitute.org/sites/default/files/AAI_wp_behavioral%20remedies_final.pdf, 22.

to be effective, than structural remedies.[6] Structural remedies, in contrast, have been seen as requiring only a targeted intervention to create a market structure that prevents the exercise of post-merger market power. Structural remedies are seen as having the virtue of not legislating a firm to act against its interests, and not requiring substantial ongoing monitoring by the agencies.[7]

The thesis of this article is that this distinction is not as clear as it has been made out to be. A look back at past settlements by the agencies shows that though it is helpful as a general guide, the simple dichotomy of structural versus behavioral does not illuminate the greyer area into which most remedies, containing both structural and behavioral elements, fall (for case examples, *see* section II). A better categorization of the workability of remedies may be their overall complexity, rather than whether they are nominally "structural" or "behavioral." Structural remedies usually require some behavioral components to operate effectively and be deemed acceptable by the agencies. These may include, for instance, supply agreements in which the merging parties provide key inputs to the purchaser of divested assets until the purchaser can line up suppliers on its own, contract manufacturing agreements in which the merging party manufactures the divested product for the purchaser until manufacturing processes can be transferred and proper approvals obtained, restrictions on interfering with movement of personnel to the purchaser, or agreements to transfer know-how and help defend against future intellectual property (IP) infringement-related suits based on that know-how, among other provisions. Each of these components of a nominally "structural" remedy involves some of the same definitional and monitoring issues as a purely behavioral remedy. If anything, these behavioral elements of structural remedies have become more common over time.

As a guide to what remedies are most effective, it may be better to think less in terms of structural versus behavioral and more in terms of greater or lesser "complexity." Complexity might be increased by the sheer number of harms to be remedied. For instance, in 2016, former Assistant Attorney General Bill Baer declared in response to divestiture proposals put forward by the parties in the proposed Halliburton-Baker Hughes merger that the merger was "unfixable."[8] This was likely due at least in part to the inherent complexity of any proposal designed to remedy harms in the 23 distinct yet linked markets of harm that the complaint alleged.[9]

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6 U.S. Department of Justice, Antitrust Division, "Antitrust Division Policy Guide to Merger Remedies," Oct. 2004, 7–8. *Also see* Federal Trade Commission, "Negotiating Merger Remedies: Statement of the Bureau of Competition of the Federal Trade Commission," Jan. 2012, *available at* https://www.ftc.gov/system/files/attachments/negotiating-merger-remedies/merger-remediesstmt.pdf, 5.

7 U.S. Department of Justice, Antitrust Division, "Antitrust Division Policy Guide to Merger Remedies," Oct. 2004, 7–8.

8 Department of Justice, "Assistant Attorney General Bill Baer Delivers Remarks at Press Call Announcing that the Justice Department Seeks to Block Halliburton's Acquisition of Baker Hughes," press release, Apr. 6, 2016, *available at* https://www.justice.gov/opa/speech/assistant-attorney-general-bill-baer-delivers-remarks-press-call-announcing-justice.

9 Complaint, *United States of America, v. Halliburton Co., and Baker Hughes Inc. (*1:16-cv-00233-UNA), Department of Justice, (D.D.C. Apr. 06, 2016).

Alternatively, complexity might be increased by the extent and nature of behavioral components required to make a structural remedy work. For instance, the recent FTC evaluation of the success of past remedies found that generic drug divestitures, though largely successful, were much less successful when the divestiture involved a transfer of manufacturing to the buyer, with accompanying behavioral elements to ensure a smooth transition, rather than just re-contracting with an existing third-party supplier that could begin producing immediately for the buyer.[10] More generally, that study found that divestiture of an "ongoing business," which is inherently less complex than divesting particular sets of assets that do not necessarily constitute a standalone business by themselves, "are most likely to maintain or restore competition."[11] Conversely, a proposed divestiture of piecemeal assets tends to be discouraged given that it can require the agencies, as noted in the proposed Halliburton-Baker Hughes merger, "to devote substantial resources over many years to supervise the remedy in an attempt to see that it works."[12]

In this paper, we discuss the components of remedy complexity, and how they have differed over time and across agencies. We examine in detail some of the behavioral elements more and less commonly used in structural remedies, and discuss some purely behavioral remedies that likely lie at the outer reaches of the level of complexity that might be acceptable to the agencies. In the final section, we focus on differences in generic drug divestitures as an illustration of the notion that simpler, less complex remedies are more likely to be both workable and acceptable to the antitrust agencies, and that even remedies that seem simple and "structural" on their surface can lead to unanticipated difficulties.

II. THE COMPONENTS OF REMEDY COMPLEXITY

The purpose of a merger remedy is to preserve the efficiencies of a merger while removing the sources of anticompetitive harm. The set of remedies that may be implemented are ones that are both acceptable to the merging parties as not too damaging to the underlying rationale of the merger and acceptable to the agencies as limiting the potential for anticompetitive harm.

As a basic matter, the more complex the remedy, and the more substantial it is relative to the size of the overall merger, the less likely it is to be acceptable to both the agencies and the parties. The agencies may worry about the administrability of a complex remedy,

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10 Federal Trade Commission, "The FTC's Merger Remedies 2006–2012: A Report of the Bureaus of Competition and Economics," Jan.2017, *available at* https://www.ftc.gov/system/files/documents/reports/ftcs-merger-remedies-2006-2012-report-bureaus-competition-economics/p143100_ftc_merger_remedies_2006-2012.pdf, 31.

11 *Id.,* at 5. The FTC defines an "ongoing business" as one that "most typically" includes an established customer base, a fully-staffed facility, or an otherwise self-contained business unit that includes key assets and resources including ancillary agreements and third-party contracts. This need not have been operated as an autonomous business before the divestiture, but the buyer "could buy and be operational the next day, selling to all the same customers." *Id.,* footnote 8.

12 Department of Justice, "Assistant Attorney General Bill Baer Delivers Remarks at Press Call Announcing that the Justice Department Seeks to Block Halliburton's Acquisition of Baker Hughes," press release, Apr. 6, 2016, *available at* https://www.justice.gov/opa/speech/assistant-attorney-general-bill-baer-delivers-remarks-press-call-announcing-justice.

while parties may balk at a remedy that involves substantial portions of the assets involved in the merger. The most acceptable remedies to both sides are thus structural remedies of existing lines of businesses that are small relative to the size of the overall merger and that require few behavioral components to be effective In Regal Cinema's 2009 acquisition of Consolidated Theaters, for example, the DOJ required divestiture of four movie theaters in North Carolina with minimal behavioral components.[13] Similarly, in the recent Emerson acquisition of switchbox manufacturer Pentair, the FTC required the divestiture of a standalone Pentair switchbox business unit to the already-identified buyer Crane Co. with minimal behavioral components.[14] When these types of remedies are available, they can provide a relatively easy fix that is acceptable to both the parties and the agencies.

On the other end of the spectrum are intricate behavioral remedies that potentially cover a wide range of disparate assets. When a purely behavioral remedy is the only option, either agency may question whether a remedy is viable at all, and may see blocking the merger as the only way to prevent anticompetitive harm.[15] This presents a particular problem in vertical mergers, where there may be no real structural remedy available, and yet inherent efficiencies in combining complementary goods may mean that there is a good argument for trying to remedy the merger rather than blocking it entirely. For this reason, the agencies historically have tended to be most willing to accept purely behavioral remedies in vertical mergers, though the DOJ seems to have explicitly rejected this option in its recent consideration of the AT&T/Time Warner vertical merger.[16]

Below we discuss the components of remedies in increasing order of complexity: from the "standard" components of most structural remedies—which include some behavioral provisions—to non-standard structural remedies that sometimes add significant behavioral components, to intricate, purely behavioral remedies that form the outer reaches of what may be acceptable to the agencies.

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13 Final Judgment, *United States of America v. Regal Cinemas, Inc., and Consolidated Theatres Holdings, GP* (1:08-cv-00746-RJL), Department of Justice, (D.D.C. Oct. 30, 2008) at 3.

14 Decision and Order, *In re of Emerson Electric Company, a corporation, and Pentair plc, a corporation* (C-4615), Federal Trade Commission, (D.D.C. Jun. 12, 2017) at 14-15.

15 Given public reports and the recent statements by AAG Delrahim, this is the stance the DOJ seems to have taken in its recent evaluation of the AT&T/Time Warner merger.

16 The DOJ defines vertical mergers as those involving firms "that do not operate in the same markets, and may not result in an overlap between the assets of the purchaser and the acquired entity." *See "*Antitrust Division Policy Guide to Merger Remedies," *U.S. Department of Justice: Antitrust Division,* June 2011: 12. The FTC provides a similar definition in its online guidance on the competitive effects of mergers—"vertical mergers involve firms in a buyer-seller relationship" such as a "manufacturer merging with a supplier of an input product." *Also see* "Mergers: Competitive Effects," *Federal Trade Commission, available at* https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/mergers/competitive-effects. The current DOJ in its AT&T/Time Warner merger review seems to take a harder line against purely behavioral remedies even in the context of a vertical merger than in the past. *See, e.g.,* Brian Fung, "The Justice Department is suing AT&T to block its $85 billion bid for Time Warner," *Washington Post,* November 20, 2017, *available at* https://www.washingtonpost.com/news/the-switch/wp/2017/11/20/the-justice-department-just-sued-att-to-block-its-85-billion-bid-for-time-warner/?utm_term=.62af79e5e55d

A. Standard Components of Structural Remedies

We reviewed all merger remedies imposed by both agencies in 2008–2009—the end of the Bush administration and the beginning of the Obama administration—and 2016–2017—the end of the Obama administration and the beginning of the Trump administration.[17] Though there are some changes across the two time periods, there is a high degree of consistency both across agencies and over time in remedy design.

With few exceptions, consent decrees expire after 10 years.[18] During that period, the agencies typically require some type of compliance reporting, though the DOJ and FTC differ in both the frequency and method in which this is required. The DOJ usually requires defendants to submit reports or respond to written interrogatories "upon request," or triggered by specific market events. The FTC, in contrast, often mandates that the defendants submit compliance reports after 30 days, followed by intervals of decreasing frequency until the final judgment term has ended.

The agencies generally reserve the right to establish a divestiture and/or monitoring trustee to ensure that the divestiture is sold to an effective buyer and that the provisions of the remedy are followed by the parties. Sometimes that trustee is named in the final judgement but usually it is not. The assets to be sold to a buyer are typically mandated to be kept separate, distinct, and saleable in the period between the merger and the divestiture—the DOJ calls this a "hold separate" provision.[19]

Since use of divested assets typically involve a level of specific know-how, or, in some cases, specialized knowledge of the relevant supply chain, the agencies typically either mandate or allow the acquirer the option to accept a transitional services agreement whereby the divestor must assist the acquirer of the assets with technical or administrative issues that come up during the transition. When transitional services are stipulated, they range from a period of a couple months to at most two years and need to be provided at cost or at "commercially reasonable" terms.

Both agencies also often place restrictions on the post-merger movement of personnel to ensure that the acquirer does not lose key staff members. These restrictions can include 1) facilitating the buyer's hiring of key employees from the merging parties and 2) establishing non-interference or non-solicitation clauses to prevent the merging parties from poaching employees who may initially move to the buyer of the assets.[20]

Even these standard provisions, present in most structural remedies, contain behavioral elements—the level of assistance given in transition services agreements are

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17 These two periods were selected due to the difference in political administrations and non-trivial separation of years.

18 Though the court can choose to grant an extension in the DOJ filings.

19 U.S. Department of Justice, Antitrust Division, "Antitrust Division Policy Guide to Merger Remedies," June 2011, 25.

20 Sometimes these restrictions are accompanied with time expirations, such as in the McCormick-Unilever merger; the merging parties cannot interfere with hiring key employees for a period of one year. Decision and Order, *In re McCormick & Company, Incorporated, a corporation (C-4225),* Federal Trade Commission (D.D.C. Sep. 12, 2008) at 14.

difficult to monitor, for instance, and "commercially reasonable terms" for services that have never actually been offered may be difficult to determine. A number of nominally structural remedies, however, have gone beyond these standard terms to include a number of additional behavioral elements that the agencies deem are necessary to ensure that the remedy restores competition lost by the merger, but that add to merger complexity

B. Non-Standard Behavioral Elements of Structural Remedies

Adding additional behavioral components to a nominally structural remedy adds to its administrative complexity, but may be required to make the remedy workable in the eyes of the agencies. Three of the most common of these "non-standard" behavioral elements include 1) the provision of a supply and/or tolling agreement 2) mandatory licensing arrangements 3) firewalls.

Depending on the nature of the firms and the merger agreement, the agencies may require as part of a consent decree a supply and/or contract manufacturing agreement that guarantees a buyer a supply of key inputs, or the product itself, until it can establish its own supply relationships and manufacturing capabilities. For example, in generic drug mergers, it is not atypical for the FTC to require that the merging parties initially supply the final product and/or drug ingredients to the buyer at "economically reasonable terms" to assist the smooth transition of production and sales.[21] Typically, these agreements expire after a period of time that the agencies deem sufficient for the acquirer to begin producing the product on its own. For example, the consent decree in the ChemChina—Syngenta merger (2017), obligated the merging parties to supply finished crop protection products for up to two or three years (depending on the active ingredient in the product), at the option of the buyer.[22] This provision is designed to give the buyer time to gain the institutional knowledge and/or manufacturing know-how required to eventually produce the finished good independently of the seller.

Mandatory licensing provisions requires the merging parties to license certain intellectual property (IP) to the buyer on reasonable terms, or for free, which gives the buyer the means to produce and in some cases continue to develop the divested product.[23] For example, in the recent Danone-WhiteWave dairy products merger, the divestiture package included a non-exclusive, perpetual, and royalty-free license to use the Brown Cow Greek Formula, which allowed the acquirer to produce certain Stonyfield dairy products.[24] Further complexity can occur if licensed (or transferred) IP is the subject of a patent infringement suit. One might imagine that the acquirer of new IP would lack important information that would allow it to defend itself against patent

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21 For example, in the 2016 Mylan-Meda merger, the FTC required that the merging parties supply any requested Contract Manufacture Product at "supply cost." *See* Decision and Order, *In re Mylan N.V., a corporation* (C-4590), Federal Trade Commission (D.D.C. Sep. 7, 2016) at 20.

22 Decision and Order, *In re China National Chemical Corporation, a corporation, et al.* (C-4610), Federal Trade Commission (D.D.C. Jun. 13, 2017) at 10.

23 On some occasions, the FTC stipulates that the merging parties cannot sue the acquirer for IP products related to the divestiture in an effort to protect the acquirer from the risks attributed to IP that they did not create.

24 Final Judgment, *United States of America v. Danone S.A. and The WhiteWave Foods Company.* (1:17-cv-00592), Department of Justice, (D.D.C. Apr. 03, 2017) at 5.

infringement claims, so remedies sometimes include a provision whereby the merging parties must provide knowledgeable individuals to assist the buyer in its defense of any patent claims. For instance, in the 2009 Pfizer-Wyeth merger, the FTC required that the merging parties provide such individuals to the buyer, at no cost, in the event of a patent infringement suit.[25]

In instances where the dissemination of certain information within a firm could facilitate anticompetitive behavior, the agencies may deem it necessary to implement an information firewall as a condition for merger approval. For instance, in the 2016 merger of AMC and Carmike Cinemas, in addition to requiring the merged entity to divest movie theaters in 15 local markets, AMC was required to divest most of the ownership and all of its governance rights of National Cinemedia ("NCM"), a preshow services and cinema advertising firm, because Carmike owned significant equity in a competitor of NCM, Screenvision.[26] The merged firm was allowed to retain up to 4.99% ownership of NCM, without governance rights, but was required to implement and maintain firewalls to ensure that it did not act as a conduit for NCM or Screenvision's competitively sensitive information.[27]

One can imagine some of the problems normally ascribed to purely behavioral remedies being caused by behavioral provisions of mostly structural remedies. For supply or contract manufacturing agreements, there can be issues of timeliness or quality of supply or of how to determine the price paid. For licensing or other technology transfer arrangements, delineating all the relevant IP can be challenging, and if the buyer subsequently becomes embroiled in IP litigation, determining whether the seller is providing an appropriate level of assistance to the buyer may not be an easy thing to determine. Firewalls can be difficult to monitor and enforce. These behavioral provisions are included to protect against dimensions of possible remedy failure, but they add to the complexity of the remedy.

C. Purely Behavioral Remedies

In some cases a structural remedy may not be possible. Vertical mergers, for instance, are often not amenable to structural remedies.[28] In that case, when the agencies face an anticompetitive merger, they may confront a choice between implementing a purely behavioral remedy and simply blocking the merger. In certain cases, especially when expected efficiencies are high, it may make sense from the agency's perspective to try to design a purely behavioral remedy despite the challenges inherent in such a remedy.

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25 Decision and Order, *In the Matter of Pfizer Inc., and Wyeth* (C-4267), Federal Trade Commission, (January 25, 2010) at 45.

26 Competitive Impact Statement, *United States of America v. AMC Entertainment Holdings and Carmike Cinemas, Inc.*. Case 1:16-cv-02475, (D.D.C. Dec. 20, 2016) at 3.

27 *Id.*

28 In horizontal mergers, to alleviate the loss in head-to-head competition resulting from one of the merging parties effectively "exiting" the market, it is not surprising that remedies consist of selling off overlapping assets to a viable competitor that is intended to restore the lost competition. Vertical mergers, by definition, do not involve combining ownership of direct competitors. Instead, the agencies are more concerned with issues such as vertical foreclosure or the denial or degradation of a competitor's access from the upstream component of the supply chain.

In its 2011 Antitrust Division *Policy Guide to Merger Remedies,* the DOJ seemed to open the door to increased use of behavioral remedies relative to its earlier 2004 guidance, in particular with respect to vertical mergers. The *Guide* advised that "conduct remedies can be an effective method for dealing with competition concerns raised by vertical mergers."[29] The guidance as a whole was interpreted by some as the DOJ endorsing behavioral remedies to a greater degree than either agency had previously.[30]

Around this time, the DOJ implemented a number of complex behavioral remedies for vertical mergers—for instance in the Comcast-NBC, Google-ITA, and GrafTech-Seadrift Coke merger—that seemed to represent a greater level of behavioral complexity than the DOJ had historically found acceptable. These types of remedies may represent the outer bound of the level of complexity acceptable to the agencies.

