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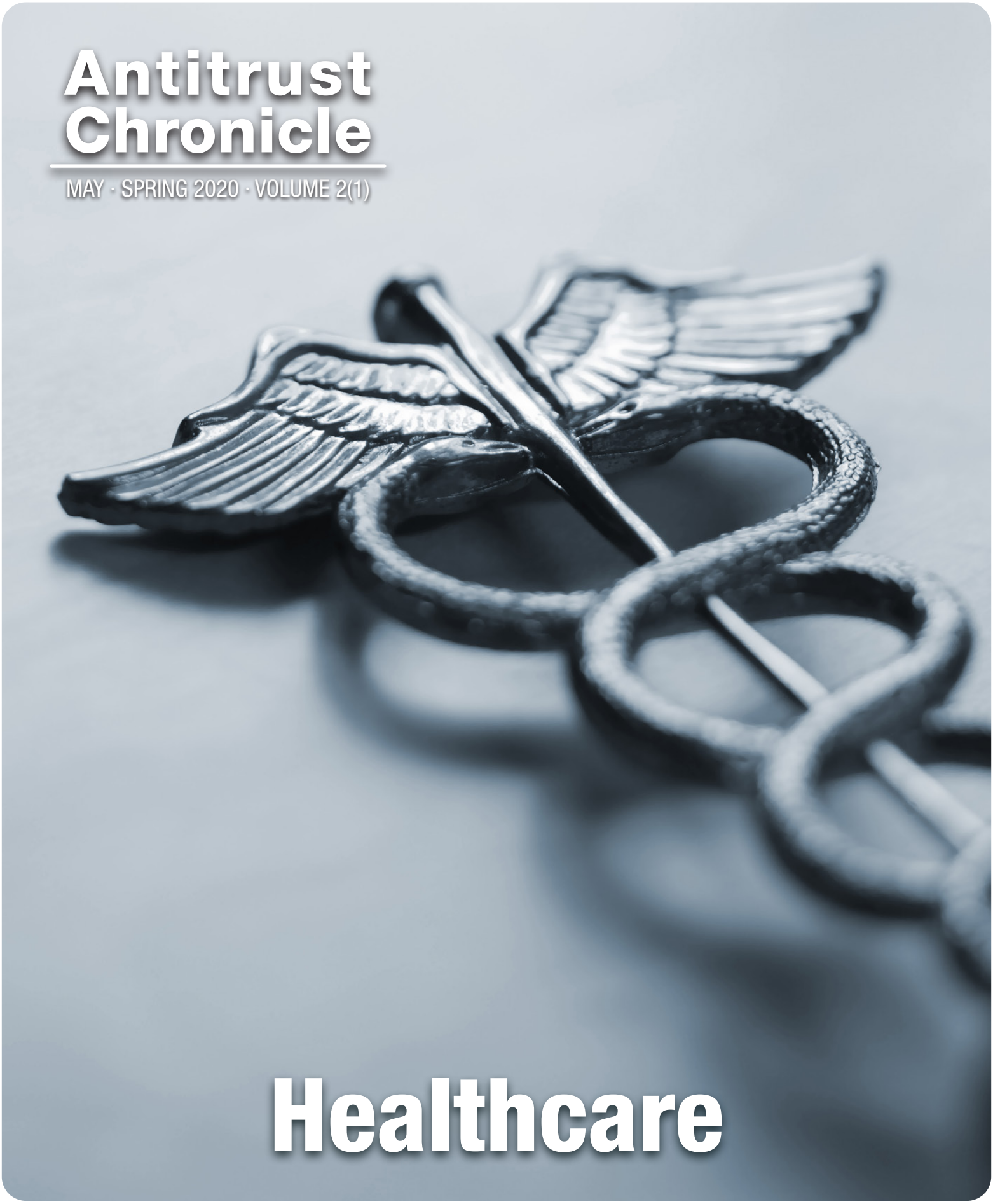

Healthcare

CPI COMPETITION POLICY INTERNATIONAL

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LETTER FROM THE EDITOR

Dear Readers,

In this Chronicle we turn to the timely issue of healthcare and competition.

In light of the COVID-19 pandemic, the healthcare industry, in all its facets, including the development of pharmaceuticals, the provision of healthcare, and health insurance, has never been as vital. Antitrust rules have a key role to play to ensure that drug companies continue to innovate, vital care is provided to the public, and, above all, that patients receive the care they need.