1. Comcast-NBC Universal

In late 2009, the DOJ and the Federal Communications Commission (FCC) began reviewing the acquisition by Comcast, a large multi-video programming distributor ("MVPD"), of a 51% stake in NBC Universal ("NBCU"), a large creator of video programming content. In early 2011, the DOJ allowed the acquisition to proceed after imposing a number of behavioral conditions to address concerns that the merged firm would harm competition by foreclosing access to NBCU content by emerging online video distributors ("OVDs") that competed with Comcast (the FCC at the same time imposed its own set of conditions). The DOJ consent decree required the merged firm to provide all video programming it provides to any MVPD to OVDs on "economically equivalent" terms.[31] It also included anti-retaliation provisions designed to prevent the merged entity from "retaliating" or "punishing" any broadcast network, cable programmer, production studio, local television station, or network affiliate for providing programming to a MVPD or OVD competitor.[32]

These provisions depend on oversight and review of potential ambiguous terms like "economically equivalent" and "retaliation." Retaliatory behavior can occur in several different forms (*e.g.,* foreclosure of access, raising prices), so, accusations of retaliation would need to be reviewed on a case-by-case basis. Though the decree was approved, the court was skeptical of the efficacy of some of its provisions:

> Because of the way the Final Judgement is structured, the government's ability to "enforce" the Final Judgement and, frankly, this Court's ability to oversee it, are, to say the least, limited. . . . And despite the Government's assurances that "this Court retains jurisdiction to

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29 U.S. Department of Justice, Antitrust Division, *Antitrust Division Policy Guide to Merger Remedies,* June 2011, 12.

30 John E. Kwoka and Diana L. Moss, "Behavioral Merger Remedies: Evaluation and Implications for Antitrust Enforcement," The American Antitrust Institute*, 2011, available at* https://www.antitrustinstitute.org/sites/default/files/AAI_wp_behavioral%20remedies_final.pdf 1.

31 Final Judgment, *United States of America et al. v. Comcast Corp. et al.* (1:11-cv-00106), Department of Justice, (D.D.C. Sep. 01, 2011) at 9.

32 Final Judgment, *United States of America et al. v. Comcast Corp. et al.* (1:11-cv-00106), Department of Justice, (D.D.C. Sep. 01, 2011) at 19.

issue orders and directions necessary and appropriate to carry out or construe any provision of the Final Judgement," Supp. Stmt. At 6, and "to enforce compliance, and to punish violations of its provisions," . . . I am not completely certain that these safeguards, *alone,* will sufficiently protect the public interest in the years ahead. [33]

2. Google-ITA

In 2011, the DOJ allowed the merger of Google and ITA, the latter being a provider of a back-end airfare pricing and shopping system called QPX. This was a vertical merger because Google planned to create a consumer-facing airfare search product and to use ITA on the back end of its product, as a number of consumer-facing airfare search firms (*e.g.,* Kayak, Orbitz) already did.[34] The DOJ concluded that the merger would give Google the incentive and ability to use its ownership of ITA to foreclose competitors in "comparative flight search services" by degrading or denying access to QPX and related software.[35] To alleviate concerns that Google would leverage its ownership of ITA by degrading flight search rivals' access to ITA products and thereby harming competition, the DOJ imposed a number of behavioral restrictions, including mandated licensing, firewalls, and provisions to ensure continued investment in ITA's pricing and shopping software for use by firms other than Google. Among these was a requirement that the merged entity devote "substantially as many (or more) engineering resources (in terms of budget and full-time-equivalent employees) to the research and development and maintenance of QPX and the InstaSearch service" compared to the two years prior to the acquisition.[36]

The enforceability of these provisions seems difficult. One commentator contemporaneously flagged possible risks of these provisions, which highlight the inherent difficulty in envisioning and covering every possible scenario when designing complex behavioral remedies.

- . . . as confident as the DOJ appears, the following risks were not adequately addressed:
  - Google will provide competitors with its latest code but *will it provide timely notification of changing code specifications and interface designs?. . .*
  - Google has agreed that it will not perform data mining on competitors but, *really, is it possible to know if Google were abusing competitors' sensitive information?. . .*

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33 Memorandum Order, *United States v. Comcast Corp.,* No. 1:11-CV-00106, at 6–7 (D.D.C. Sep. 1, 2011).

34 For discussion, *see* John Kwoka*, Mergers, Merger Control, and Remedies* (Cambridge, MA: MIT Press, 2015), 136.

35 Complaint, *United States of America v. Google Inc. and ITA Software, Inc. (*1:11-cv-00688 (RLW), Department of Justice, (D.D.C. Apr. 08, 2011) at 10.

36 Final Judgment, *United States of America v. Google Inc. and ITA Software, Inc.* (1:11-cv-00688 (RLW), Department of Justice, (D.D.C. Oct. 05, 2011) at 15–16. InstaSearch was one of ITA's products that was used to reduce response times for innovative flight features that enabled consumers greater flexibility in their search for fares. *See* Complaint, *United States of America v. Google Inc. and ITA Software, Inc.* (1:11-cv-00688 (RLW), Department of Justice, (D.D.C. Apr. 08, 2011) at 11.

- Google has promised to provide its competitors with fair access to ITA's latest software, *but will Google provide these competitors with fair access to the customers they are all seeking to serve?* Nowhere does the decree explicitly mention Google's future obligation to provide other firms with access to customers by ensuring that Google will not preference its own offerings by placing them higher on the search page.[37]

3. GrafTech-Seadrift

In April 2010, the graphite electrodes manufacturer GrafTech International announced its intention to acquire Seadrift Coke. Seadrift was a major supplier of petroleum needle coke, one of the key inputs into the production of graphite electrodes.[38] The DOJ identified a potential vertical concern in that GrafTech was a buyer and would continue to be a buyer of petroleum needle coke from one of Seadrift's main competitors, Conoco. Part of GrafTech's agreement with Conoco involved a most-favored nation (MFN) pricing agreement with accompanying audit rights, including the right to access cost information, production schedules, and third-party pricing information. The DOJ was concerned that if GrafTech routinely acquired this information about one of Seadrift's main competitors, it could use that information to coordinate pricing and output in the market for petroleum needle coke.[39]

To resolve that concern, the DOJ and the parties agreed to modify the Conoco supply agreement with GrafTech to eliminate its audit and MFN provisions, and to not include such provisions in any future contract with Conoco. The DOJ also added a variety of transparency provisions, mandating that defendants were required to provide to the DOJ quarterly updates on contracts between defendants and Conoco relating to the provision of petroleum needle coke, Seadrift's projections of demand and sales, year-to-date production and sales of petroleum needle coke, and changes to production capacity or other major capital projects by Seadrift.[40] In addition, if Seadrift made a change in its capacity and production that caused annual output to shift by more than 10%, the merging parties were required to report outside of the normal quarterly reporting.[41] Finally, various provisions of the consent decree instituted firewalls between certain Seadrift and GrafTech employees.[42]

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37 Eric Clemons and Nehal Madhani, "The Google Consent Decree: Consumers Should Be Afraid, Be Very Afraid," *Huffington Post: The Blog,* Apr. 21, 2011 (updated June 21, 2011), *available at* http://www.huffingtonpost.com/eric-k-clemons/post_1954_b_851696.html.

38 Business Wire, "GrafTech Agrees to Acquire Seadrift Coke L.P. and C/G Electrodes LLC, Concludes $260 Million Revolving Credit Facility Refinancing and Reports GrafTech's First Quarter 2010 Results," April 29, 2010, *available at* http://www.businesswire.com/news/home/20100429005864/en/GrafTech-Agrees-Acquire-Seadrift-Coke-L.P.-CG

39 Complaint, *United States of America v. Graftech International LTD. and Seadrift Coke L.P.* (1:10-cv-02039), Department of Justice (D.D.C. Nov. 29, 2010) at 8–9.

40 Final Judgment, *United States of America v. Graftech International LTD. and Seadrift Coke L.P. (*1:10-cv-02039), Department of Justice, (D.D.C. Mar. 24, 2011) at 6.

41 *Id.* at 6-7.

42 *Id.* at 7-8.

4. Summary

These behavioral remedy provisions may fall on the more complex end of those acceptable to the agencies. They all occurred around the time of the revision of DOJ's merger guidance in 2011. It is difficult to know until the new administration has a number of decisions under its belt whether these types of complex behavioral remedies of vertical mergers will continue to be acceptable under current DOJ and FTC leadership, but based on the recent DOJ decision to sue to block the merger of AT&T and Time Warner rather than accept a behavioral remedy, the answer may be no.

III. DIFFERENCES IN REMEDY COMPLEXITY ACROSS TIME AND AGENCIES

With the possible exception of the vertical mergers in the 2010–2012 period, the types of remedies the agencies accepted and their standard provisions have been fairly consistent in recent years. The most important change seems to be the increasing frequency of identifying the buyer of a particular package of assets in the consent decree itself—a so-called "upfront buyer" provision—as opposed to identifying the buyer after the consent decree has been filed.[43] The DOJ went from identifying zero upfront buyers in the 2008–2009 remedies to identifying up-front buyers for 50% of its cases in the 2016–2017 period, and the frequency at the FTC increased significantly as well. The change in frequency in use of upfront buyers from the 2008-2009 period to the 2016–2017 period across the two agencies is shown in Figure 1.[44]

Figure 1. Up-front buyers are increasingly used

	DOJ			FTC		
Year	**No**	**Yes**	**% Yes**	**No**	**Yes**	**% Yes**
2008–2009	20	0	**0%**	10	11	**52%**
2016–2017	5	5	**50%**	5	14	**74%**
All four years	25	5	**17%**	15	25	**63%**

Source: DOJ Final Judgments and FTC Decision and Orders

Another change over time has been the increasing use of transitional services agreements across both the DOJ and FTC: 76% of the cases reviewed in 2016–2017 compared to only 52% in 2008–2009, as shown in Figure 2.[45]

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43 *See* U.S. Department of Justice, Antitrust Division, "Antitrust Division Policy Guide to Merger Remedies," June 2011, 22–23.

44 The percentages in Figure 1 through Figure 3 were calculated by aggregating and then tabulating information found in the DOJ Final Judgments and FTC Decision and Orders, which were both downloaded from the agencies' respective websites for the years 2008, 2009, 2016 and 2017.

45 While the period of comparison used is 2011 and 2015, Dechert LLP's Gregory Luib has also pointed out the increased frequency in which the agencies require the use of upfront buyers. *See* Gregory Luib, "The Antitrust Agencies' Recent Merger Challenges: Is the Remedial Tail Wagging the Dog?", *The Threshold,* Summer 2016 at 41.

Figure 2. Transitional services agreements are increasingly mandated ("yes")

	DOJ and FTC		
Year	**No**	**Yes**	**% Yes**
2008–2009	20	22	52%
2016–2017	7	22	76%

Source: DOJ Final Judgments and FTC Decision and Orders

While remedies are usually similarly structured across agencies, our review of recent remedies indicates that, in general, the FTC may be more willing than the DOJ to accept behavioral components of structural remedies. For instance, as shown in Figure 3, supply or toll agreements accompanying a structural remedy are much more common in FTC remedies than in DOJ remedies. In addition, FTC is nearly three times as likely to use an upfront buyer in the set of recent remedies we reviewed. These differences between DOJ and FTC remedies could also be a function of the differences in types of mergers reviewed across agencies, however.

Figure 3. Comparison of select remedy elements between the DOJ and FTC (2008–2009 and 2016–2017)

	Transitional services provided?	Up-front buyer identified?	Supply or toll agreement?
DOJ	52%	21%	16%
FTC	68%	63%	56%

Along with a higher prevalence of certain behavioral components, the FTC generally has more stringent reporting requirements than the DOJ. The FTC usually requires merging entities to proactively file written compliance reports at a regular intervals until the 10-year term of the Decision and Order has expired. The DOJ, instead, commonly requires the submission of compliance affidavits, which only need to be filed until the divestiture itself has been completed. Additionally, the FTC far more frequently than the DOJ establishes at the time of the remedy a monitoring trustee to oversee compliance with remedy orders.

IV. GENERIC DRUG DIVESTITURES

In both of its merger remedy effectiveness studies, the FTC singled out pharmaceuticals for separate discussion.[46] We now review some of the issues that arise concerning the complexity and efficacy of these remedies.

46 Federal Trade Commission, "A Study of the Commissions Divestiture Process," 1999. *See also* "The FTC's Merger Remedies 2006–2012: A Report of the Bureaus of Competition and Economics," Jan. 2017.

A. Issues in the Enforcement in Pharmaceuticals Competition

Divestitures in the pharmaceuticals industry raise some issues particular to that industry in that the economic analysis depends on which type of drugs are considered. Specifically, within the space of drug competition, there is a distinction between what is sometimes called therapeutic competition and competition between bio-equivalents.[47] The former concerns competition between different branded drugs that target the same diseases. Rather than competing on price, the main nexus of competition in therapeutic competition is the clinical profile of the drugs, including the means of administering the drug, possible side effects, possible interactions with other drugs or treatments, etc. As a result, market definition and competitive effects assessments, around which remedies are based, follows a differentiated products market analysis in which determining diversion is quite complex. Therapeutic competition is further complicated by the importance of patents. If a merger is found to raise competitive concerns that might be alleviated by a divestiture, the potential for future IP litigation raises additional issues, as the acquirer of the divested asset may not be in the same position as was the original owner to defend itself.

In contrast to therapeutic competition, competition between bio-equivalents concerns competition between generic drugs, or between generics and an incumbent brand. One might expect that, similar to therapeutic competition, a set of generics that target the same diseases are first identified as the potential relevant product market and that clinical profiles and other characteristics of the drugs determine the extent of the product market. However, in practice the analysis is much simpler. Bio-equivalents share the exact same active ingredients, and the large buyers—doctors, hospitals, pharmacies, wholesalers, and retail chains—stock all variants of a drug and do not substitute between different delivery methods of an active ingredient. Therefore, the relevant product market is characterized by an active ingredient (molecule) and delivery method. Moreover, and in contrast to therapeutic competition, by the nature of the products, potential IP litigation does not raise to the level of concern as it does with therapeutic competition, at least for the case of products already in production. As a result, competition between bio-equivalents is largely based on price, with the market often evolving into two-tier price competition: an incumbent branded variant of the drug able to command a price-premium with multiple generics at a lower price point. This suggests that assessing competitive effects and devising remedies when needed may be straightforward when it comes to competition in the generic drug market. However, despite features that would otherwise suggest a commodity-like market, merger remedies in generic drugs are not straightforward, due in part to regulatory oversight of the markets.

Production and distribution of a drug by a new market participant requires FDA approval. This process can take years and is further complicated because most pharmaceuticals are produced in plants in which several drugs are manufactured. Part of the FDA approval process concerns the production facility, and when individual drugs are divested the regulated assets require a more cumbersome review process when production is moved to another location—as is routinely the case. Indeed, when the

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47 For a detailed discussion, *see* Richard G. Frank and Raymond S. Hartman, "The Nature of Pharmaceutical Competition: Implications for Antitrust Analysis," *International Journal of the Economics of Business*, 2015, 22:2, 301–343.

transfer of production is required, filing the Drug Master Files (DMFs) with the FDA and stability and other testing easily takes several years.

The transfer of production from one manufacturer to another has additional implications for production costs, as both scale on scope economies play an important role in the manufacture of generics. Thus, when a drug is divested to a smaller rival, scope economies that were present with the divestee may not transfer, putting the acquirer at a cost disadvantage. Similarly, whether the acquirer is able to effectively replace the competition that is otherwise lost due to the merger may require that a sufficient scale of production and sales are achieved.

The bottom line is that even what may appear as standard horizontal product line divestitures can be quite complex in the context of pharmaceuticals, even in the case of generic drugs. As a result, two of the three "non-standard" behavioral elements of structural remedies that we identity in section B are common in the context of merger remedies in generic drug divestitures: the provision of a supply and/or tolling agreement, and mandatory licensing arrangements. To illustrate this we briefly consider specific mergers of generic drug manufacturers.

B. Mergers in Generic Drug Transactions

The FTC's 2017 merger remedies study reviews the efficacy of merger remedies imposed from 2006–2012. It includes 24 orders involving pharmaceutical mergers, the majority of which pertain to prescription generic drugs. In our two benchmark periods, 2008–2009 and 2016–2017, we overlap with the FTC study on two mergers in the earlier period.[48] In addition, we report on one transaction (*i.e.,* Teva-Allergan) that was beyond the 2012 scope of FTC study. Our small sample of only three transactions does not yield strong conclusions concerning trends; however, there are some noteworthy differences among the three transactions that also dovetail with the FTC study.

1. Sun-Taro

In 2008, Sun Pharmaceutical Industries announced its intention to acquire Taro Pharmaceutical Industries. In the FTC's complaint, the agency alleged that relevant lines of commerce were three oral forms of carbamazepine tablets—immediate-release, chewable, and extended-release.[49] The FTC identified Torrent Pharmaceuticals ("Torrent") as the most suitable upfront buyer for two reasons: one, due to its position as a "growing generic manufacturer," and two, its lack of presence in the carbamazepine tablet market.[50]

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48 Federal Trade Commission, "The FTC's Merger Remedies 2006–2012: A Report of the Bureaus of Competition and Economics," Jan. 2017, 30–31.

49 Complaint, *In re of Sun Pharmaceutical Industries LTD., a corporation* (C-4230), Federal Trade Commission, (D.D.C. Aug. 12 2008) at 3. Carbamazepine is a medication used to control and prevent epileptic seizures, nerve pain, and bipolar disorder.

50 "Analysis of Agreement Containing Consent Orders to Aid Public Comment," *In re of Sun Pharmaceutical Industries Ltd., File No. 071-0193,* Federal Trade Commission, Aug. 13, 2008 at 4.

Competitive concerns in the Sun-Taro transaction were tied to oral solids—generally the largest group of generics that are subject to divestiture orders and frequently also the least complex transfers. To ensure the effective transfer of divested assets in the Sun-Taro transaction, the FTC stipulated the provision of a tolling agreement, mandatory licensing of relevant IP, and transitional services to enable Torrent to obtain all of the necessary approvals from the FDA.[51]

2. Teva-Barr

Also in 2008, Teva Pharmaceuticals entered into an agreement to acquire Barr for $8.9 billion. In its complaint, the FTC evaluated a total of 29 generic pharmaceutical products across various drug forms including oral solids (*e.g.*, trazodone HCI tablets), oral liquids (*e.g.*, cyclosporine liquid), and injectables (*e.g.*, deferoxamine injection).[52] Given that some of the 29 overlapping drugs were being developed but yet to be produced and sold, one of the FTC's concerns was the threat to or elimination of future competition due to the merger.[53] To address anti-competitive concerns, the FTC ordered the divestiture of an assortment of generic drugs to the two upfront-buyers: Watson Pharmaceuticals (now Actavis) and Vintage Pharmaceuticals.[54]

The 2008 Teva-Barr transaction raised concerns tied to liquid orals and injectables, which are generally understood to be harder to successfully divest than oral solids. Along with the divestiture, the FTC required the merging parties to supply the divestiture product "for a period of time sufficient" to allow the acquirers to obtain all relevant product approvals necessary to manufacture the divested product in commercial quantities.[55]

3. Teva-Allergan

In mid-2015, Teva Pharmaceuticals announced its intentions to purchase Actavis Generics, Allergan's generic pharmaceutical business, for $40.5 billion. At the time, the deal combined the world's largest generic-drug company by sales with the third-largest competitor in generic drugs.[56] Additionally, the deal alone represented nearly 90% of the

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51 Decision and Order, *In re of Sun Pharmaceutical Industries LTD., a corporation* (C-4230), Federal Trade Commission, (D.D.C. Sep. 16 2008) at 4 and 20. *See also* "Analysis of Agreement Containing Consent Orders to Aid Public Comment," *In re of Sun Pharmaceutical Industries Ltd., File No. 071-0193,* Federal Trade Commission at 4.