The articles in this volume address the key issues relevant to antitrust and healthcare around the world. Notably, in present circumstances, antitrust rules must be sufficiently flexible to allow collaboration between erstwhile competitors to rapidly develop new therapies, while not undermining the competitive process. Patients must reap the benefits of generic drugs, while not undermining the incentives of pharmaceutical companies to innovate. Physicians must be incentivized to develop and grow medical practices, and to protect patient-specific investments, but without overly hindering competition through non-compete agreements. And patients must be protected from price gouging in times of unprecedented demand.

These issues have long been subject to antitrust scrutiny, but their importance, and the delicate balancing acts they entail, have never been more vital. The contributions to this edition of the Chronicle draw on the authors' wealth of experience and insight in this field from jurisdictions around the world.

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

Sincerely,

CPI Team

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Potential and Nascent Competition in FTC Merger Enforcement in Health Care Markets

By Michael R. Moiseyev

Continuing calls for more vigorous enforcement against mergers and acquisitions by digital technology platforms increasingly focus on deals involving potential and nascent competitors. The FTC has been applying future competition theories in the healthcare sector for years, including litigating the government's first merger challenge on actual potential competition grounds since the mid-80s. It also challenged mergers under Section 2 "nascent competition" theories, a close cousin of an actual potential competition, in two recent matters. This paper examines Agency's experience in these cases, highlights some of the differences between the two approaches, and suggests how the FTC may apply this thinking in other contexts, including acquisitions by technology platforms.

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Price Transparency: Friend or Foe? How Price Transparency May Impact Competition in the Health Care Industry

By Dionne Lomax & Sophia Sun

The U.S. health care system is in the midst of disruptive changes designed to expand access, improve quality, and lower costs. Price transparency is now a hotly debated issue in the wake of the government's recent push for transparency in certain sectors of the health care industry. This paper argues that while price transparency in the health sector is necessary, price transparency, standing alone, will not solve the problem of growing health care costs. While the notion of injecting free-market principles into health care is intuitively sound, this paper argues that if the Administration's price transparency rules are implemented as proposed, provider rates may actually increase to the detriment of consumers and thwart the rules' efficacy. Instead, legislators and industry experts should consider a more targeted approach that balances consumer preferences with antitrust principles.

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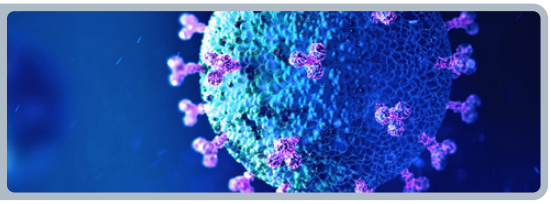

Antitrust & COVID-19 in The U.S.: Four Key Issues for Healthcare Providers

By John D. Carroll & Alexis J. Gilman

The COVID-19 pandemic continues to disrupt industries around the globe, and the impact on the healthcare industry has been especially profound. Healthcare providers are working to combat the virus and treat patients while dealing with significant challenges. The COVID-19 pandemic is not just affecting clinical and business operations, but also the legal environment in which businesses operate. In the U.S., the healthcare industry has been a primary focus of federal and state antitrust enforcement and litigation, with antitrust enforcement agencies' aggressively scrutinizing provider transactions and various types of conduct. This scrutiny has continued, and will continue, during the COVID-19 pandemic, with the FTC and the DOJ adopting various measures to adjust their processes for investigating competitive issues. This article provides an overview of four key antitrust issues for healthcare providers in the U.S. in light of the COVID-19 pandemic.

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Pay-For-Delay: Who Does the Generic Industry Lobby Represent?

By Michael A. Carrier

The generic industry lobby, Association for Accessible Medicines ("AAM"), often represents the public interest. In the pharmaceutical industry, it challenges brand drug companies' anticompetitive conduct. It fights for lower prices for consumers. And it has built up goodwill for its work in these areas. But there is one glaring exception. Brand and generic companies often settle patent litigation. And sometimes they do so with the brand paying the generic to delay entry. To state the obvious, generics do well when brands pay them to stay off the market. But AAM's fierce advocacy in favor of these "pay-for-delay" settlements has not received the attention it deserves. This essay addresses this gap. It analyzes AAM's advocacy against congressional pay-for-delay legislation and its briefs in two recent cases involving a Federal Trade Commission challenge and California legislation. The essay concludes that in defending these blatantly anticompetitive deals, AAM does not represent the public interest.

SUMMARIES

WHAT'S NEXT?

For June 2020, we will feature Chronicles focused on issues related to (1) **Self-preferencing**; and (2) **Monopsony**.

ANNOUNCEMENTS

CPI wants to hear from our subscribers. In 2020, we will be reaching out to members of our community for your feedback and ideas. Let us know what you want (or don't want) to see, at: antitrustchronicle@competitionpolicyinternational.com.

CPI ANTITRUST CHRONICLES JULY 2020

For July 2020, we will feature Chronicles focused on issues related to (1) **Algorithms**; and (2) **Sustainability**.

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

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

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

POTENTIAL AND NASCENT COMPETITION IN FTC MERGER ENFORCEMENT IN HEALTH CARE MARKETS

BY MICHAEL R. MOISEYEV[1]

1 Former Assistant Director in the Bureau of Competition of the Federal Trade Commission. The views expressed do not necessarily reflect the views of the Federal Trade Commission, any Commissioner, nor anyone else aside from the author.

I. INTRODUCTION

Popular interest in antitrust has been growing significantly in recent years, fueled in large part by a concern about what (if anything) can or should be done about "big tech." Critics argue that these companies owe their dominance, at least in part, to "hundreds of mergers," most of which involve what they term "nascent competitors."[2] While acquisitions of future competitors are gaining attention in the technology sector, the FTC has been scrutinizing these types of deals in the healthcare sector for years. Experience with the FTC's approach to these transactions may provide a roadmap to how the agency may evaluate transactions in other industries, including high tech, in the future.

The FTC considers the risk that a merger may lessen future competition under two related theories. One is the actual potential competition doctrine[3] of Section 7 of the Clayton Act, which condemns transactions between firms that do not currently compete, but may in the future, if certain criteria are met. Historically, the most difficult of those has been establishing the requisite likelihood that the entry will actually occur. The second involves looking at these transactions as a form of monopolization under Section 2 of the Sherman Act. Though that imposes a different set of requirements — particularly that one of the parties be a monopolist — it may accommodate less certainty that the non-incumbent will mature into a full-blown competitor. The difference between these two approaches can be seen by comparing the FTC's unsuccessful litigation to block the *Steris/Synergy* merger under Section 7, and its complaints that led to settlement and abandonment in the *Questcor/Novartis* and *Illumina/PacBio* deals under Section 2.

II. FUTURE COMPETITION THEORIES

A. Actual Potential Competition

Although the Supreme Court has not fully endorsed the actual potential competition doctrine, it set out the requirements for its successful invocation over forty years ago in the *Marine Bancorporation* case. According to the Court, a prerequisite for any potential competition case is that the market at issue be "substantially concentrated." Beyond that, it identified "two essential preconditions." The first is that the potential competitor must have "available feasible means for entering" the market other than through the merger in question. Second, "those means must offer a substantial likelihood of ultimately producing deconcentration of that market or other significant procompetitive effects."[4] In *Marine Bancorp*, the Court opted not to rule on the validity of the theory because it was satisfied that the entry could not occur due to the state banking regulatory regime, and formally reserved that question.

Subsequent cases accepted actual potential competition as a viable theory of harm, but most of the government's challenges failed. Courts, it turned out, were reluctant to find that the government had shown a sufficient likelihood the non-incumbent would actually enter, perhaps because many of these cases relied on "objective evidence" to show that the firm would enter. That is, the government asserted that the potential entrant had the incentive and ability to enter, so it likely would. Courts seemed suspicious of the government's hypothesizing, and established stiff probability requirements.[5] Some set the bar at "reasonable probability," "likely," or some close variant. Others required clear or unequivocal proof that the acquiring firm, in fact, would have entered the relevant market.[6] Some courts also added a temporal dimension by requiring proof that the hypothesized entry would occur in the near future.[7] By the time the FTC reconsidered the theory in 1984, it adopted a "clear proof" standard that was so strict that a concurring Commissioner declared that for "the Commission at least, actual potential competition theory is dead."[8]

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2 See, e.g. Tim Wu & Stuart A. Thompson, "The Roots of Big Tech Run Disturbingly Deep," New York Times June 7, 2019, available at https://www.nytimes.com/interactive/2019/06/07/opinion/google-facebook-mergers-acquisitions-antitrust.html.