52 Complaint, *In re of Teva Pharmaceutical Industries Ltd., a corporation, and Barr Pharmaceuticals, Inc., a corporation* (C-4242), Federal Trade Commission, (D.D.C. Feb. 9, 2009) at 2–4.

53 Complaint, *In re of Teva Pharmaceutical Industries Ltd., a corporation, and Barr Pharmaceuticals, Inc., a corporation* (C-4242), Federal Trade Commission, (D.D.C. Feb. 9, 2009) at 8–9.

54 Decision and Order, *In re of Teva Pharmaceutical Industries Ltd., a corporation, and Barr Pharmaceuticals, Inc., a corporation* (C-4242), Federal Trade Commission, (D.D.C. Feb. 9, 2009) at 24–26.

55 Decision and Order, *In re of Teva Pharmaceutical Industries Ltd., a corporation, and Barr Pharmaceuticals, Inc., a corporation (*C-4242), Federal Trade Commission, (D.D.C. Feb. 9, 2009) at 28.

56 Jonathan D. Rockoff, Dana Mattioli and Liz Hoffman, "Teva to Buy Allergan Generics for $40.5 Billion," *The Wall Street Journal,* July 27, 2015, *available at* https://www.wsj.com/articles/teva-to-buy-allergan-generics-for-40-5-billion-1437988044.

value of all generic drug pharmaceutical deals in 2016.[57] The FTC identified concerns in a record 79 relevant product markets across a broad variety of drug forms including oral solids, oral liquids, injectables, creams, transdermal patches and films, and gels.[58] Due to the sheer number and breadth of overlapping generic drugs, the FTC identified 11 divestiture buyers.[59]

The transaction was viewed by many as symptomatic of the increased consolidation in the generic drug market. In recognition of the complications that often arise in connection with the transfer of manufacturing of drugs and given that these acquirers had limited experience in manufacturing the divested products, Teva was required to supply the acquirers with the active pharmaceutical ingredient for a period of at least four years at commercial quantities.[60]

C. Efficacy of Merger Remedies in Generic Drug Competition

Given the main thesis of our paper, namely that the likely effectiveness of a divestiture is more tied to the complexity involved than solely a superficial distinction between structural versus behavioral remedies, we now assess what can be said about the impact of divestiture orders in the pharmaceutical industry—specifically in regard to generic drug mergers.

In reviewing the recent FTC remedies study, in all cases in which third-party manufacturing agreements existed that could simply be transferred to an acquirer, the FTC found that the acquirer did have a presence in the market post-divestiture, which fell under its definition of a "successful remedy."[61] As the FTC notes, these divestitures do not require transfer of manufacturing with the attendant complexities. In contrast, in cases where the transfer of manufacturing was required, more than a third of the acquired drugs failed to be brought to market by the acquirer; and this rate raises to above 70% of transfers that did not result in the acquirer bringing the drug to market in the case of drugs that were not oral solids (*e.g.,* oral liquids, injectables, dermatologicals, ophthalmics, or systemics).[62] That is, as the manufacture of a drug becomes more

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57 Marc-André Gagnon and Karena D. Volesky, "Merger mania: mergers and acquisitions in the generic drug sector from 1995 to 2016," *Globalization and Health,* Aug. 22, 2017 at 3 and 5.

58 Complaint, *In re of Teva Pharmaceutical Industries LTD., a corporation; and Allergan PLC, a corporation* (C-4589), Federal Trade Commission, (D.D.C. July 26, 2016) at 2–18. *Also see* Lisa Schencker, "Teva agrees to largest-ever drug divestiture in FTC pharma merger case," *Modern Healthcare,* July 27, 2016, *available at* http://www.modernhealthcare.com/article/20160727/NEWS/160729894.

59 Decision and Order, *In re of Teva Pharmaceutical Industries LTD., a corporation; and Allergan PLC, a corporation* (C-4589), Federal Trade Commission, (D.D.C. Sep. 7, 2016). *Also see* "Teva, Allergan win U.S. antitrust approval for generics deal," *Thomson Reuters,* July 27, 2016, *available at* http://www.reuters.com/article/us-allergan-m-a-teva-pharm-ind/teva-allergan-win-u-s-antitrust-approval-for-generics-deal-idUSKCN1072GM.

60 Decision and Order, *In re of Teva Pharmaceutical Industries LTD., a corporation; and Allergan PLC, a corporation* (C-4589), Federal Trade Commission, (D.D.C. Sep. 7, 2016) at 75–76.

61 Federal Trade Commission, "The FTC's Merger Remedies 2006–2012: A Report of the Bureaus of Competition and Economics," Jan.2017, *available at* https://www.ftc.gov/system/files/documents/reports/ftcs-merger-remedies-2006-2012-report-bureaus-competition-economics/p143100_ftc_merger_remedies_2006-2012.pdf, 30.

62 *Id.,* at 31.

complex, the successful transfer also becomes less likely. Thus, while a proposed remedy in generic pharmaceuticals may appear to be straightforward in that it is structural and has an up-front buyer, its implementation may nonetheless be complex and less likely to result in a successful remedy.

D. Criteria for Success Used in FTC Study

The role of complexity in the generic drug divestiture process is clouded by the criterion the FTC uses to evaluate these divestitures in its 2017 study. The purpose of divestitures is to preserve or restore competition that is lost due to the merger.[63] This is the criterion used throughout most of the 2017 FTC study.[64] However, in the assessment of pharmaceutical orders, the study defines success as "the buyer sold the product in the market post-divestiture," whether or not it replaced lost competition.[65] Indeed for the case of pipeline drugs, a mere transfer of the assets was considered a success.[66]

Given the complexity involved in these cases, it is hard to find fault in the use of alternate measures of what constitutes a success. However, the instance of a sale does not speak to the competitive impact of the buyer, let alone the preservation or restoration of competition lost due to the merger.

One can imagine more informative (albeit also imperfect) metrics to shed light on the potential efficacy of divestitures in the context of merger review in generic drug markets. Most importantly, of course, is determining prices. A complicating factor here is that list and sales prices differ and thus prices may be hard to ascertain. Similarly, market share data would also be indicative of the successful establishment of a buyer post-divestiture. Related to this is the question of the incidence and extent of possible supply disruptions that periodically plague the industry.[67]

Another critical dimension is to consider appropriate timeframes. How quickly does a buyer manage to establish itself? And does the presence of the buyer manifest itself in substantial market share several years post-transaction? These data, too, may not always be readily available. However, these questions become all the more important with the market for generics becoming increasingly consolidated; especially given the studies that

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63 U.S. Department of Justice, Antitrust Division, *Antitrust Division Policy Guide to Merger Remedies,* June 2011, 1.

64 Specifically, "The goal of any remedy is to preserve fully the existing competition in the relevant markets," and "A remedy was rated as a success if the competition in the relevant market remained at its pre-merger level or returned to that level within a short time (two to three years) after the Commission issued the order." *See* Federal Trade Commission, "The FTC's Merger Remedies 2006–2012: A Report of the Bureaus of Competition and Economics," Jan.2017, *available at* https://www.ftc.gov/system/files/documents/reports/ftcs-merger-remedies-2006-2012-report-bureaus-competition-economics/p143100_ftc_merger_remedies_2006-2012.pdf, 15.

65 *Id.,* at 30

66 *Id.,* footnote 44.

67 Marc-André Gagnon and Karena D. Volesky, "Merger mania: mergers and acquisitions in the generic drug sector from 1995 to 2016," *Globalization and Health,* Aug. 22, 2017, at 1–2.

suggest that this consolidation is directly impacting competition and prices, and that generic remedies are often not effective.[68]

Of course, a ready corollary to supply disruptions, increased concentration and increased prices in a complex market, is that determining the appropriate but-for world is a hard undertaking. Ultimately, though, the criteria and metrics used to determine potential harm to competition in the course of the merger review should also be the criteria and metrics that are employed to determine whether a particular divestiture can viewed as successful.

V. CONCLUSION

The lines between structural and behavioral remedies have become somewhat blurred. In thinking about the acceptability and ultimate success of a divestiture, it may be more useful to think in terms of the complexity of the divestiture, which may have many dimensions, rather than making a simple differentiation between structural and behavioral remedies. The generic drug market in particular, highlights the degree to which the distinction between structural and behavioral remedies is perhaps blurred. And, more to the point, it highlights how nominally "structural" remedies can be quite complex and difficult to evaluate.

68 *Id.,* at 1–2. *See also* Department of Health and Human Services, "ASPE Issue Brief: Understanding Recent Trends in Generic Drug Prices," Jan. 27, 2017. *See also* V. Dave Chintan, et al. "High Generic Drug Prices and Market Competition," *Annals of Internal Medicine, 167(3),* Aug. 1, 2017, 145–152.

RETHINKING HEALTHCARE DATA BREACH LITIGATION

By Jay Edelson and Aaron Lawson[1]

I. INTRODUCTION

In the wake of the Equifax data breach, the risk to consumer data is something that not only individuals are facing, but also companies dealing in that commodity. Maciej Ceglowski, a web developer and Silicon Valley-based entrepreneur, likens collections of personal data to radioactive waste: "easy to generate, easy to store in the short term, incredibly toxic, and almost impossible to dispose of."[2] Bruce Schneier analogizes data to a "toxic asset."[3] Ceglowski and Schneier both advocate for companies to limit the data they collect and store, if for no other reason than for companies to limit their own exposure to the fallout from data breaches, hacks, and other leaks of personal information.

Most firms, however, treat consumer data not as toxic but as beneficial: data generates value, and effort should be put into figuring out how best to wring profits from collected personal data.[4] On some level, most consumers are aware of this. Thus, the maxim "if the product is free, that means you're the product."[5]

But whether a company treats consumer data as a beneficial asset to be used or a toxic asset to be disposed of quickly, it frequently ignores the perspective of the party most affected by the nigh, ubiquitous collection of personal data: the consumer. Consumers must hand over their data to transact just about any kind of business, and this data, when aggregated can paint a remarkably revealing and intimate portrait of a given individual.[6] Consumers have an obvious interest in the security of this data, despite their choice to surrender it in a given transaction. Not only does the decision to disclose information in one circumstance not constitute blanket permission to use this data in any way the

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2 Maciej Ceglowski, "The Internet with a Human Face," http://idlewords.com/talks/internet_with_a_human_face.htm (accessed Sept. 12, 2017); *see also* Maciej Ceglowski, "Haunted by Data," http://idlewords.com/talks/haunted_by_data.htm (accessed Sept. 12, 2017).

3 Bruce Schneier, CNN, "Data is a toxic asset, so why not throw it out?," http://www.cnn.com/2016/03/01/opinions/data-is-a-toxic-asset-opinion-schneier/index.html (Mar. 1, 2016, 7:12 a.m.).

4 *See* D. Daniel Sokol & Roisin Comerford, *Antitrust & Regulating Big Data,* 23 Geo Mason L. Rev. 1129, 1139 (2017) ("a firm needs to focus on developing both the managerial toolkit and organizational competence that allows them to turn Big Data into value to consumers in previously impossible ways").

5 *See also In re Nickelodeon Consumer Privacy Litig.,* 827 F.3d 262, 265 (3d Cir. 2016) ("Most of us understand that what we do on the Internet is not completely private. How could it be? We ask large companies to manage our email, we download directions from smartphones that can pinpoint our GPS coordinates, and we look for information online by typing our queries into search engines. We recognize, even if only intuitively, that our data has to be going somewhere.").

6 The ubiquity of data collection and aggregation creates what some call a "womb-to-tomb dossier". Daniel Solove, *Access & Aggregation: Public Records, Privacy & the Constitution,* 86 Minn. L. Rev. 1137, 1192-93 (2002).

acquiring firm might want, but "the power of compilations to affect personal privacy that outstrips the combined power of the bits of information contained within."[7]

Moreover, most assessments of the costs and benefits associated with collecting and storing consumer data ignore a key, and growing, piece of the puzzle: ransomware. Data breaches can lead to bad press, customer turnover, or regulatory action; but in many cases the most immediate cost in any data breach will be the price paid for the return of access to a given system. Since most firms pass costs onto the consumer at the end of the day, this means that consumers might pay double for a firm's lax data security: once because their sensitive data has been compromised, and once because they bear a share of the ransom paid.

Both firms and courts have given insufficient attention to the consumer's interest in data privacy and security. These interests are paramount in the healthcare space. Privacy interests in healthcare-related data are both more complicated and more intuitively grasped, as demonstrated by the fact the healthcare privacy is subject to one of the most comprehensive privacy schemes.

Moreover, for institutions in the healthcare sector, heeding the suggestions of Ceglowski and Schneier—to collect as little data as possible and dispose of it as quickly as possible—is simply not feasible. Hospitals, for instance, cannot function without vast stores of information about their patients. If a doctor doesn't know what other medicines a patient is taking, she runs the risk of prescribing a lethal cocktail of medications. Likewise, a doctor that is unaware of a patient's medical history might misdiagnose a condition, accidentally delaying life-saving treatment. Hospitals must also store payment information, information on a patient's insurance, and information on family members. In short, hospitals possess a trove of incredibly sensitive information about scores of individuals.

The past few years have seen a number of data breaches in the healthcare space, notably Anthem and Premera. These should be a call to arms. Significant players in the healthcare space, however, have not responded to these incidents with the urgency that, we believe, the situation requires. They are instead content to cast themselves as unwitting victims, even when best practices dictate more proactive measures. The failure to act appears to rest on a misperception of the consumer's interest in data security. Ultimately, this failure of perception requires legislators and the courts to intervene before it is too late.

It is time we re-think how we assess data security and data breaches. Regulatory action, whether judicial or legislative, shouldn't focus on the aftermath of a breach; it should focus on preventing them in the first place.

II. HEALTHCARE FIRMS ARE UNDERVALUING DATA SECURITY

We contend that actors in the healthcare space undervalue data security, so let's begin by examining how they do value data security. One widely read study on the costs of a data breach is published annually by the Ponemon Institute. According to the Ponemon

7 *U.S. Dep't of Justice v. Reporters Committee for Freedom of the Press,* 489 U.S. 749, 765 (1989).

Institute, the cost of a data breach in 2016 was $221 per breached record.[8] According to the Ponemon study, the largest drivers of this cost are: (1) customer turnover in the wake of a breach, (2) investigating the size of the breach, and (3) defending against resulting lawsuits.[9] (These costs are greater in the healthcare space.[10])

The Ponemon study also identifies several ways in which firms can mitigate, reduce, or eliminate these costs: having a response team dedicated to data security, extensive use of encryption, training employees in proper data handling, among others.[11] In other words, data breaches and their attendant costs can be prevented by investing in data security. The Ponemon study thus strongly suggests that the interests of firms are aligned with the interests of consumers, and that both should want to invest in data security.

So what are firms doing? If an investigation by *Ars Technica* is any indication, the answer is "not much." In 2016, a series of hospitals fell prey to data breaches. According to *Ars Technica,* in each case the same network vulnerability was an issue.[12] An *AP* report on one such attack noted that the vulnerability had been known since 2007, and could have been fixed with a simple patch.[13] The vulnerability stems from the decision to use a version of an application server that has been deemed "end of life," meaning basically, obsolete.

If, as the Ponemon study suggests, both company and consumer incentives are aligned in favor of greater data security, then the persistent decision of healthcare systems not to update their networks, and thus leave them vulnerable even to unsophisticated hackers, is irrational. The problem, of course, is that healthcare firms don't see taking steps to bolster data security and prevent data breaches as financially beneficial. This appears to result from market inefficiency. For publicly traded companies, investors neither know nor care about a company's data security or vulnerability to a data breach.[14] And, of course, consumers (not to mention employees, whose data also is vulnerable) rarely have access to this information, and lack the means to agitate for change.

The Ponemon study also reveals a fatal blind spot in how companies value data security; the study never once includes ransom as a cost of a data breach. But a number of recent data breaches were also ransomwareattacks.[15] In a ransomware attack, not only

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8 Ponemon Institute, 2016 Cost of a Data Breach Study: United States, at 1.

9 *Id.* at 16.

10 *Id.* at 7 (average cost of a breached record in the healthcare sector is $402).

11 *Id.* at 9.

12 Sean Gallagher, "Two more healthcare networks caught up in outbreak of hospital ransomware," Ars Technica (Mar. 29, 2016, 4:11 p.m.).

13 Tami Abdollah, "Hackers broke into hospitals despite software flaw warnings," Associated Press (Apr. 5, 2016).

14 Kevin Magee, "Why Cybersecurity is Financially Undervalued," CFO Magazine, http://ww2.cfo.com/cyber-security-technology/2017/06/cybersecurity-financially-undervalued/ (June 23, 2017).

15 *See* Abdollah, *supra* at note 12.

are a company's files breached, but the intruder holds the files "hostage," denying access to them until a ransom is paid.[16]

This blind spot may well be because most ransom demands to date have been essentially nominal. Many early ransom demands asked for 1 Bitcoin, a cryptocurrency whose value has never exceeded $5,000. More recent demands have been closer to $80,000. Still, for a large healthcare organization, that sum is a drop in the bucket. Ransomware attacks can generate a lot of press, but if the cost does not sting, then the press coverage itself won't move the needle.

But ransomware attacks need to be seen as a new entrepreneurial front in the broader hacking economy. A normal entrepreneurial cycle begins with proof of concept. Early investments are small—a product is introduced in one market or one store, just to see if it catches on. If it does, a second round of investment spurs further development or production, and then further investment is sought as needed until supply and demand reach equilibrium. At the same time, new firms, seeking to capitalize on whatever innovation has captured the market's imagination, enter and offer their own version of the product.

Many of these same concepts are regularly applied to hacking, and apply easily to ransomware.[17] As it relates to hacking, hackers often locate vulnerabilities and then release "proof of concept" source code.[18] When this is done by "white hat" hackers, the idea is to fix the vulnerability before it becomes widely exploited. When done by "black hat" hackers, of course, the motives are far less pure.[19]

A similar framework applies easily to ransomware. Early hackers may ask only for a small ransom. The sum will grow larger as hackers try to determine what firms are willing to pay to regain access to their computer systems. Once the price reaches a certain level newer actors enter the fray. For instance, the government of North Korea has entered the ransomware game: it famously held up a bitcoin news website using a strain of malware that was previously used to cripple Britain's National Health Service.[20]

Ransomware-related costs, which are attributable to lax data security, are high and getting higher. But traditional cost studies don't account for them, and what information is available may undervalue the costs. In 2016, hospitals suffered 450 data breaches; one

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16 *See* Paul DeMuro, *Keeping Internet Pirates at Bay: Ransomware Negotiation in the Healthcare Industry,* 41 Nova L. Rev. 349, 353 (2017).

17 *See* Steven Bellovin, *et al., Lawful Hacking: Using Existing Vulnerabilities for Wiretapping on the Internet,* 12 Nw. J. Tech. & Intell. Prop. 1, 62-63 (2014); Meiring de Villiers, *Reasonable Foreseeability in information Security Law,* 30 Hastings Comm. & Ent. L.J. 419, 462 (2008).