3 "Actual potential competition" differs from "perceived potential competition" in that the former focuses on the future effect of entry, while the latter is a form of current competition from a firm that is not (yet) actually in the market. The perceived potential competition theory requires evidence that the non-incumbent is already affecting competition in the market, which is often absent in future competition cases.

4 418 U.S. 602, 633 (1974).

5 Cf. *Id.* at 623 (stating that the government's case asked the Court "[t]o assume, *on the basis of essentially no evidence*, that the challenged merger will tend to produce a state-wide linkage of oligopolies[.]") (emphasis added))

6 See ABA Antitrust Section Antitrust Law Developments (8th ed.) (Cataloging the standards for the likelihood of entry potential courts have applied in actual competition cases).

7 BOC Int'l v. FTC, 557 F.2d 24, 28-29 (2d Cir. 1977).

8 See, e.g. B.A.T. Indus., 104 F.T.C. 852, 947 (1984).

About a decade later, the FTC began facing a string of mergers in the pharmaceutical sector, some of which raised important future competition questions. Unlike the earlier actual potential competition cases, in these there was ample "subjective evidence" — a commitment at the decisional levels of the companies, accompanied by substantial capital expenditures — that the parties were, in fact, *trying* to enter. But the development process often results in failure and FDA approval, is far from certain even for drugs that are in advanced clinical trials, so the language of the actual potential competition cases could have been an obstacle to challenging future overlaps in these cases. Nevertheless, the FTC has taken the view that because the pharmaceutical products at issue faced limited competition, new entry could produce significant pro-competitive benefits, even adjusting for the entry's probability of success.

B. Monopolization

Section 2 of the Sherman Act is directed at conduct by a monopolist. To be actionable, the conduct must be engaged in by a monopolist, be willful, and must be something other than competition on the merits. The latter requirement excludes a whole category of activity — for example, innovation or non-predatory aggressive pricing — that may harm competitors, but not competition, and therefore is not the type of conduct Section 2 prohibits. For the remainder, the question is whether the conduct is anticompetitive, whether there are genuine and legitimate business justifications for it, and, if so, whether its anticompetitive effect outweighs any procompetitive effect.[9]

Mergers can be a form of prohibited conduct under Section 2,[10] since, as some commenters have observed, nothing can be more certain to exclude a competitor than eliminating it altogether.[11] At the same time, the common belief is that Section 7 "requires much less" to prove a violation.[12] That may not be true, however, when the target is a future competitor because of the difference in way courts have treated potential competitors under Section 7 and nascent competitors under Section 2, respectively. While Section 7 decisions have permitted acquisitions when the non-incumbent's entry is less than "probable," Section 2 has taken a harsher view of conduct aimed at nascent competitors. As the *Microsoft* court stated, "it would be inimical to the purpose of the Sherman Act to allow monopolists free reign to squash nascent, albeit unproven, competitors, at will."[13] Applying that reasoning to mergers, acquisitions by monopolists of nascent competitors could be a form of anticompetitive conduct under Section 2.

The question of what qualifies as a nascent competitor thus becomes pivotal in a Section 2 merger case. In *Microsoft*, the court considered whether Microsoft's exclusionary practices toward middleware providers — Netscape and Java — could constitute anticompetitive conduct. In reaching the conclusion that it could, the court favorably referenced the district court's "ample findings" that these middleware providers "showed potential."[14] The district court's findings focused mostly on the *threat* they posed to Microsoft, including that (1) Microsoft viewed middleware as a threat to Windows; (2) the middleware providers strove to reduce reliance on Microsoft's OS; and (3) these views were shared by other industry participants.[15] Thus, the evidence that middleware posed a threat to Windows was sufficient to make them "nascent competitors."