18 Bellovin, *supra,* at 39.

19 *See* Gallagher, *supra* note 11 (noting that multiple hospitals suffering the same security vulnerability had been hacked and held for ransom).

20 *See* Yuji Nakamura & Sam Kim, "North Korea is Dodging Sanctions with a Secret Bitcoin Stash," Bloomberg, https://www.bloomberg.com/news/articles/2017-09-11/north-korea-hackers-step-up-bitcoin-attacks-amid-rising-tensions (Sept. 11, 2017, 1:00 p.m.).

report suggests that 26.8% of these were the result of ransomware, hacking, or malware.[21] Yet only 9 ransomware incidents were reported to the government.[22] This may well be because existing law doesn't mandate disclosure, particularly if the ransomware, though it might badly disrupt hospital operations, doesn't compromise patient records.[23]

Whatever the reason, this cost flies generally under the radar. Ransomware attacks might garner more press coverage than a typical data breach, but since reporting obligations are unclear and the current ransom demands are relatively low, firms don't seem to be taking them seriously. This compounds the more general disinterest in shoring up data security, leaving patient data exposed, and imposing costs on consumers in the wake of data breaches.

The end result is bad for patients: They pay up front, because healthcare firms focus on compensating officers and directors rather than investing in data security. They pay when a breach occurs, because their sensitive data is exposed. And they pay afterwards, as the costs of remediating security vulnerabilities are inevitably passed on. Unsurprisingly, many affected patients turn to the courts for recourse. But, as we explain next, they don't fare much better there.

III. COURTS ARE UNDERVALUING DATA SECURITY

As we note above, actors in the healthcare space recognize that there are costs, even legal costs to a data breach. And it is true that a data breach is nearly certain to precipitate litigation. But a review of these cases demonstrates that courts are barely even accounting for data security.

The first hurdle any data-breach case must clear is a motion to dismiss for lack of standing.[24] The core premise of such a motion is that individuals whose data has been compromised have not been "injured" in a legal sense.[25] For these purposes, an "injury" is some invasion of a legally cognizable interest.[26] So a data-breach defendant asserting that a plaintiff lacks standing is necessarily asserting that the victims of a data breach have no legally cognizable interest in data security; indeed, most defendants argue that

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21 Jessica Davis, "Experts: There's no gray area with ransomware breach reporting," Healthcare IT News, http://www.healthcareitnews.com/news/experts-there%E2%80%99s-no-gray-area-ransomware-breach-reporting (June 20, 2017, 2:36 p.m.).

22 *Id.*

23 *See* Meg Bryant, "Ransomware attacks can fall below the radar via underreporting," Healthcare Dive, http://www.healthcaredive.com/news/ransomware-attacks-can-fall-below-the-radar-via-underreporting/445351/ (June 20, 2017).

24 *See* Fed. R. Civ. P. 12(b)(1).

25 *See Spokeo, Inc. v. Robins,* 136 S. Ct. 1540, 1547-50 (discussing the "injury in fact" requirement of standing). Our discussion of standing, a federal doctrine, implies (correctly) that many of these cases proceed in federal court, under both the diversity and federal question jurisdictions. The standing problem dogs data-breach cases in state court, as well, however. In *Maglio v. Advocate Health & Hospitals Corp.,* the Illinois Appellate Court concluded that an increased risk of identity theft was too speculative to support the plaintiff's standing. 2015 IL App (2d) 140782, ¶ 24.

26 *See Sargeant v. Dixon*, 130 F.3d 1067, 1069 (D.C. Cir. 1997).

plaintiffs aren't injured until their compromised data is used to their detriment and they've suffered monetary harm.[27]

For the most part, courts have not pushed back on these premises. Most courts faced with data-breach based lawsuits agree to dismiss them for lack of any cognizable injury. The reasoning follows similar paths in most cases: (1) the risk of identity theft is too speculative;[28] (2) no part of any payment is earmarked for data security, so there is no financial harm;[29] (3) relatedly, even when hospitals promise to ensure the privacy of medical data, that promise does not encompass general data security, so there is no breach of contract that would support a lawsuit.[30]

Each of these conclusions is contestable. The second is the most defensible—the underlying theory is that your insurance premiums or hospital bills could pay for better data security, but if the market would bear the same price regardless, then any claim of financial injury is implausible. The third conclusion reflects questionable assumptions about what we mean by privacy. If data privacy is promised (and under federal law it must be[31]), why do we assume that such promises are limited to intentional disclosures? Courts (and defendants) seem to assume that a promise of data privacy can't be broken negligently, but that assumption is thus far unexamined in the cases.[32] (This, however, is largely a question of contract law.)

The first conclusion is, we think, the most troubling. If identity theft (or other misuse of personal data) is required before a plaintiff may sue, then the legally cognizable interest in these cases appears to be a narrow financial interest. Identity theft is, of course, quite costly to the victim.[33] Courts, in other words, refuse to recognize any interest in the security of personal information absent specific negotiation for that security.

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27 *See, e.g.,* Motion to Dismiss, *Khan v. Children's Nat'l Health Sys.,* No. 8:15-cv-2125 (D. Md. Filed Sept. 8, 2015), 2015 WL 12804514 (arguing that victims of data breach whose personal data had not been misused could not sue based on an increased risk of identity theft, the expenses they had incurred to protect their identities in light of the breach, the invasion of privacy occasioned by the breach, or any decrease in the value of their personal information).

28 *See, e.g., Beck v. McDonald,* 848 F.3d 262, 274 (4th Cir. 2017); *Chambliss v. CareFirst, Inc.,* 189 F. Supp. 3d 564, 570 (D. Md. 2016); *Khan v. Children's Nat'l Health System,* 188 F. Supp. 3d 524, 532-33 (D. Md. 2016).

29 *See, e.g., Fero v. Excellus Health Plan, Inc.,* 236 F. Supp. 3d 735, 754-55 (W.D.N.Y. 2017); *Khan,* 188 F. Supp. 3d at 533.

30 *See, e.g., Khan,* 188 F. Supp. 3d at 533; *Case v. Miami Beach Healthcare Grp., Ltd.,* 166 F. Supp. 3d 1315, 1319-20 (S.D. Fla. 2016).

31 42 U.S.C. § 1320d-2.

32 Similarly, many cases reject the idea of a "negligent invasion of privacy," *i.e.*, a claim for invasion of privacy centered on the defendant's negligence in permitting the invasion to occur. *See, e.g., Malloy v. Sears, Roebuck & Co.,* No. 4:96-cv-157, 1997 WL 170313, at *3-*4 (N.D. Miss. Mar. 4, 1997). A handful of cases proceeding on a similar theory related to data security have been filed, but they are generally under seal. After all, it defeats the purpose of suing to fix a security vulnerability to publicly file suit, thus exposing the critical vulnerability to the world.

33 *Holmes v. Countrywide Fin. Corp.,* No. 08-cv-205, 2012 WL 2873892, at *3 (W.D. Ky. July 12, 2012) ("The FTC has estimated that 5% of adults are affected by identity theft, resulting in annual losses to consumers of $53 billion. ") (citing a 2005 article).

Some judges believe the standing problem in data-breach cases is not injury but traceability, that is, whether any injury can be attributed to the breached organization. For instance, the dissenting judge in *Resnick v. AvMed, Inc.* would have concluded that, despite well-pleaded allegations that the defendant failed to secure a pair of laptops chock full of unencrypted patient data, any harm to the plaintiffs could not be traced to the defendant.[34] That reasoning makes plain that data security is not the focus of the court's inquiry. If it were, the lax data security itself would be identified as an injury traceable to the defendant's conduct. Another judge, in a case outside the healthcare space, would have reached a similar conclusion in *Galaria v. Nationwide Mutual Insurance Co.* The dissenting judge there reasoned that the hackers were responsible for any harm that befell the plaintiffs, not Nationwide.[35] There were no allegations, the judge thought that could connect any harm back to Nationwide.[36] Of course, the fact of a hack is evidence enough that a system has *some* vulnerability. Whether it was exploited is irrelevant to the question whether the data was properly secured in the first place. Again, this reasoning has no room for a plaintiff's interest in have their data held securely.

Even the small minority of cases that conclude that plaintiffs have standing are problematic. In general, courts will conclude that plaintiffs may proceed with a lawsuit if some stolen data has already been misused, on the theory that any risk that a particular person's data will be misused is no longer speculative.[37] But that conclusion again focuses on the financial harms that stem from identity theft, harms that are analytically separate from any interest in data security. Other cases make clear that the dispositive point in the plaintiff's favor is the existence of a statutory right that can plausibly be read to encompass preventing disclosure of the information at issue.[38] Here again, though, the legally cognizable interest is not in data security. (No statute of which we are aware creates an entitlement to data security).

And although decisions on standing to sue exhibit a modicum of consistency, data-breach decisions on the merits are all over the place. In general, plaintiffs tend to allege several theories of liability. Given the inconsistent holdings of the courts, that approach has something to recommend it.

For instance, the Eleventh Circuit in *Resnick v. AvMed*[39] concluded that an unjust enrichment claim under Florida law could proceed in the wake of a data breach, on the theory that the defendant used a portion of the plaintiff's monthly premium to "pay for the administrative costs of data management and security," and that, given the breach, it was inequitable to allow the defendant to retain those funds.[40] *Resnick* also permitted

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34 *Resnick v. AvMed, Inc.,* 693 F.3d 1317, 1331 (11th Cir. 2012) (Pryor, J., dissenting).

35 *Galaria v. Nationwide Mut. Ins. Co.,* 663 F. App'x 384, 392-93 (6th Cir. 2016) (Batchelder, J., dissenting).

36 *Id.*

37 *Brush v. Miami Beach Healthcare Grp., Ltd.,* 238 F. Supp. 3d 1359, 1365 (S.D. Fla. 2017); *Tierney v. Advocate Health & Hospitals Corp.,* No. 13 CV 6237, 2014 WL 5783333, at *2 (N.D. Ill. Sept. 4, 2014).

38 *In re Horizon Healthcare Servs. Data Breach Litig.,* 846 F.3d 625, 635 (3d Cir. 2017); *Tierney,* 2014 WL 5783333, at *2.

39 693 F.3d 1317 (11th Cir. 2012).

40 *Id.* at 1328.

contract and negligence claims to proceed, on the theory that the theft of the plaintiffs' identities was potentially connected to the breach of the defendant's systems, though the court did not address whether any element other than causation was adequately alleged in that case.[41]

By contrast the court in *In re Anthem, Inc. Data Breach Litigation* dismissed negligence, contract, and unjust enrichment claims.[42] Regarding negligence, the court concluded that the issue was better addressed to the legislature and that the common law imposed no relevant duty of care.[43] The contract claims were based on the privacy policy promulgated by the insurer, but the court concluded that those policies didn't contain any language specific enough to have been broken by a data breach.[44]

The *Anthem* court did, however, permit the plaintiffs to litigate state-law consumer protection claims. A California claim could proceed, the court held, in light of the strong California public policy in the protection of consumer data.[45] A New York consumer protection claim could proceed, the court held, to recoup damages in the form of the loss in value of the plaintiffs' personally identifiable information attributed to the Anthem breach and for benefit-of-the-bargain damages, essentially a form of overpayment theory.[46]

Across the country, the court in *Fero v. Excellus Health Plan, Inc.*[47] also permitted a New York statutory consumer-protection claim regarding a healthcare data breach to proceed[48] and further permitted a contract claim based on the language of the defendant's privacy policy to go forward.[49] But the court concluded that benefit-of-the-bargain damages could not be recovered in light of the filed rate doctrine.[50] If the conflict between *Fero* and *Anthem* isn't dizzying enough, *Fero* also conflicts with a New York state trial court decision that dismisses a similar contract claim on the ground that a privacy policy contains no actionable terms regarding data security.[51] And *Abdale's* conclusion is in line with *Brush v. Miami Beach Healthcare Group, LLC,* which dismisses a contract claim based on the theory that a data breach caused a violation of a similar privacy policy.[52] Whether or not the hospitals or healthcare firms might have breached their policies, these

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41 *Id.* at 1326-27.

42 162 F. Supp. 3d 953, 974-84 (N.D. Cal. 2016).

43 *Id.* at 974-78.

44 *Id.* at 978-81.

45 *Id.* at 990.

46 *Id.* at 993-96.

47 236 F. Supp. 3d 735 (W.D.N.Y. 2017).

48 *Id.* at 774-79.

49 *Id.* at 759-61.

50 *Id.* at 789-91. This conclusion is arguably incompatible with the court's decision not to dismiss the plaintiffs' unjust-enrichment claim. *Id.* at 770.

51 *Abdale v. North Shore Long Island Jewish,* 49 Misc.2d 1027, 1040 (Sup. Ct. Queens Cnty. 2015).

52 238 F. Supp. 3d 1359, 1367 (S.D. Fla. 2017).

cases hold, the policies do not create the kinds of contractual relationships that permit someone to bring suit.

This brief survey suggests that even when courts can agree that data security is important, they can't quite agree why. That kind of disagreement likely stems from both a misunderstanding of the costs of poor data security and of the value of good data security. But we don't think the time is right to give up on the courts.

As we've already laid out, there are good reasons why actors of all stripes should value data security. And we think the ordinary development of the common law should ultimately encourage healthcare firms to place a premium on data security. In the next section, we lay out why. But we also recognize that there are limits to what courts can do. Legislators, therefore, also have a key role to play in this debate. What's more, change needs to happen soon. The costs of poor data security are only going up.

IV. COURTS SHOULD RETHINK THEIR APPROACH TO DATA SECURITY

As we explained in the previous section, the approach of courts to questions of jurisdiction in data-breach cases assumes that any injury is suffered by virtue of identity theft, not the exposure of your personal information to hackers or the world at large by virtue of a vulnerable computer system. And to the extent courts address the merits, there is further disagreement about why any particular legal interest receives judicial protection. The result is wildly divergent rulings, on both jurisdictional and merits grounds.

We believe that courts would achieve some measure of harmony on these questions in data-breach cases, however, if they would focus on a plaintiff's underlying interest in data security. Let's begin with the foundational tort: negligence. A negligence claim asks whether the defendants failed to act with due care towards the plaintiffs. And due care is "a function of the probability and magnitude of an accident and the costs of avoiding it."[53] In perhaps the most classic formulation of negligence, Judge Learned Hand reasoned that the "duty to provide against resulting injuries" is triggered when "the burden of adequate precautions" outweighs the product of the "probability" of injury and the likely "gravity" of the resulting injury.[54]

Seen through the lens of data security, we think it clear that negligence law should have something to say about data breaches. As we've already discussed, the burden on firms of taking adequate precautions is far cheaper than the costs of remediating a data breach. What's more, only one party is even in a position to prevent the injuries that result from a data breach. Consumers and patients have no real means to force increased data security on companies.

But the real error in analysis to date comes in undervaluing the likelihood of injury and the gravity of any resulting injury. First, focus, as courts have, solely on identity theft. Anyone who watches television for long enough is bound to see an advertisement

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53 *In re Rhone-Poulenc Rorer, Inc.,* 51 F.3d 1293, 1300 (7th Cir. 1995).

54 *United States v. Carroll Towing Co.,* 159 F.2d 169, 173 (2d Cir. 1947).

for companies like Life-Lock, which promise to help you prevent identity theft.[55] These ads discuss the frequency of identity theft, but how prevalent is identity theft really? The short answer is, "its hard to know." In 2005, for instance, one think tank estimated that the crime had affected 44 million people, but the Federal Trade Commission fielded only 246,000 identity theft complaints that year, and another study pegged the number of identity theft victims in a given year at 160,000, less than one percent of the population.[56] The number of victims has undoubtedly gone up, but by how much is unclear.

And what is the gravity of the resulting injury? With the caveat that definitional and methodological differences color the research, consider a recent study from Javelin Strategy & Research: They estimate that in 2016, 15.4 million Americans were victims of identity theft, resulting in the theft of around $16 billion dollars.[57] That means the average victim lost around $1,000.

So take this data and plug it into the *Carroll Towing* equation. The likelihood of identity theft is difficult to show, but some evidence suggests that it isn't very likely at all. And while some victims of identity theft may suffer hundreds of thousands of fraudulent charges, the average victim suffers a more pedestrian $1000 in charges (many of which they might not even bear, given that credit card companies aren't allowed to charge cardholders for charges they don't incur). Under *Carroll Towing,* then, a court would only impose upon companies the burden of taking steps to avoid this harm if the costs of these preventive measures were very small.[58]

The calculus changes significantly if we refocus the analysis on data security. First, let's look at the likely gravity of harm. In this analysis we, can appropriately take account of the type of data a given firm has. Exposure of healthcare information puts an individual at risk for an incredibly serious invasion of their privacy. Health records contain some of the most sensitive information we provide to businesses. While it is difficult to quantify the harm that such an invasion of privacy causes,[59] the harm is undoubtedly great. What's more, a focus on identity theft naturally lends itself to a focus on strict monetary harms, which narrows the class of people thought to be harmed in a given data breach. A more general recognition of the privacy interests at stake shows that the set of individuals injured by a data breach is much broader.

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55 If the focus is on identity theft, services like these also factor into the burden analysis. If consumers can easily shoulder the burden of preventing identity theft, there is no reason to shift that burden to companies.

56 *See* Bob Sullivan, "Just how common is ID theft?" NBC News, http://www.nbcnews.com/id/8409283/ns/technology_and_science-security/t/just-how-common-id-theft/#.Wc1JJBNSxTY (June 30, 2005, 7:55 p.m.).

57 Herb Weisbaum, "Identity Fraud Hits Record Number of Americans in 2016," NBC News, https://www.nbcnews.com/business/consumer/identity-fraud-hits-record-number-americans-2016-n715756 (Feb. 2, 2017, 7:21 a.m.).

58 *Cf. In re City of New York,* 522 F.3d 279, 285 (2d Cir. 2008) (imposing duty to avoid small risk of harm because burden of taking precautions was also very slight).

59 *Pine v. Rust,* 535 N.E.2d 1247, 1251 (Mass. 1989) ("privacy interests . . . are by their very nature lacking in clear definition and difficult to quantify")

The focus on identity theft also causes courts to miss the costs imposed by the breaches themselves. First, as discussed, companies have to take steps to patch vulnerabilities in their systems, retrain their employees, and anything else necessary to remediate the harm caused by the data breach. These costs are inevitably passed on to consumers. Second, there are the costs that come with ransomware. In addition to all the normal costs imposed by a data breach, a ransomware attack can impose further costs simply to regain access to a computer. We can expect these costs, too, to be passed on to consumers.

And how likely are consumers to suffer these injuries? At least in the healthcare field, the answer is "very." As we discussed above, 450 hospitals were breached in 2015. These breaches exposed the data of every patient at these hospitals.

If we revisit *Carroll Towing* with this new focus, it is clear that tort law already provides a solid basis to hold companies liable for failing to take steps to prevent data breaches, particularly in vulnerable fields like healthcare. At a basic level, we see that both the gravity of the harm and the likelihood of the harm are much greater if we focus on data security as a standalone interest. And both of these variables become even weightier in fields with particularly sensitive data or greater-than-normal exposure to hacking. The healthcare field fits both bills.

Carroll Towing suggests that, in these circumstances, we should be much more comfortable imposing on hospitals and health insurers liability for failing to take steps to adequately secure data. What's more, failure to shore up a known vulnerability may be the kind of "extreme departure from the ordinary standard of care" that qualifies as gross negligence.[60]

But while the common law already possesses the tools necessary to take a stand against poor data security, legislation and regulation may provide a surer path to meaningful reform. The development of the common-law that we describe is unlikely to move the needle much unless it can successfully be implemented through a class action.[61] A "fusillade of small-stakes claims"[62] is unlikely when data security is at issue—the costs simply to litigate the issue are substantial, and the knowledge needed to bring the suit in the first place is a hurdle most ordinary litigants can't clear on their own.

But this itself poses a problem: Negligence claims like those we have highlighted above have been deemed unsuitable for class-action treatment.[63] Judge Posner's opinion in *Rhone-Poulenc* canvases the several ways in which states can organize their laws of negligence, as well as the many "subsidiary" notions bound up in negligence doctrine.[64] At bottom, his point is simple: negligence law is complicated, involves choosing between competing objectives and making trade-offs, so it should be

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60 47 Am. Jur. 2d *Negligence* § 227.

61 *See Hughes v. Kore of Ind. Enter., Inc.,* 731 F.3d 672, 677 (7th Cir. 2013) (highlighting the substantial deterrent effects of class actions).

62 *Murray v. GMAC Mortg. Corp.,* 434 F.3d 948, 953 (7th Cir. 2006).

63 *Rhone-Poulenc,* 51 F.3d at 1300-02.

64 *Id.* at 1300.

allowed to develop on its own. A multistate class action arrests that development in unacceptable ways, Judge Posner thought.

Rhone-Poulenc is approvably cited in the mass tort context.[65] And it might make sense to think of data breaches as giving rise to a digital-age mass tort. Mass torts can be successfully litigated on a class basis when the harm is confined to a single jurisdiction.[66] And many hospitals or insurers only serve a single state. So we may be overstating the issue of relying on the development of tort law. But many larger breaches span multiple states. The Anthem data breach, for instance, affected individuals in all 50 states.

One ordinary response to the problem of certifying mass tort cases is to rely on state consumer-protection law. As discussed above, some lawyers have taken that approach in data breach cases, and with some success. But this path, too, is limited, and for several reasons. First, several decisions reject the idea that generic consumer-protection statutes are intended to cover harms related to data breaches.[67] And the remaining states' laws reflect "diverse policy judgments" resulting in a "patchwork of rules"[68] that renders certification a decidedly uphill battle.[69] Perhaps a choice-of-law analysis might dictate that only a single state's law applies to a given lawsuit related to a particular data breach, but that seems unlikely. Courts generally decline to apply consumer-protection laws outside the particular state.[70]

In other words, specific protections are needed. Many states do impose data breach *reporting* requirements, but these protections do nothing to promote *ex ante* the kind of data security that can prevent the breach or ransomware attack in the first place. That regulatory gap leaves consumers unprotected. In the case of hospitals or healthcare firms, the gap is especially troubling.

V. CONCLUSION

Our current approach to litigating and regulating data breaches focuses on the prevention of identity theft. But that approach ignores the serious consequences that stem simply from the exposure of sensitive personal data to bad actors. Moreover, our current account of the costs and benefits of data security omits any discussion of ransomware.

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65 *See Castano v. American Tobacco Co.,* 84 F.3d 734, 746-50 (5th Cir. 1998).

66 *See In re Federal Skywalk Cases,* 95 F.R.D. 483 (W.D. Mo. 1982) (certifying under Rule 23(b)(3) a class proposing to litigate claims related to the collapse of two skywalks at the Hyatt Regency in Kansas City).

67 *See, e.g., Hancock v. Urban Outifters, Inc.,* 830 F.3d 511 (D.C. Cir. 2016).

68 *BMW of N. Am., Inc. v. Gore,* 517 U.S. 559, 570 (1996).

69 *Siegel v. Shell Oil Co.,* 256 F.R.D. 580, 585 (N.D. Ill. 2008).

70 *See Mazza v. Am. Honda Motor Co., Inc.,* 666 F.3d 581, 592 (9th Cir. 2012) ("Getting the optimal balance between protecting consumers and attracting foreign businesses, with resulting increase in commerce and jobs, is not so much a policy decision committed to our federal appellate court, or to particular district courts within our circuit, as it is a decision properly to be made by the legislatures and courts of each state.").

Courts and legislators need to refocus. Instead of focusing on measures intended to help people prevent identity theft, regulation should focus on data security. The costs incurred in preventing a data breach are far smaller than the costs incurred in the wake of a data breach, both to company and consumer. *Ex post* efforts to assign blame for a data breach miss the point: True commitment to data security benefits everyone. And that lesson should inform both judicial and policymaking judgments.

THE PROXIMATE CAUSE REQUIREMENT IN PRIVATE REVERSE PAYMENT ANTITRUST LITIGATION

By Sarah H. Trela and Kenneth R. O'Rourke[1]

I. INTRODUCTION

An unlitigated patent is a bit like Schrödinger's cat:[2] until challenged and adjudicated, the patent arguably appears as though it is both valid and invalid.[3] This ambiguity has led certain courts and legal scholars to observe that, at the time a reverse payment settlement is executed, the brand pharmaceutical company really owns a "probabilistic patent" that may or may not give it the right to exclude competition.[4] In the context of private antitrust litigation involving reverse payment settlements, patent ambiguity has tempted some to substitute proxies or presumptions for actual proof of proximate cause. That will not do. Proximate causation is an element a private plaintiffs must prove in all cases; reverse payment settlements do not create an exception.

Following the Supreme Court's 2013 opinion in *FTC v. Actavis, Inc.,*[5] a government enforcement case, courts have split in how they approach the proximate cause requirement in private reverse payment cases. Several recent appellate and district courts have properly required proof that the patent supposedly blocking a generic's entry is, in fact, invalid before finding that a reverse payment proximately caused any antitrust

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2 Schrödinger's cat refers to a hypothetical experiment by particle physicist Erwin Schrödinger. To paraphrase: a cat is sealed inside a closed box with a poison that will be randomly released. An observer can open the box and determine if the cat is alive or dead, but until this observation is made, the cat is in a state of "quantum superposition" and must be treated as simultaneously both alive and dead. *See* John D. Trimmer, *The Present Situation in Quantum Mechanics: A Translation of Schrödinger's 'Cat Paradox' Paper*, Proceedings of the American Philosophical Society 124:5 at 323 (Oct. 10, 1980).

3 Other patent observers have referenced the paradox of Schrödinger's cat in discussing patent ambiguity prior to adjudication. *See, e.g.,* Richard H. Stern, *FTC v Actavis: Patent Validity, Schrödinger's Cat and Reverse Payments,* 35 Eur. Intellectual Prop. R. 743 (2013), Pablo Ibáñez Colomo, *GC Judgment in Case T-427/13, Lundbeck v. Commission: on Patents and Schrödinger's Cat,* ChillingCompetition.com, Sept. 13, 2016, https://chillingcompetition.com/2016/09/13/gc-judgment-in-case-t-47213-lundbeck-v-commission-on-patents-and-schrodingers-cat (discussing patent validity presumptions underlying a European Commission General Court judgment); Robert Plotkin, *Software Patents Are Only As Dead as Schrödinger's Cat,* IPWatchdog.com, Oct. 6, 2014, http://www.ipwatchdog.com/2014/10/06/software-patents-are-only-as-dead-as-schrodingers-cat/id=51549/ (analyzing uncertainty around software patents).

4 *See In re Cipro Cases I & II,* 61 Cal. 4th 116, 143 (2015) (citing Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. Econ. Perspectives 75, 88 (2005)). A reverse payment patent settlement, generally speaking, refers to the settlement of patent litigation in which a patent-holding brand pharmaceutical company pays the allegedly infringing generic manufacturer for a promise by the generic not to enter the market before a future date prior to patent expiration. There are variations, and this article does not focus on a specific definition or differing circumstances.

5 *FTC v. Actavis, Inc.,* 133 S. Ct. 2223, 2236–37 (2013).

injury.[6] Other courts have relied on a few select phrases in *Actavis* to eschew the causation element entirely, using the size of the reverse payment as a proxy for patent invalidity.[7] But, *Actavis* was a Federal Trade Commission (FTC) enforcement action that did not require proof of actual causation.[8] Thus, this latter approach is inapplicable in private antitrust cases because it imports the different and lighter standard from government enforcement actions into Clayton Act claims.

Under the better approach to private reverse payment claims, the parties must open Schrodinger's box and determine the cat's welfare, rather than simply presuming the worst.

II. CAUSATION IN PRIVATE ANTITRUST LITIGATION

A. *Proximate Causation Is an Essential Element*

Private antitrust plaintiffs can maintain their damages claim under the Clayton Act only if they are injured "*by reason of* anything forbidden in the antitrust laws." 15 U.S.C. § 15(a) (emphasis added). Courts have interpreted this as a "proximate cause" requirement.[9] In order to establish such a causal link between a reverse payment settlement and antitrust injury, a plaintiff must show that "*if not* for the challenged settlement agreement, there *would have* been earlier entry of generics into the market."[10]

This "but-for" world is necessary, because if a pharmaceutical manufacturer has a valid patent, it also has a protected legal right to exclude other market entrants throughout the patent term.[11] If a party with a valid, enforceable patent makes a reverse payment to a competitor in exchange for delayed entry before patent expiration, the reverse payment merely upholds that right and maintains the existing market conditions; it causes no

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6 *See, e.g., In re Wellbutrin XL Antitrust Litig.,* 868 F.3d 132, 169–70 (3d Cir. 2017); *In re Nexium (Esomeprazole) Antitrust Litig.,* 842 F.3d 34, 64 (1st Cir. 2016); *Apotex, Inc. v. Cephalon, Inc.,* 2017 U.S. Dist. LEXIS 87936, at *20–26 (E.D. Pa. June 8, 2017); *In re Wellbutrin XL Antitrust Litig.,* 133 F. Supp. 3d 734, 764 (E.D. Pa. 2015); *In re Actos End Payor Antitrust Litig.,* 2015 U.S. Dist. LEXIS 127748, at *84–85 (S.D.N.Y. 2015); *In re Nexium Esomeprazole Antitrust Litig.,* 42 F. Supp. 3d 231, 265 (D. Mass. 2014).

7 *See, e.g., Cipro,* 61 Cal. 4th 116; *In re Aggrenox Antitrust Litig.,* 2015 U.S. Dist. LEXIS 94516, at *32 (D. Conn. 2015). *But see Wellbutrin,* 868 F.3d at 168 (summarizing amicus brief filed by a group of antitrust economists to explain why the size of a settlement is not a good proxy for a brand's success in patent litigation).

8 *Actavis,* 133 S. Ct. at 2236–37.

9 Associated General Contractors v. Cal. State Council of Carpenters, 459 U.S. 519, 533–37 (1983); 2660 Woodley Rd. Joint Venture v. ITT Sheraton Corp., 369 F.3d 732, 740 (3d Cir. 2004); Sullivan v. NFL, 34 F.3d 1091, 1103 (1st Cir. 1994). See also Holmes v. Sec. Investor Prot. Corp., 503 U.S. 258, 269 (1992) (antitrust injury must be proximately caused "by reason of" the antitrust violation); Ian Simmons, Kenneth R. O'Rourke, & Scott Schaeffer, Viewing FTC v. Actavis Through the Lens of Clayton Act Section 4, Antitrust 28:1 at 24 (Dec. 2013) (discussing the "by reason of" causation requirement in private antitrust actions for damages).

10 *Aggrenox,* 2015 U.S. Dist. LEXIS 94516, at *32; *Nexium*, 42 F. Supp. 3d at 265, *Wellbutrin,* 868 F.3d at 164–65 (plaintiffs "must show that the harm they say they experienced—increased drug prices for [the brand drug] (and its generic equivalents)—was caused by the settlement they are complaining about.").

11 *See Actavis,* 133 S. Ct. at 2231.

further delay in generic entry or antitrust harm.[12] Thus, in order for a plaintiff to prove that the settlement caused delay that harmed competition, the plaintiff must establish the generic entrant could have and would have launched a competing product earlier without violating the brand's patent—in other words, that generic entry in the but-for world would have been early and would not have infringed on a valid patent. "After all, if the launch were stopped because it was illegal, then the [plaintiffs'] injury (if it could still be called that) would be caused not by the settlement but by the patent laws prohibiting the launch."[13]

B. *Proximate Causation Unnecessary in Government Actions*

On the other hand, the government has the authority to enforce antitrust laws directly, without the need to "satisfy the additional burdens imposed by" Sections 4 and 16 of the Clayton Act.[14] The FTC must prove an antitrust violation, but does not need to prove actual harm (*i.e.,* proximate causation) or actual damages resulting from the alleged violation.[15] Consequently, the government need only prove that a defendant's action is "*likely* to cause injury." 15 U.S.C. § 45(4)(A)(i) (emphasis added).[16] This standard underlies the Supreme Court's reasoning in Actavis, where Justice Breyer explained that the size of a reverse payment can serve as a proxy for the strength of a patent in assessing whether there is an antitrust violation:

> [A]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent survival. And that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market . . . [so] the size of the unexplained reverse payment can provide a

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12 *See, e.g., Cipro,* 61 Cal. 4th at 138 ("[I]f a patent were known to be valid, an agreement foreclosing competition no more than the statutory monopoly would not restrain trade beyond what federal law permitted."); *see also* Simmons, O'Rourke, & Schaeffer, *supra* at 9 (stating that "some form of patent analysis and litigation is necessary in private actions post-Actavis if the defense asserts that it was the branded company's patents that foreclosed the generic company's market entry."); Phillip E. Areeda & Herbert Hovenkamp, Fundamentals of Antitrust Law § 3.04[B] (rev. 4th ed. Supp. 2015) ("[A] plaintiff cannot be injured in fact by private conduct excluding it from the market when a statute prevents the plaintiff from entering that market in any event.").

13 *Wellbutrin,* 868 F.3d at 165.

14 *See* Brief of Federal Trade Commission as Amicus Curiae Supporting No Party, *In re Nexium (Esomeprazole) Antitrust Litig.,* No. 12-md-02409-WGY, Doc. 00116958619 at 21 (1st Cir. Feb. 12, 2016).

15 *See Cal. v. Am. Stores Co.*, 495 U.S. 271, 295–96 (1990) (contrasting the government and private plaintiffs' burdens); *Nexium*, 842 F.3d at 60 (explaining that "Private plaintiffs and the FTC as government enforcer stand in different shoes" and private plaintiffs "must therefore satisfy the additional evidentiary burdens"); *Apotex*, 2017 U.S. Dist. LEXIS 87936, at *26 n. 3 (noting that "[i]n antitrust cases, the FTC is held to a less stringent causation standard than private plaintiffs. As such, although the Actavis Court stated that 'it is normally not necessary to litigate patent validity to answer the antitrust question.' that statement does not address a private plaintiffs' causation requirement nor does it preclude examination of the validity of the patent where necessary.") (citation omitted).

16 *See also Wellbutrin,* 133 F. Supp. 3d at 764.

> workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.[17]

But even the Court in *Actavis* was not united: Chief Justice Roberts explained in dissent that, "settling a patent claim cannot possibly impose unlawful anticompetitive harm if the patent holder is acting within the scope of a *valid* patent and therefore permitted to do precisely what the antitrust suit claims is unlawful."[18]

C. *Patent Validity Plays a Role in Analyzing Antitrust Causation*

As *Actavis* indicates, the Court struggled with the fact that a patent's validity is not known until it is litigated.[19] While a patent application goes through an examination process, an issued patent is not unassailable. The California Supreme Court has stressed that a patent is not "ironclad," but simply gives "holders a potential but not certain right to exclude. . . . A patent is, in effect, a right to ask the government to exercise its power to keep others from using an invention without consent."[20]

Courts confront a similar issue in deciding the threshold question of whether there is an antitrust violation at all, let alone whether the added causation element is present. As the Supreme Court explained in *Actavis,* even a reverse payment settlement regarding a valid patent can potentially violate the antitrust laws.[21] Thus, to determine whether a particular reverse payment settlement violates the antitrust laws,[22] courts apply the "rule of reason," requiring that courts balance a reverse payment's anticompetitive effects against procompetitive benefits.[23] This includes, but is not limited to, an assessment of the patent. Notably, in *Actavis* the Court rejected the FTC's suggestion that "reverse payment settlement agreements are presumptively unlawful." [24] By contrast, the Court held that such "presumptive rules" were not appropriate because reverse payment settlements are not the type of activity where a "rudimentary understanding of economics

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17 *Actavis,* 133 S. Ct. at 2236–37.

18 *Id.* at 2244 (Roberts, C.J., dissenting) (emphasis added).

19 *Id.* at 2230–31.

20 *Cipro,* 61 Cal. 4th at 143.

21 *Actavis,* 133 S. Ct. at 2234–36.

22 Courts have held that "[c]ertain agreements, such as horizontal price fixing and market allocation, are thought so inherently anticompetitive that each is illegal per se *without inquiry into the harm it has actually caused." Copperweld Corp. v. Independence Tube Corp.,* 467 U.S. 752, 768 (1984) (emphasis added); *see also* Mark A. Lemley & Christopher R. Leslie, *Categorical Analysis in Antitrust Jurisprudence,* 93 Iowa L. Rev. 1207, 1213–15 (2008). This article does not address those cases, but focuses on the causation requirement for alleged reverse payment antitrust violations that are subject to the rule of reason analysis.

23 *Actavis*, 133 S. Ct. at 2237–38; *Wellbutrin*, 868 F.3d at 160–61; *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 551 n.12 (1st Cir. 2016) (stating that *Actavis* did not "overhaul the rule of reason" in reverse payment cases); *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 398 n.15 (3d Cir. 2015) (reverse-payment claims are subject to the "traditional, full-fledged rule of reason standard").

24 *Actavis,* 133 S. Ct. at 2237. Such a presumption would shift the burden of proof to defendants to show that a reverse payment settlement had pro-competitive effects. *Id.*

could conclude that the arrangements in question would have an anticompetitive effect on customers and markets."[25]

Courts have struggled to decide whether, under the rule of reason, it is appropriate to look beyond the day of the transaction in assessing these potential effects. As the court explained in *Nexium,* "[r]egardless of the absolute validity or invalidity of patents, business players make reverse payment decisions in an environment in which that validity has not yet been adjudicated. They take into account the risk of litigation and the possibility that patents may be adjudicated invalid or uninfringed."[26] Some find that the rule of reason analysis is restricted to the time of the settlement, and others assess the actual effect of the settlement as it played out in the market.[27]

That debate relates to a separate issue that this article does not address: under what circumstances is a reverse payment settlement an antitrust violation at all (*i.e.*, liability). Whether there is an antitrust violation does not speak to whether there is proximate causation—private antitrust plaintiffs must prove both.[28] Even courts that do not undertake an assessment of patent validity as part of the rule of reason to determine whether there has been an antitrust violation might take a different approach in assessing causation, applying a stricter standard that considers patent's validity.[29] For this reason, it is important to isolate the causation analysis from the antitrust violation analysis. This article addresses only the causation issue.