It is important to stress that none of the district court's findings went to whether middleware had a substantial likelihood of displacing Windows or otherwise deconcentrating the market in the near future. Indeed, the *Microsoft* court emphasized that was not even germane to its inquiry. "[T]he question in this case is not whether Java or Navigator *would actually have developed* into viable platform substitutes."[16] The court also had no concern that "[i]t would take several years for middleware ... to evolve ... into a product that can constrain operating system pricing."[17] Areeda & Hovenkamp agree with this formulation as it applies to mergers. They would condemn an acquisition by a monopolist of "any firm that has the economic capabilities for entry and is a *more-than-fanciful possible entrant* ... unless the acquired firm is no different ... from many other firms."[18] Therein lies a fundamental difference between Section 2 and Section 7: Section 7 has been interpreted to require a

9 *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966); *United States v. Microsoft*, 253 F.3d 34, 58-59 (D.C. Cir. 2001).

10 See, e.g. *Grinell*, 384 U.S. 563.

11 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 912b, at 92 (stating that an acquisition "tends to maintain a monopoly by cutting off an avenue of future competition before it has a chance to develop. As a result, condemnation under § 2 is appropriate").

12 *Fraser v. Major League Soccer, LLC*, 284 F.3d 47, 61 (1st Cir. 2002).

13 *Microsoft*, 253 F.3d at 59, 79.

14 *Id.* at 79.

15 *United States v. Microsoft*, 84 F. Supp. 2d 9, 28-30 (D.D.C. 1999).

16 *Microsoft*, 253 F.3d at 79 (emphasis added).

17 *Id.* at 54.

18 Areeda & Hovenkamp, *supra* note 11, ¶ 701d.

counterfactual showing that, but for the merger, the market likely would become more competitive, while Section 2 focuses on whether the firm is a threat at the time of the acquisition.[19]

The final step in a Section 2 case is to assess any "procompetitive justification — a non-pretextual claim that [the monopolist's] conduct is indeed a form of competition on the merits because it involves, for example, greater efficiency or enhanced consumer appeal," and balance it against the anticompetitive effect of the acquisition.[20] Efficiency claims are common in merger cases, and there is an extensive body of Section 7 law and guidelines that could govern how the FTC and courts might asses them. Under the *Merger Guidelines* and case law, only verifiable, merger specific efficiencies qualify.[21] That filter may also apply in a Section 2 case. It is an open question, however, as to how the balancing of any remaining pro-competitive efficiencies against a merger's anticompetitive effect would play out, since courts rarely reach that stage in Section 2 cases. Regardless, merging parties could face an uphill battle in front of the antitrust agencies since the *Merger Guidelines* state, "Efficiencies almost never justify a merger to monopoly or near-monopoly,"[22] a view consistent with the "overwhelming, substantial" efficiencies Areeda & Hovenkamp would require in Section 2 merger cases.[23]

III. FUTURE COMPETITION IN FTC HEALTH CARE MERGER CASES

A. Section 7 Actual Potential Competition Cases

The Commission has challenged — and obtained divestitures in — numerous pharmaceutical merger cases under an actual potential competition theory where one (or both) of the merging parties had a product in development that could provide important competition to the other at some future date. The FTC's recent settlement in the *Bristol-Myers Squibb/Celgene* matter is a good example of the type of pharmaceutical case where it routinely seeks relief.[24] At the time of the deal, Celgene had a popular oral psoriasis drug on the market, Otezla, and BMS had an oral psoriasis drug in development that would compete closely and directly with Otezla, if approved. Although the drug development process is inherently uncertain and protracted, there was a strong, bi-partisan consensus that the relief was warranted, as there has been for years in similar cases.[25]

The FTC's challenge to the *Steris/Synergy* merger shows how difficult it can be to prove that entry is "probable" in litigation.[26] Steris Corporation was one of only two companies providing gamma-ray sterilization services to medical device firms in the United States, and Synergy Health plc was a British company that offered sterilization services around the world, but did not have gamma-ray sterilization capabilities in the United States. Synergy recognized this gap limited its attractiveness to some global players, so it was keen to bring this service the United States market. Its problem was that there were no available sources of the required radioactive material, so it had been developing a new, potentially superior, technology for several years. By the time of the merger, according to the complaint, Synergy was in the advanced stages of planning its entry into the United States, including negotiating for physical locations for its facilities, contracting for the required equipment, and assembling a U.S. sales and marketing team. Then, in the middle of the merger review process, the company terminated this effort — just after FTC staff advised Synergy of its concerns. At trial, Synergy officials testified that they had scuttled their plans for legitimate reasons, asserting that the

19 *Accord*, *Microsoft*, 253 F.3d at 79 (quoting Areeda & Hovenkamp, Antitrust Law ¶ 650c (1996)) (stating that "courts [may] infer 'causation' from the fact that a defendant has engaged in anticompetitive conduct that 'reasonably appears capable of making a significant contribution to . . . maintaining monopoly power'").