III. MOST COURTS ASSESS THE UNDERLYING PATENT'S VALIDITY

In applying proximate causation, a building majority of courts—including both the First and Third Circuits, along with district courts in the Second Circuit—closely examine the validity of the underlying patent in assessing proximate cause. These courts have held that for there to be a finding of causation, the court must first find that the brand manufacturer's "patent claims were invalid and the infringement actions against the

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25 *Id.* at 2237.

26 *Nexium,* 842 F.3d at 64.

27 *Compare, e.g.*, *Apotex*, 2017 U.S. Dist. LEXIS 87936 at *17 (holding that "the relevant rule of reason analysis is conducted on an ex ante basis, that is, as of the time the settlements were executed.") and *Cipro*, 61 Cal. 4th at 158–59 ("Agreements must be assessed as of the time they are made, at which point the patent's validity is unknown and unknowable."), *with Jefferson Par. Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 29 (1984) (requiring that plaintiffs prove under the rule of reason that an anticompetitive act "as it *actually operates* in the market, has unreasonably restrained competition.") (emphasis added) and *United States v. Microsoft Corp.*, 253 F.3d 34, 95 (D.C. Cir. 2001) ("[P]laintiffs must show that [defendant's] conduct unreasonably restrained competition. Meeting that burden 'involves an inquiry into the actual effect' of [defendant's] conduct on competition.") (citation omitted).

28 *Nexium,* 842 F.3d at 60; *Atl. Richfield Co. v. USA Petroleum Co.,* 495 U.S. 328, 344 (1990).

29 *See Wellbutrin,* 868 F.3d at 164–69, *Apotex* 2017 U.S. Dist. LEXIS 87936 at *26 ("[N]othing in the albeit limited case law suggests that the strict ex ante lens that applies to the rule of reason under *Actavis* must also apply to the question of causation.").

Defendants would have failed."[30] These opinions properly distinguish between the private causation standard and the lower standard applicable in government enforcement actions.

For instance, the Eastern District of Pennsylvania has stressed this point in both *Wellbutrin* and *Apotex,* stating that "although the *Actavis* Court stated that 'it is normally not necessary to litigate patent validity to answer the antitrust question,' that statement does not address a private plaintiff's causation requirement nor does it preclude examination of the validity of the patent where necessary."[31] Comparing government and private actions, the court further emphasized that while "it is understandable that an analysis of patent validity may normally be unnecessary in actions brought under the FTC Act," "the Clayton Act does demand such an analysis, and nothing in *Actavis* altered the Clayton Act's causation requirement."[32]

In *Wellbutrin,* the courts confronted claims by consumers who alleged that they paid inflated prices for Wellbutrin, an antidepressant, because the manufacturer, GlaxoSmithKline, entered into reverse payment settlements with generic pharmaceutical companies that allegedly prevented competing generic versions of the medication from entering the market.[33] The district court granted the defendants' motion for summary judgment because a patent arguably prevented the launch of the generic's product, so there was no proof that the settlement—"as opposed to an independent patent, prevented market entry."[34] The Third Circuit recently affirmed the district court's holding, observing that the generic's entry into the market was "effectively blocked by federal patent law."[35] It stated that *Actavis* was inapplicable to the private litigation, and noted that it cannot determine whether patent law would have allowed the generic to enter "without considering the merits of the underlying patent dispute."[36]

The district court's opinion in *Wellbutrin* was cited with approval by the First Circuit in Nexium, which similarly affirmed the requirement that there be "some evidence of the patents' invalidity or non-infringement before allowing the plaintiffs to

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30 *Actos,* 2015 U.S. Dist. LEXIS 127748, at *84–85, *rev'd on other grounds,* 848 F.3d 89, 98 (2d Cir. 2017). *See also Wellbutrin,* 868 F.3d at 169; *Nexium,* 842 F.3d at 64*; In re Namenda Direct Purchaser Antitrust Litig.,* 2017 U.S. Dist. LEXIS 83446, at *61 (S.D.N.Y. 2017) (noting in dicta that while reverse payments may violate the Sherman Act, proving it will require, among other things, "the presence of 'evidence suggesting that the settlement agreements did, in fact, delay generic entry,' which will presumably require proof that the [] Patent would likely have been found invalid or not infringed by the Generic Competitors."); *Valley Drug Co. v. Geneva Pharms.,* 344 F.3d 1294, 1310–11 (11th Cir. 2003) (rejecting a rule that reverse payments are per se anticompetitive because "[w]hen the exclusionary power of a patent is implicated, however, the antitrust analysis cannot ignore the scope of the patent exclusion").

31 *Apotex,* 2017 U.S. Dist. LEXIS 87936, at *26 n. 3; *see also Wellbutrin,* 133 F. Supp. 3d at 764 ("[T]he FTC Act's causation requirement is broader and more relaxed than the Clayton Act's, no showing of proximate cause is required. *Compare* 15 U.S.C. 45(n) with 15 U.S.C. § 15(a). The hurdle, therefore, that independent regulation poses for causation under the Clayton Act is not necessarily present in FTC Actions.").

32 133 F. Supp. 3d at 764.

33 *Id.* at 142.

34 *Wellbutrin,* 133 F. Supp. 3d at 762–63.

35 *Wellbutrin, 868 F.3d at 165.*

36 *Id.* at 166 n. 58.

pursue an at-risk launch theory."[37] That case involved a settlement agreement between AstraZeneca, a brand manufacturer, and a generic manufacturer who agreed to delay launch of a generic acid reflux medication until a certain date in exchange for a license after that date.[38] But in *Nexium*, the plaintiffs did not present any evidence about the patent's validity or strength, leading the district court to grant a judgment as a matter of law on any theory related to the patent invalidity.[39] When the plaintiffs subsequently attempted to argue causation, the court rejected their argument and affirmed summary judgment for AstraZeneca.[40] The First Circuit explained that because the plaintiffs did not present evidence that AstraZeneca's patents were invalid, there was nothing "that would allow the plaintiffs to overcome the likelihood that AstraZeneca's patents, not its reverse payment to [the generic], were the bar to a generic launch."[41]

Under a somewhat different procedural posture, *Apotex* dealt with settlements from brand manufacturer Cephalon to several generic manufacturers related to a narcolepsy medication. The plaintiffs both brought antitrust claims and sought a declaratory judgment invalidating the relevant patent.[42] The court separated the claims, beginning a patent trial on a separate track from the antitrust claims and ultimately finding the patent was invalid.[43] As the antitrust claims approached trial, Cephalon attempted to argue that the finding of invalidity was irrelevant to plaintiffs' antitrust claims.[44] The court disagreed, concluding that "the prior patent ruling is highly probative in the context of Plaintiffs' at-risk launch theory of causation" and admitting the evidence for that purpose.[45]

This reasoning highlights why it is usually essential to determine a patent's validity. Because "a valid and uninfringed patent would interfere with the plaintiffs' chain of causation: a valid patent independently 'preclude[s] competition' apart from any agreement and an 'at risk' launch is unlawful absent a later finding of patent invalidity or non-infringement,"[46] it is inappropriate to use proxies or presumptions in place of an actual evaluation of patent validity. As the district court concluded in *Wellbutrin,* noting that "the Clayton Act's 'by reason of' causation requirement cannot be satisfied by using

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37 842 F.3d at 63. The relevant portion of the opinion focuses on plaintiffs' post-trial appeal of a grant of summary judgment on causation issues. When the case went to trial, the jury found that although there was an antitrust violation, the violation did not cause any injury. *Id.* at 39.

38 *Id.* at 42.

39 *Id.* at 62–63.

40 *Id. a*t 63–64.

41 *Id.* at 63 (citing *In re Wellbutrin,* 133 F. Supp. 3d at 767 ("the 'patent served as an independent regulatory bar to [the generic's] launch.")).

42 2017 U.S. Dist. LEXIS 87936 at *11–12.

43 *Id.*

44 *Id.* at *15–16.

45 *Id.* at *26.

46 *Id.*

the size of the payment as a proxy for patent strength and the success of the underlying patent litigation."[47]

The use of proxies as a substitute for proximate causation is inappropriate because "[w]hile the size of a reverse payment may have some relevance in determining how confident a litigant is in the strength of its case . . . it is far from dispositive."[48] The Third Circuit has affirmed this perspective, noting that "risk aversion makes it difficult to use the size of a settlement as a proxy for the brand-name's likelihood of success in [patent] litigation."[49]A successful private antitrust claim requires more than that anticompetitive conduct creates an increased *risk* of injury—it requires actual causation of injury.

It is not unusual for courts to need to determine a subsidiary legal issue before proceeding on to the main claim. For example, courts must "litigate patent validity in antitrust cases . . . when plaintiffs allege *Walker Process* fraud."[50] There is no more reason to short circuit the necessary additional analysis in the reverse payment context than there is in the *Walker Process* context. Even if litigating patent validity may make the antitrust claim more complex and consume additional judicial resources, that is an unavoidable consequence of the standard of proof for private litigants seeking treble damages.

IV. FEWER COURTS IMPROPERLY USE PROXIES FOR CAUSATION

Some courts—notably the Supreme Court of California and the District of Connecticut—have shied away from looking into questions about patent validity on top of already complex antitrust actions. These courts rely on select phrases in *Actavis* to skirt the requisite causation analysis and hold that, even in private plaintiff reverse payment cases, the parties need not litigate the validity of the patent. Some of these courts even expressly acknowledged that they were importing the standard from FTC enforcement cases to private actions. As the *Aggrenox* court explained in its clarifying order:

> If private antitrust plaintiffs must fully litigate the validity of the patent anyway in order to show but-for causation, then *Actavis*'s insistence that litigating the patent is not normally necessary to show that a large and unjustified reverse-payment settlement violated antitrust law would have no practical effect in private suits, and *Actavis* itself therefore would have no practical application except in suits by the government. That is not an impossible interpretation of the case—and it would act as a powerful brake to *Actavis*'s potentially disruptive impact in the world of pharmaceutical patent litigation—but I consider it dissonant with the decision's reasoning and on the whole a very unlikely interpretation.[51]

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47 *Id. See also* Simmons, O'Rourke, & Schaeffer, *supra* at 9 ("But whatever the merits of using settlement amounts as surrogates for patent validity and scope, that shortcut should not apply in private actions.").

48 *Id.*

49 *Wellbutrin,* 868 F.3d at 168.

50 Ian Simmons, Kenneth O'Rourke, & Stephen McIntyre, *The Continuing Relevance of Patent Validity in Reverse-Payment Litigation,* Concurrences 2014:2 at 25, 27–28 (observing that "litigating patent validity in antitrust cases is old hat for U.S. courts" and that courts frequently determine supplementary legal issues in professional malpractice and sham litigation cases).

51 *Aggrenox,* 2015 U.S. Dist. LEXIS 94516, at *33–34.

Courts that apply such a weak proximate cause requirement to analyze reverse payment claims typically highlight the "expected life" of the patent, maintaining focus on what the parties knew at the time of the reverse payment before the validity of the patent could be adjudicated.[52] As such, they emphasize that consideration of reverse payment settlements "will not turn on whether the patent would ultimately have proved valid or invalid," but that "what matters is whether a settlement postpones market entry beyond the average point that would have been expected at the time in the absence of agreement."[53]

The California Supreme Court offers a key example of this reasoning in *Cipro*. There, the plaintiffs brought claims related to brand manufacturer Bayer's settlement payments to a generic manufacturer over rights to sell an antibiotic.[54] After (pre-*Actavis*) federal courts granted summary judgment for the defendants, Bayer sought summary judgment in state court as well.[55] While the trial and appellate courts affirmed summary judgment, the California Supreme Court applied *Actavis* and disagreed. It concluded that a plaintiff has established causation where the court applies the rule of reason and determines there is an antitrust violation because the settlement excludes competition beyond the "expected life" of the patent.[56] The "expected life" is the term of the patent discounted by the risk the patent will be found invalid.[57]

The District of Connecticut followed *Cipro* in *Aggrenox,* where it dealt with the patent-owning brand manufacturer Boehringer's settlement with would-be generic manufacturers of Aggrenox, a medicine used to lower the risk of stroke.[58] The court's initial opinion declining to dismiss the antitrust claims relied heavily on its interpretation of *Actavis*'s language regarding when it is unnecessary to litigate the patent's merits.[59] After the defendants argued that the initial order conflated causation and liability, the court issued a clarifying order to reaffirm that while the plaintiffs must prove causation, *Actavis* limited the need to assess the actual patent in connection

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52 *See Cipro,* 61 Cal. 4th at 159; *In re Aggrenox Antitrust Litig.,* 94 F. Supp. 3d 224, 241 (D. Conn. 2015) ("The salient question is not whether the fully-litigated patent would ultimately be found valid or invalid—that may never be known—but whether the settlement included a large and unjustified reverse payment leading to the inference of profit-sharing to avoid the risk of competition."); *In re Opana Er Antitrust Litig.,* 162 F. Supp. 3d 704, 720 (N.D. Ill. 2016) (denying a motion to dismiss and noting that "Defendants favor a rule that requires litigating the patents' merits — at least in some abbreviated fashion — in order to determine whether the settlement violates antitrust law. But the Supreme Court in *Actavis* expressly disclaimed this line of analysis.").

53 *Cipro,* 61 Cal. 4th at 159; *see also Aggrenox,* 2015 U.S. Dist. LEXIS 94516, at *37–38.

54 *Id.* at 130–33.

55 *Id.* at 133, 142 (observing that while interpretation of the federal Sherman Act is not dispositive of claims under California's Cartwright Act, federal law is dispositive to the extent "its analysis establishes the metes and bounds of patent law and policy.").

56 *Id.* at 149–150, 158 n.19.

57 *Id.* at 150.

58 *Aggrenox,* 94 F. Supp. 3d at 236.

59 *Id.* at 329–40 (dismissing defendants argument that resolving such a claim "required litigating the patents' merits, at least in some abbreviated fashion, in order to determine whether a settlement violates antitrust law. That would be a logical (however impractical) way to avoid presuming either the patent's validity or invalidity, but the Supreme Court expressly disclaimed it.").

with that burden.[60] The court stated its agreement with the reasoning of *Cipro* and presented the anticompetitive harm at issue as the diminished "risk of competition."[61] Notably, the clarifying order also granted a motion to certify the ruling on causation for interlocutory review. In so doing, it noted that "*Actavis* is a new Supreme Court precedent with clear potential for a disruptive effect on very large-scale litigation, and [] it provides limited guidance to the lower courts . . . the question that most clearly warrants review is the substantive standard of *Actavis* . . . what constitutes proof under *Actavis* of an antitrust violation and causation of antitrust injury."[62] However, the Second Circuit declined to hear the interlocutory appeal.[63]

Where *Aggrenox, Cipro,* and other courts err is in treating an antitrust violation—which, as discussed above, is subject to the rule of reason—as synonymous with causation and injury. For example, in *Aggrenox,* the court stated that if plaintiffs prove that a "large and unjustified reverse payment . . . did effectively extend the life of the patent beyond its expected life in the absence of settlement; and [] a generic could have entered the market at that earlier time. . . . then the plaintiffs will have proved an antitrust violation *and* causation of antitrust injury."[64] But these are not the same inquiry; collapsing them buries the assumption that a generic could have entered the market only if the patent were invalid at that time. In private litigation, a presumption derived from the "expected life" of the patent cannot substitute for that proof about causation. Courts that maintain the strong proximate causation requirement for private reverse payment claims reach the correct conclusion that decisions like *Cipro* and *Aggrenox* incorrectly "relax Section 4's causation requirement for the specific circumstance of challenges to reverse payment settlements."[65]

V. ROLE OF REGULATION IN PATENT VALIDITY

Requiring courts to determine patent invalidity in order to find proximate causation is consistent with a robust line of case law holding that independent regulatory activity can be an intervening factor that cuts the chain of causation.[66] In the context of pharmaceuticals, this is commonly FDA regulatory activity, though it can also include

60 *Aggrenox,* 2015 U.S. Dist. LEXIS 94516 at *33–38.

61 *Aggrenox,* 2015 U.S. Dist. LEXIS 94516 at *33–38.

62 *Id.*

63 *See* ECF No. 362, 3:14-md-2516 (2d Cir. Sept. 16, 2015).

64 *Aggrenox,* 2015 U.S. Dist. LEXIS 94516, at *37–38 (emphasis original).

65 *Wellbutrin,* 133 F. Supp. 3d at 765 n.45.

66 *Wellbutrin,* 868 F.3d at 165 ("That a regulatory or legislative bar can break the chain of causation in an antitrust case is beyond fair dispute."); *Wellbutrin,* 133 F. Supp. 3d at 765 ("Where a regulation—such as patent law—precludes competition, that regulation cuts off the chain of causation.").

patent law and other regulatory actions.[67] On reconsideration of the *Nexium* district court case, the District of Massachusetts, framed its task as assessing "whether a reasonable jury could find that [a generic defendant] would have overcome regulatory and other hurdles to enter the market before [the agreed date in the reverse payment settlement], if it had not entered its settlement with [a brand manufacture]. If [it] would not have overcome such hurdles, then these obstacles were independent causes of [the] delayed launch and thus break the causal chain between the [] Settlement and the Plaintiffs' injuries."[68] The court found that, with respect to one generic, there was no evidence that the FDA would approve the generic's product before the reverse payment period expired, and, even if it would have been approved, there was no evidence suggesting the generic would have risked the patent litigation that inevitably would have followed.[69]

Of course, not all regulatory action is "independent," and courts have found that the misuse of the patent process in order to prompt certain FDA action makes that action an insufficient barrier to causation.[70] This argument is not confined to the pharmaceutical antitrust arena; cases spanning many industries and areas of law have held that, if injury arises due to the independent actions of government regulators, there is no causation.[71]

VI. CONCLUSION

As recent appellate decisions have confirmed, private antitrust litigants must prove that a reverse payment settlement proximately caused their antitrust injury without resort to proxies or presumptions. This means that courts will need to assess whether a patent potentially preventing the generic from entering the market was or was not invalid. On the other hand, courts that extend the reach of *Actavis* ignore that *Actavis* considered claims by the FTC, which do not involve the same causation burden as private plaintiffs' claims.

Unlike the indeterminate cat in Schrodinger's hypothetical, courts are quite capable of resolving the parties' differing perspectives about a particular patent's validity, thereby avoiding the need to resort to probabilistic or paradoxical assumptions about the state of the patent. This approach is not only feasible; it is obligatory under the causation requirement of the Clayton Act.

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67 *See, e.g., Meijer, Inc. v. Ranbaxy Inc.,* 2016 U.S. Dist. LEXIS 120780, at *54–55 (D. Mass. June 16, 2016); *In re Canadian Import Antitrust Litig.,* 470 F.3d 785, 791 (10th Cir. 2006) (holding that the lack of Canadian competition in the US prescription market "is caused by the federal statutory scheme adopted by the United States government, not by the conduct of the defendants"); *In re Asacol Antitrust Litig.,* 2016 U.S. Dist. LEXIS 94605, at *24 (D. Mass. July 20, 2016) ("Even if [generic defendant] could have negotiated an earlier entry date, the lack of FDA approval today remains 'the limiting factor' in [generic defendant's] ability to bring its generic drug to market.").

68 *Nexium,* 42 F. Supp. 3d at 269–70.

69 *Id.* at 272.

70 In re Actos End-Payor Antitrust Litig., 848 F.3d 89, 98 (2d Cir. 2017).

71 *See RSA Media, Inc. v. AK Media Grp., Inc.,* 260 F.3d 10, 12–15 (1st Cir. 2001) (holding that there was no antitrust liability because the plaintiff "was not excluded from the market for outdoor billboards because of [defendant's] threats; it was excluded because of the Massachusetts regulatory scheme that prevents new billboards from being built"); *City of Pittsburgh v. W. Penn Power Co.,* 147 F.3d 256, 265 (3d Cir. 1998) (holding that plaintiffs' alleged injuries resulted from 'the realities of the regulated environment' and not the defendants' actions).

UNCERTAINTY AND SCIENTIFIC COMPLEXITY: AN INTRODUCTION TO ECONOMIC FORCES THAT DRIVE CURRENT DEBATES IN HEALTHCARE ANTITRUST

By Paul Wong, Ph.D.[1]

Healthcare antitrust is a subset of antitrust law and economics that focuses on the healthcare industry. A vast number of lawyers and economists have devoted their careers to this "sub"-field addressing a large and integral part of our nation's (and California's) economy. Healthcare accounts for 18 percent of national GDP (over $3 trillion)[2] and is, perhaps, one of the most important "goods" that our society consumes, since it is essential to the welfare and wellbeing of each of us. The "antitrust" component of healthcare antitrust is equally important and interesting, as the structure of the American healthcare system is unique globally for its reliance on competition.[3] The healthcare system in the United States is also virtually unparalleled due to the presence of nearly every canonical market "friction."[4] As I discuss below, there are many topical and complicated questions that practitioners (lawyers, economists, regulators, and courts) continue to grapple with in healthcare antitrust. Greater discussion can help evolve thing surrounding the more complicated issues, and because of all of the economic twists and turns that healthcare presents, there are countless ideas and concepts that can be generalized to inform antitrust law and economics as they are applied in other industries. So, for my colleagues in all areas of law and economics, it is worth following issues in healthcare antitrust closely in the years to come.

There are two economic forces ever present in healthcare that I will focus on in this article. First, many industry actors, including patients, providers,[5] and payors,[6] face a tremendous amount of uncertainty, and each of those actors faces asymmetry in that uncertainty. This breeds a host of market frictions, such as adverse selection and agency problems, which may complicate the application of the standard paradigm that antitrust

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2 Sean P. Keehan, et al., *National Health Spending Projections Through 2020 Economic Recovery And Reform Drive Faster Spending Growth*, 36 Health Affairs 553 (2017).

3 Martin Chalkley and James M. Malcomson, *Government Purchasing of Health Services,* 1 Handbook of Health Economics 847 (2000).

4 Martin Gaynor and William B. Vogt, *Antitrust and Competition in Health Care Markets,* 1 Handbook of Health Economics 1405, 1409 (2000) ("Health care markets are characterized by multiple imperfections, in large part deriving from the uncertainty and asymmetry of information between buyers and sellers that are inherent in the nature of health and medical care.").

5 The term "provider" is generally used in health care to mean any person or firm providing a health care service or good, including both those mainly providing facilities and infrastructure ("facility provider"), such as hospitals, and those mainly providing labor and professional services ("professional provider"), such as physicians.

6 Insurance companies and government programs (*e.g.*, Medicare) are referred to as "payors" because they are typically responsible for the majority of reimbursement of providers on behalf of patients at the point of care.

law follows. Second, the scientific complexity of medicine necessitates a high level of specialization and intricate technology. This creates strong economies of scale and scope and requires coordination among different industry actors, which may also complicate the application of the standard paradigm. In turn, the healthcare financing and delivery system was built with these forces in mind, but it has evolved in such a way that there is a web of interlinking actions for every episode of care, and government plays a large role as both an industry actor and a regulator.

All of this—the economic forces of uncertainty and scientific complexity, coupled with a complicated healthcare system—implies that it is important to distinguish economic conduct that is unlawful and reduces social welfare from economic conduct that is naturally occurring or that ultimately benefits society. This places a great onus on healthcare antitrust practitioners to evaluate matters on a case-by-case basis (even more so than would otherwise be true) since there may not be clear-cut archetypes to follow for any given healthcare antitrust matter. I will provide some examples to illustrate these points, including those involving ambiguities over contracting at various stages of the healthcare financing and delivery system, the role of Accountable Care Organizations (ACOs), and debate concerning the potential for market power.

I. BACKGROUND

Separately, antitrust law and the healthcare industry are each straightforward enough to define. Broadly speaking, antitrust law has three main principles. First, it establishes that competition should operate freely—separate economic entities should not cooperate or collude in any instance where their natural incentive is to otherwise compete head-to-head. Many models in the economic literature hold that unfettered competition achieves the socially optimal outcome.[7] Second, it states that monopoly (or more broadly significant "market power") is likewise bad for society—a firm holding a monopoly may not face the incentive to produce its goods or services at the socially optimal price and quantity. Third, various activities might violate the first two general principles under some conditions, including price discrimination, exclusive dealings, multi-product tying, and mergers of competing firms. These three principles are intended to apply to nearly all industries, healthcare included.

The healthcare industry can be divided into two segments. First, it consists of what I shall call the "payor-provider" segment, which includes all actors focused on the direct delivery of healthcare. This includes patients (*i.e.*, "consumers"), insurance companies ("payors"), hospitals ("facility providers"), and physicians ("professional providers"). This segment also includes government (*e.g.*, Medicare, Medicaid, and the Veterans Administration), other benefits managers (*e.g.*, stand-alone pharmacy benefits managers and stand-alone dental and vision insurers), other facility providers (*e.g.*, laboratories, dialysis centers, and pharmacies), other professional providers (*e.g.*, mid-level practitioners, registered nurses, and therapists), and other suppliers (*e.g.*, firms focused on the delivery or rental of medical equipment and supplies). Each of these actors interacts within a large network of relationships and transactions.

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7 This concept dates back to Adam Smith's "Invisible Hand." *Somewhat more recently*, William S. Comanor and Harvey Leibenstein, *Allocative Efficiency, X-Efficiency and the Measurement of Welfare Losses*, 36 Economica 304 (1969); Ross Parish and Yew-Kwang Ng, *Monopoly, X-efficiency and the Measurement of Welfare Loss*, 39 Economica 301 (1972).

Second, the healthcare industry also consists of what I shall call the "pharmaceutical and medical device" segment, which includes all of the actors focused on the creation, development, and regulation of medical technology. This includes large and small pharmaceutical and medical device companies, generic pharmaceutical companies, other medical supply companies, government regulators (*e.g.*, the United States Food and Drug Administration), and diversified technology, electronics, and chemical companies (*e.g.*, Philips, 3M, and Johnson & Johnson). Due to the size and complexity of both segments, I will focus mainly on the payor-provider segment in this article, and I will treat "healthcare" as synonymous with payor-provider matters. This is not to diminish the importance or complexity of the pharmaceutical and medical device segment, but rather to acknowledge that this segment's issues are disparate and complex enough that they deserve discussion in a separate article.

Healthcare antitrust is the intersection of antitrust law and policy and the healthcare industry (again, here, payor-provider). The field investigates and applies antitrust principles to any and all of the healthcare actors, their relationships, and their economic interactions. As the cacophonous list above perhaps implies, the many actors, coupled with a host of economic issues that come in-tow, are what make healthcare antitrust unique and interesting.

To that end, healthcare antitrust primarily encounters two primal economic forces that make analysis more difficult: (a) uncertainty and (b) scientific complexity. Uncertainty arises, for example, because patients do not know when or with what severity a health malady might strike. Patients may, as a consequence, seek out insurance coverage from payors and care from providers, but even these specialized actors may not be able to perfectly forecast the severity or timing of patients' healthcare needs. Moreover, patients may privately know that healthcare is needed before payors and providers find out, and some patients may then have an incentive to withhold information from payors and providers.[8] Uncertainty arises for other reasons as well, including the fact that there may not be consensus over the definition of "quality" in a given clinical setting, an actor may not fully observe the price of a transaction, and there may be ambiguity concerning the proper course of medical treatment. These issues create a variety of market frictions, including adverse selection,[9] moral hazard,[10] and agency problems,[11] all of which may or may not impede the benefits of competition as compared with other industries.[12]

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8 For example, an uninsured patient may have a pre-existing health condition, such as diabetes. If the patient were insured, the patient's diabetes [Q: should the word 'medications' be inserted here?] would likely be covered by insurance and the patient would pay less money out of pocket. The insurer, on the other hand, would rather not cover that condition and pay additional costs of care all else equal. The patient, as a result, has an incentive to withhold information about the pre-existing condition when applying for insurance coverage. This is a standard example of adverse selection. George A. Akerlof, *The Market for Lemons: Quality Uncertainty and the Market Mechanism*, 84 The Quarterly Journal of Economics 488 (1970); Michael Rothschild and Joseph Stiglitz, *Equilibrium in Competitive Insurance Markets: An Essay on the Economics of Imperfect Information*, 90 The Quarterly Journal of Economics 629 (1976).

9 *Ibid*.

10 Bengt Holmstrom, *Moral Hazard and Observability,* 10 Bell Journal of Economics 74 (1979).

11 Sanford J. Grossman and Oliver D. Hart, *An Analysis of the Principal-Agent Problem*, 51 Econometrica 7 (1983).

12 Gaynor and Vogt, *supra* note 3.

Scientific complexity exists because treatment of medical conditions is highly individualized to a given patient, and it requires complicated medical technology and skilled, specialized professionals and techniques. These requirements, in turn, breed the need for expensive equipment and complex organizations, and require coordination among multiple actors and institutions. Economies of scale and scope are borne out of all of these factors—complicated equipment can be better mastered with more frequent use, physicians may require breadth in their case work and high enough volume to maintain their specialized skills, or a given medical condition might require two or more specialists to work together. For instance, some surgeons may require more than ten years of post-graduate schooling and training and, even then, require repeated practice to master complicated procedures.[13] As another example, the medical literature increasingly recognizes the joint incidence of medical conditions and the value of treating these conditions jointly,[14] and it has pushed for better coordination of care across different providers, such as primary care physicians and specialists or surgeons and rehabilitation providers.[15] These benefits of specialization and coordination provide an impetus for different industry actors to work in concert, and this, in turn, fuels incentive for firms to merge and integrate or for independent actors to communicate and coordinate—all behaviors that may fall under a watchful eye from antitrust regulators.

The healthcare financing and delivery system has evolved to account for these economic realities. To address market frictions and scientific complexity, the system exhibits a web of different payments and interactions among the many actors for even the provision of a single routine incidence of care. Likewise, because of market frictions, both federal and state governments play a large role as healthcare payors,[16] which consolidates a significant proportion of patients into one purchasing body, but also leads to a large and complicated regulatory framework that must interact with the competitive process. Economies of scale and scope created by scientific complexity push some actors toward centralization and integration, but this leads to a significant number of independent actors (namely patients) at one level of the system who must interact with large actors (government, payors, and hospitals) at other levels of the system, creating tension between heterogeneity and uniformity. And finally, the market frictions and dynamic changes in medical technology and techniques have pushed policymakers to create a substantial amount of healthcare-specific law and regulation, which must coexist with general antitrust law.

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13 Ann Barry Flood, et al., *Does Practice Make Perfect?*, 22 Medical Care 98 (1984); Harold S. Luft, et al., *The Volume-Outcome Relationship: Practice-Makes-Perfect or Selective-Referral Patterns?*, 22 Health Services Research 157 (1987); Martin Gaynor, et al., *Recent Developments in Health Economics: The Volume-Outcome Effect, Scale Economies, and Learning-by-Doing*, 95 The American Economic Review 243 (2005).

14 *See, e.g.*, Steven L. Gortmaker, et al., *Chronic Conditions, Socioeconomic Risks, and Behavioral Problems in Children and Adolescents*, 85 Pediatrics 267 (1990) at 267 ("Analyses confirmed that chronic physical conditions were a significant risk factor for behavior problems . . . ."); Danson R. Jones, et al., *Prevalence, Severity, and Co-occurrence of Chronic Physical Health Problems of Persons with Serious Mental Illness,* 55 Physician Services 1250 (2004) (studying "co-occurrence of physical illness within a representative sample of persons with serious mental illness").

15 Thomas Bodenheimer, *Coordinating Care—A Perilous Journey Through the Health Care System*, 358 The New England Journal of Medicine 1064 (2008).

16 Keehan, *et al., supra* note 1.

Navigating these issues to conform to the three basic antitrust principles requires practitioners to undertake detailed analyses. For example, because of the market frictions and the complicated healthcare system meant to address these frictions, collaboration, coordination, and multidimensional strategies may be needed to improve the delivery of healthcare. It is important to identify when competition in a market has been harmed by misconduct versus when a market has merely failed due to large market frictions. To name a commonly cited worry, it is possible that price competition among insurers in the face of adverse selection can drive outright market failure.[17] If insurers develop ways to discriminate against patients or if payors and providers coordinate extensively to share information, this may address some of the potential causes of market failure, but it may also blunt competition between some actors. Whether that runs counter to general antitrust principles must be determined for each case and circumstance. As another example, because of the scientific complexity of the industry and the specialization and coordination it drives, there may be large benefits to integration and mergers. It is important to separate situations in which consolidation of firms is carried out in the name of economies of scale and scope, and those in which consolidation is merely an attempt to gain market power. For instance, a merger of many small physician groups into a large multi-specialty group practice may help coordinate care across specialties or allow the group to bear greater financial risk, but it may also run the risk of creating a large, indispensable physician practice on which payors or hospitals rely significantly. These sorts of ambiguities are issues that must be weighed in nearly every healthcare antitrust matter.

I will list a few of the more current and interesting antitrust questions (and cases) that arise out of the environment described above and will devote the rest of the article to discussing these in more detail. First, contracting ambiguities abound in healthcare antitrust. It may be difficult without detailed analysis to determine whether a given contract is lawful (*i.e.*, good for competition and society) or unlawful (*i.e.*, harmful to society and competition). To name some recent and specific questions that have been raised:

- Who is the true "customer" for hospitals and how are prices actually set?
- Are exclusive or bundled (or both) contracts lawful, and is it possible to establish general antitrust rules for healthcare that guide these behaviors?

Second, there is a recent emphasis on the importance of Accountable Care Organizations (ACOs) for improving quality and lowering healthcare costs, yet the competitive implications of ACOs are still the subject of much controversy.[18] Further, some healthcare providers are finding it difficult to balance healthcare policy encouraging building ACOs on the one hand, with antitrust law limiting certain types of coordination on the other hand. This has raised questions of its own:

- What are the benefits of ACOs? Are they financial, clinical, or both? And what delineates coordination from collusion?

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17 Rothschild and Stiglitz, *supra* note 7.

18 Centers for Medicare and Medicaid Services, *Accountable Care Organizations (ACO)*, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ACO; Elliott S. Fisher and Stephen M. Shortell, *Accountable Care Organizations: Accountable for What, to Whom, and How?*, 304 J. Am. Med. Assoc 1715 (2010).

- Does the push toward designing and building ACOs by industry and in policy (*e.g.*, the Affordable Care Act (ACA)) justify greater healthcare consolidation?

Third, it may require extensive analysis to measure and determine market power (or lack thereof) in healthcare antitrust. Healthcare is a prime example of an industry in which simple metrics, such as market share, do not tell the whole story about market power. Regulators and courts may ask as a result:

- Does market power exist in a given healthcare market?
- What can or should be done if it does?

Some have raised concerns about different levels of the industry, including insurers, such as large national insurance carriers, hospitals, such as multi-hospital systems and Academic Medical Centers (AMCs), and physicians, such as large multi-specialty group practices. All three of the above areas of inquiry are on the frontline of healthcare antitrust today.

This also applies specifically to California, as many of these same healthcare antitrust issues are at play within the state. First, California has long been a leader in integrated healthcare delivery systems, and there is much innovation and experimentation with ACOs (or ACO-like models) in California. Second, California has many different markets and a large variety of firm sizes and structures. Some have raised concerns about market power within California. And finally, third, California is active and deeply involved in healthcare policy relative to other states. For example, California's public health insurance exchange ("Covered California") is among the largest in the country and continues to evolve,[19] and California is constantly seeking ways to adjust the healthcare financing and delivery system.[20]

II. AMBIGUITIES IN HEALTHCARE CONTRACTING

There are many antitrust questions about contracting in healthcare that lack a *prima facie* answer. To understand why this is the case, consider the way that healthcare is typically financed and delivered in the United States. First, individuals (*i.e.*, patients) make payments to insurers (or the government) via insurance premiums (taxes). Then, insurers negotiate coverage and prices with providers on behalf of the patients the insurers represent. Finally, patients and physicians (and/or insurers) jointly decide when and how much care is utilized, and insurers and patients (via co-payments) reimburse providers for the healthcare services actually rendered. All told, this series of multiple payments and decisions creates a triangular set of transactions rather than the linear chain that is typical in most industries.

If the structure of the system alone is not enough to convince one of the difficulties in evaluating contracting in healthcare, consider some other nuances that complicate healthcare transactions:

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19 Covered California, *Key Ingredients to Creating a Viable Individual Market That Works for Consumers*, http://hbex.coveredca.com/data-research/library/CoveredCA_Key_Ingredients-05-18-17.pdf.

20 *See, e.g.,* California Secretary of State, *Prop 61: State Prescription Drug Purchases. Pricing Standards. Initiative Statute*, http://voterguide.sos.ca.gov/en/propositions/61/.

- Insurers typically negotiate the prices of healthcare services, but often patients and physicians are unaware of these prices when deciding how or when to receive care.

- The primary decision to receive care (and what or how much) might be significantly influenced by any one of the three typical actors, which may shift from case to case:
  - The patient may have strong personal preferences and "self-refer" himself or herself to a given provider or request a particular type of care.[21]
  - The physician may have other clinical considerations and, based on those, direct the location or type of care provided, notably if the patient is a complicated case or the physician needs a particular care team or specialized technology.
  - The insurer may influence the location or type of care via benefit design (*e.g.*, a narrow insurance network) or by steering activity (*e.g.*, prior authorization).

- Contracts are designed to correct or take into account numerous market frictions, including:
  - Uncertainty over medical outcomes and the ultimate costs of care.
  - Private information, which generates adverse selection, moral hazard, and agency problems.
  - A high degree of heterogeneity on one side of the market that is not necessarily matched on the other side of the market.

- Medical specialization and the need for coordination of care create large economies of scale and scope for insurers and providers, often causing these actors to be large, diverse, and cover vast geographies. These actors must transact both with one another and with individual patients, and contracts must be sufficiently adaptable and complex to account for both types of interactions.

These are just some of the wrinkles that must be considered when analyzing a particular contract in healthcare.

Notably, the challenges for healthcare antitrust analysis described above raise an ongoing question that was particularly salient in recent hospital merger litigations. Unlike many other industries, there is a debate in healthcare concerning who is the "purchaser" and what is the "transaction" to be analyzed. When assessing the competitive effects of a hospital merger or the economic impact of a given contract (between different providers or between insurers and a provider), should one place more emphasis on the data and reactions of insurers or patients, and are the most relevant economic decisions the negotiations of prices in advance of the provision of care or the individual choices to utilize care once it is needed? Moreover, how does one measure price if it is stochastic and varies with every patient, and might insurers be at once purchasers and direct competitors to the providers at issue?

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21 Gaynor, *et al., supra* note 12.

These questions were very much at the forefront of *Federal Trade Commission, et al. v. Advocate Healthcare, et al.,* in which the courts attempted to weigh the effect of the merger between two hospital systems in Chicago.[22] Much of the analysis of competitive effects in the case centered around measures of patient substitution, such as patient-level diversion ratios,[23] yet both the district court and court of appeals held that "insurers, not patients, are the most relevant buyers" of hospital services.[24] As these courts found, insurers are the ones that negotiate prices, and they might be considered purchasers of healthcare whose opinions are relevant to the analysis of a given hospital merger. On the other hand, however, as stated in the analysis of competitive effects in the case, patients may make the ultimate decision on whether to receive care, and patients' decisions may not perfectly mirror testimony by insurers.

The presence of two relevant groups of actors, patients and insurers, on the purchasing side of the market poses other practical issues for antitrust analysis as well. For example, most of the data relevant to the analysis of providers follows the actions and choices of patients, such as patient-level market shares and diversion ratios. Modeling the mechanisms by which insurers react to patient preferences requires relatively complex economic theories.[25] In addition, government antitrust agencies also look to testimony by insurers in hospital merger cases, but there may be problems with placing significant weight on insurers' testimony if opposing (or supporting) the merger serves insurers' other interests. In *FTC v. Advocate*, the court acknowledged this concern noting that insurers might have acted "because they believed the merger would improve their own competitive position."[26]

The same economic forces discussed above must also be acknowledged in analyzing exclusive or bundled contracts in healthcare. On one hand, these sorts of contracts may make economies of scale and scope possible,[27] and these economies have been documented in the medical and economic literature.[28] Healthcare firms may enter into exclusive contracts, such as when a hospital contracts exclusively with one anesthesiology physician group; or into bundled contracts, such as when an insurer enters into a capitation arrangement with a large independent physicians association, to streamline incentives or eliminate duplication across separate providers. In the case of the anesthesiologists' exclusive contract, increased volume and more focused training

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22 *FTC v. Advocate Health Care Network, et al*., No. 1:15-cv-11473, 2016 WL 3387163 (N.D. Ill. Jun. 20, 2016); *FTC v. Advocate Health Care Network, et al*., No. 1:15-cv-11473, 2017 U.S. Dist. LEXIS 37707 (N.D. Ill. Mar. 16, 2017). *See also, Federal Trade Commission, et al., v. Penn State Hershey Medical Center, et al*., No. 16-2365, 2016 WL 5389289 (M.D. Pa. Sept. 27, 2016).

23 *FTC v. Advocate*, N.D. Ill. Mar. 16, 2017, *supra* note 21 at 14.

24 *Ibid. See also FTC v. Advocate Health Care, et al*., No. 16-2492 (7th Cir. Oct. 31, 2016) at 24 ("If patients were the relevant buyers in this market, those numbers would be more compelling since diversion ratios indicate which hospitals patients consider substitutes. But as we have explained, insurers are the most relevant buyers.").

25 Martin Gaynor and William B. Vogt, *Competition Among Hospitals,* 34 The RAND Journal of Economics 764 (2003); Cory Capps, *et al., Competition and Market Power in Option Demand Markets*, 34 The RAND Journal of Economics 737 (2003).

26 *FTC v. Advocate*, N.D. Ill. Mar. 16, 2017, *supra* note 21 at 24.

27 Ilya R. Segal and Michael D. Whinston, *Exclusive Contracts and Protection of Investments*, 31 The RAND Journal of Economics 603 (2000).

28 Flood, *et al.* and Luft, *et al., supra* note 12.

created by exclusivity may help eliminate errors and improve patient outcomes, and in the case of the capitation arrangement, financial risk sharing may prompt the association to eliminate redundant care. Moreover, these same contracts may also help eliminate agency problems or other incentive frictions that may exist between different actors. For example, the capitation contract may also encourage physicians to recommend alternative treatments outside of their primary specialties.

Exclusive or bundled contracts might also lead to antitrust problems under certain circumstances. Exclusive contracts may be designed to exclude competitors and to allow a firm to gain market power, and bundled contracts may be designed to gain an unfair competitive advantage if only some firms offer the bundled products. Regulators and courts, to their credit, have recognized that the possible anticompetitive effects of these sorts of contracts do not automatically disqualify any and all of them in healthcare. The risk of exclusion or unfair advantage must be weighed against the welfare enhancing gains in scale and scope or the benefits of aligning different actors' incentives. However, there may sometimes be limits to this balance. For some, economies of scale or scope may be exhausted above a certain point, or excluding even a single firm may have strong effects on competition if the market in question is already highly concentrated. Healthcare antitrust analyses must weigh these tradeoffs when evaluating exclusive or bundled contracts.

There is a recent case in California to illustrate the continuing ambiguity that exclusive or bundled contracts present in healthcare. In *Sidibe, et al. v. Sutter Health*, the Sutter Health hospital system in Northern California has been accused of unlawful efforts to bundle different healthcare services, such as inpatient and physician services, and to prevent insurers from steering patients toward competing healthcare providers.[29] It is possible, however, that these actions may instead be legitimate attempts by Sutter Health to ensure adequate economies of scope and scale. This is happening in other parts of the country, as well. For example, in *Methodist Health Services v. OSF Healthcare System*, St. Francis Hospital (*i.e.*, OSF Healthcare) was accused of unlawful exclusive contracting to the exclusion of Methodist Hospital. In this case, however, the Seventh Circuit ruled that St. Francis' exclusive contracts were, in fact, lawful means to capitalize on economies of scale.[30]

As these recent cases help illustrate, analysis of healthcare contracting and matters involving the healthcare financing and delivery system are not necessarily straightforward. The complex dance that patients, insurers, and providers must perform is borne out of the uncertainty and scientific complexity inherent in the healthcare industry, and that dance breeds a variety of other economic questions. These questions lay the groundwork for healthcare antitrust practitioners of the future.

III. ACCOUNTABLE CARE ORGANIZATIONS: GOOD OR BAD IN THE EYES OF ANTITRUST?

There has been a strong push by industry participants and policymakers toward building ACOs and other coordinated healthcare systems. It is intended that these collections unite

29 *Sidibe, et al. v. Sutter Health*, No. 14-16234 D.C. No. 3:12-cv-04854-LB (9th Cir. Jul. 15, 2016).

30 *Methodist Health Services Corp. v. OSF Healthcare System*, No. 1:13-cv-01054-SLD-JEH (7th Cir. Jun. 9, 2017) at 4 ("[A]n insurance company may get better rates from a hospital in exchange for agreeing to an exclusive contract, as exclusivity will drive a higher volume of business to the hospital.").

actors at different stages of the healthcare industry, such as between hospitals and physicians or between physicians of different specialties, in order to take greater responsibility for overall patient care and better coordinate different treatments. Perhaps best publicized, there are numerous provisions in the ACA, which provide strong incentives for providers to build new ACOs.[31]

The push to create ACOs encompasses the two ideas discussed throughout this article. First, the economic and medical literature has documented how sharing financial risk (*i.e.*, distributing the effects of an uncertain future) helps address the conflicting incentives of separate providers.[32] As different providers coordinate and bear the consequences of their actions together, they can better act in a patient's interest and provide "patient-centered" care.[33] For instance, a patient with a knee injury might be treated effectively with surgery or with intensive physical therapy. If a surgeon is prescribing care without financial integration with other providers, the surgeon has less of an incentive to recommend physical therapy. An ACO that financially unites the surgeon with a therapist, however, might increase the surgeon's incentive to recommend physical therapy. Second, the specialization that medical science often necessitates causes different providers to coordinate irrespective of the structure of the healthcare financing, and this, in turn, creates natural benefits from economies of scale and scope. For instance, medication adherence is beneficial for patients with chronic conditions, and it has been shown to reduce overall medical costs.[34] Coordination between a patient's primary care provider and a prescribing specialist may facilitate adherence, and this coordination may be more likely if the two physicians are part of the same organization. An ACO may help promote this coordination (and, hence, provide benefits to patients) by reducing the physicians' burden in executing the coordination or by providing a financial vehicle through which the physicians can share in the overall cost savings. In examples like these in healthcare, the economic forces of uncertainty and scientific complexity press firms to cooperate, coordinate, and integrate with a frequency that is not present in other industries.

But both coordination and scale have raised antitrust concerns in some cases. It may be important to see where coordination stops and collusion begins, or where efficient scale ends and market power begins. For example, coordination between a hospital and a rehabilitation center may be in the name of coordinating patients' transfers between facilities and any follow-on ("post-acute") care, and this should be separated from a scheme to foreclose a competing rehabilitation center. The core principles of antitrust warn of the potential anticompetitive effects of coordination and the accrual of scale, and this tension raises two ongoing issues for healthcare.

First, there is still no bright-line consensus concerning the boundary between collusion and coordination among ACOs. To this end, the federal antitrust agencies concede that

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31 Centers for Medicare and Medicaid Services, *supra* note 17.

32 Kurt C. Stange, *et al., Defining and Measuring the Patient-Centered Medical Home*, 25 Journal of General Internal Medicine 601 (2010); Paul Wong, *et al., Features of Patient-Centered Primary Care and the Use of Ambulatory Care*, 20 Population Health Management 294 (2017).

33 *Ibid.*

34 Michael Sokol, *et al., Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost*, 43 Medical Care 521 (2005).

there is no textbook model of financial or clinical integration that is sure to pass muster under antitrust law.[35] On the financial side, I have often heard questions like these in my own work with providers:

- How much "partial" capitation is enough to qualify as financial integration?
- Do informational firewalls provide a limit to financial collaboration?
- Can organization-wide joint contracting be done with only the merger of a select set of assets or operations?

And on the clinical side, I have heard questions in a similar vein:

- Is merging Electronic Health Records (EHR) systems enough to qualify as clinical integration?
- Can clinical coordination be achieved strictly by a professional services contract or does it require a full merger of assets?

These sorts of questions help illustrate the fact that there is a continuum of firm structures, service contracts, and collaboration efforts, many or all of which could justifiably be called ACOs for their ability to coordinate some facets of patient care.

For the antitrust analysis of the continuum of ACO structures, there can be a tension at work in how ACOs bring about changes in referral patterns, clinical practices, and duplication of services. ACOs may create new insurance products or help patients navigate the delivery system, which may change practices for the better. On the other hand, it is possible that an ACO can be designed to limit access for some actors in the market, such as by altering the referrals from a physician group to various hospitals. Depending on the circumstances, this may constitute anticompetitive foreclosure, or it may simply be competition at work, as when the competing hospitals outside the ACO still have many options for referrals.

These realities—a continuum of financial and clinical integration and a tension in how ACOs may alter the market—make it important to separate legitimate actions from attempts to gain market power. In the above example, it may be important to determine whether the second hospital is suffering from anticompetitive theft of referrals or whether the reduction in referrals is due to the success and high quality of the newly created ACO—or it may be that both legitimate and anticompetitive effects and motives are at work at once. It is the purpose of healthcare antitrust analysis to distinguish these effects from one another, but this can require extensive, detailed analysis.

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35 Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67,026, 67,028 (Oct. 28, 2011) ("The Agencies emphasize that [Accountable Care Organizations (ACOs)] outside the safety zone may be procompetitive and legal. An ACO that does not impede the functioning of a competitive market will not raise competitive concerns. The creation of a safety zone reflects the view that ACOs that fall within the safety zone are highly unlikely to raise significant competitive concerns; it does not imply that ACOs outside the safety zone necessarily present competitive concerns.").

Second, the antitrust requirements in building an ACO must also be balanced against the many goals of recent healthcare regulations. Actors at all levels of the healthcare financing and delivery system are facing this quandary. Insurers are being pushed to create additional economies of scale to meet new reporting requirements[36] and thinning margins.[37] Providers, given their difficulties in navigating financial and clinical integration, can find that ACO-like coordination is hard or impossible without a merger of assets. Further, these same providers are finding that meeting quality incentives (*e.g.*, forming "centers of excellence")[38] are difficult without expanded scale and centralization. As with the cases above, these moves to integrate and consolidate could come into conflict with antitrust principles in some markets. Antitrust authorities are generally unwilling to accept merely "the ACA compels us" as justification for a given merger. Further, industry participants at times express frustration that "the left hand" of government is not talking with "the right hand" of government.

These issues are at work in California as well. The Kaiser Permanente health system (which includes a health insurer, a hospital operator, and a physician group), for one, contains perhaps the most notable and longest standing example of a well-functioning, high-quality ACO. Yet other insurers and providers may struggle to replicate Kaiser's same offerings and high-quality care without also replicating its firm structure through a merger. And if competing with Kaiser does require a merger, are antitrust authorities willing to accept a dual motive—compete on par with an integrated system and comply with the intentions of the ACA—as sufficient justification for the merger?

IV. CHALLENGES IN ASSESSING MARKET POWER IN HEALTHCARE MARKETS

For some, consolidation in healthcare may raise concerns about market power. Recent cases involving health insurance mergers (*United States, et al. v. Anthem, et al.* and *United States, et al. v. Aetna, et al.*) have drawn attention to concentration in commercial insurance markets.[39] Or, as another example, it has been alleged that a BCBS firm accounts for a large fraction of the commercially insured population in many states.[40] Still other cases have drawn attention to concentration and the potential for market power among hospitals.[41] This may or may not implicate large hospital systems or it may implicate important AMCs. It may even implicate integrated health networks, as I have discussed above. And, finally,

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36 Centers for Medicare and Medicaid Services, *Mandatory Insurer Reporting for Group Health Plans (GHP)*, https://www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Mandatory-Insurer-Reporting-For-Group-Health-Plans/Overview.html.

37 National Associate of Insurance Commissioners, *Medical Loss Ratio*, http://www.naic.org/cipr_topics/topic_med_loss_ratio.htm.

38 Deborah Tolmach Sugerman, *Centers of Excellence*, 310 J. Am. Med. Assoc. 994 (2013).

39 *United States of America, et al. v. Aetna Inc., et al.*, No. 16-1494, 2017 WL 325189 (D.D.C. 2017); *United States of America, et al. v. Anthem Inc., et al.*, No. 16-1493, 2017 WL 527923 (D.D.C. 2017).

40 *Jerry L. Conway, D.C., et al. v. Blue Cross Blue Shield, et al.*, No. 2:13-CV-20000-RDP (N.D. Ala.).

41 *FTC v. Advocate and FTC v. Penn State, supra* note 21; *Sidibe v. Sutter, supra* note 28.

even physicians are not immune from suspicion. Recent economic literature has brought attention to the potential effects of physician mergers.[42]

Yet the economic literature does allow for the notion that market power is hard to attain, and that, in fact, a small number of firms are required to preserve competition. For example, two firms may be sufficient to maintain prices at competitive levels.[43] Or, it may be possible for the threat of entry alone to provide a constraint on existing firms' behavior.[44] Yet some of these theories rely on specific conditions, such as:

- Continuing economies of scale and scope;
- Savvy consumers who are willing to switch products or suppliers;
- Strong foresight by various actors;
- The absence of barriers to entry.

In healthcare, these conditions may or may not exist, depending on the state of the market at issue and how the various actors and levels of the delivery system interact with one another. For example, it is clear that there are economies of scale that are created by the scientific complexities of the industry, yet it can be unclear how quickly marginal returns diminish for a given set of specialties. And while insurers are typically sophisticated buyers with strong foresight, individual patients may not match insurers in this regard. If patients anticipate the future with little accuracy, this may diminish their incentive to substitute to new healthcare products or to invest in preventative care. And on top of all this, the forces of uncertainty and scientific complexity drive variation across markets, and this can affect how much bite the above conditions hold.

When assessing the implications of concentration and market power, there are a number of other questions that are raised:

- If a firm is found to have market power, can one effectively "unscramble the eggs"?[45] Even if one could for a single firm, what about the instance in which insurers, hospitals, and physicians are all large, consolidated firms in the same market?
- Which behaviors or contracts should be allowed for those with alleged market power, particularly if they are necessary to address the other economic frictions in healthcare?

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42 Thomas G. Koch, *et al., How Vertical Integration Affects the Quantity and Cost of Care for Medicare Beneficiaries*, 52 Journal of Health Economics 19 (2017); Thomas Koch and Shawn W. Ulrick, *Price Effects of a Merger: Evidence from a Physicians' Market*, FTC Working Paper Series (2017), https://www.ftc.gov/system/files/documents/reports/price-effects-merger-evidence-physicians-market/working_paper_333.pdf.

43 Andreu Mas-Colell, Michael Dennis Whinston, and Jerry R. Green, Microeconomic Theory 387(1995) (the Bertand model with two players yields perfect competition).

44 Gloria J. Hurdle, *et al.*, Concentration, *Potential Entry, and Performance in the Airline Industry*, 38 The Journal of Industrial Economics 119 (1989).

45 Federal Trade Commission, *Statement of the Federal Trade Commission's Bureau of Competition on Negotiating Merger Remedies* (2012), https://www.ftc.gov/system/files/attachments/negotiating-merger-remedies/merger-remediesstmt.pdf.

- If one were to re-fragment the industry, does this run against the aims of health policy? Is coordination harmed or are economies of scale lost if firms are broken apart?

Ongoing work in healthcare antitrust and healthcare policy may help address these questions.

V. CONCLUSION

In this article, I offered an overview of healthcare antitrust. Healthcare is unique among industries due to two key forces: (a) all actors in the industry face an enormous amount of uncertainty, and (b) there is a strong need for coordination and scale driven by scientific complexity and specialization. These forces have given rise to a complex healthcare financing and delivery system that weaves together many different actors and exhibits a host of economic frictions. These, in turn, drive a number of notable, ongoing issues in healthcare antitrust. First, courts and regulators must work to determine and understand which contracts are permissible under antitrust law. Second, the industry and policymakers continue to make a large push toward ACOs and emphasize coordination among different healthcare actors, yet ACOs must be careful not to operate at odds with antitrust law. Third, some worry about market power given ongoing concentration among insurers, hospitals, and physicians, but if market power exists for these healthcare actors, the best way forward requires additional analysis and thought. These issues are worth following as healthcare antitrust moves forward. They will not only have bearing on how the healthcare industry evolves, but they may also help inform other areas of antitrust law and other industries.

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