20 *Microsoft*, 253 F.3d at 59.

21 See, e.g. U.S. Dep't of Justice & Fed. Trade Comm'n, 2010 Horizontal Merger Guidelines §10 (hereinafter "Merger Guidelines").

22 Merger Guidelines §10. The Guidelines state that they apply to "mergers and acquisitions involving actual or potential competitors ("horizontal mergers") under the federal antitrust laws," including Section 2. *Id.* §1.

23 Areeda & Hovenkamp, *supra* note 11, ¶ 701h (stating that they would require an "overwhelming demonstration that substantial efficiencies are involved and . . . cannot be achieved in other ways" when a monopolist seeks to acquire a nascent competitor)). This standard is similar to the "*extraordinarily great* cognizable efficiencies" requirement set out in the Merger Guidelines in instances "[w]hen the potential adverse competitive effect of a merger is likely to be particularly substantial." Merger Guidelines § 10 (emphasis added).

24 Bristol-Myers Squibb Co. and Celgene Corp., Docket No. 4690 (November 15, 2019), available at https://www.ftc.gov/system/files/documents/cases/191_0061_c4690_bms_celgene_complaint_0.pdf.

25 Though some Commissioners have dissented in cases where pharmaceutical divestitures were ordered, none have cited the probability of approval as being too remote or distant to fall within the proscriptions of Section 7 in the last thirty years. See, e.g. *Bristol-Myers Squibb*, F.T.C. Docket No. 4690 (Comm'r Slaughter, *dissenting*) (stating that the divestiture "remedies a serious concern about a drug-level overlap between BMS's development-stage [product] and Celgene's on-market Otezla," but dissenting because she believed that it "does not fully capture all of the competitive consequences of [large pharmaceutical] transactions."). The last time a Commissioner dissented in a pharmaceutical case on the grounds that entry was not sufficiently probable was in 1990. See, Roche Holding, 113 F.T.C. 1086, 1107-08 (1990) (Comm'r Owen, *dissenting*).

26 *FTC v. Steris Corp.*, 133 F. Supp. 3d 962 (N. D. Ohio 2015); Steris Corp. and Synergy Health PLC, Docket No. 9365 (May 29, 2015), available at https://www.ftc.gov/system/files/documents/cases/150529sterissynergypart3cmpt.pdf.

uncertainty of the financial payback would have doomed the project before it would have made the investment. That post-acquisition rationale was enough for the court to be convinced that Synergy's entry into the United States was not "probable."

B. Section 2 Monopolization Cases Involving Acquisitions of Nascent Competitors

The FTC has brought two merger challenges under a Section 2 "nascent competition" theory in the past three years, one involving Questcor's acquisition of a drug from Novartis, and the other involving Illumina's proposed acquisition of Pacific Biosciences of California.[27] These cases had in common that they involved an acquisition by a monopolist of a firm that threatened the monopoly position, but faced considerable hurdles to entering and successfully competing. In both, the FTC appeared to be relying on Section 2 to sidestep the requirement in Section 7 case law that it prove that the entry was likely to be successful.

Mallinckrodt (which had acquired Questcor after the acquisition) involved an acquisition by the only U.S. supplier of adrenocorticotropic hormone ("ACTH"), a drug used to treat a rare form of epilepsy in infants, among other applications. In other parts of the world, a synthetic analog, Novartis's Synacthen, was used instead of Acthar. Questcor had been very aggressive in raising the price of Acthar over the preceding decade, but recognized that doing so could create an incentive for Novartis (or some other firm) to try to bring Synacthen to the United States, even though Synacthen was not FDA-approved and there was considerable uncertainty about whether it could be. Despite these barriers, according to the FTC complaint, Questcor had viewed Synacthen as a threat for years and had monitored that threat. When Questcor learned that another company was interested in acquiring the drug and bringing it to the United States, immediately submitted a take-out bid. On these facts, the FTC charged that the acquisition was a "defensive move" by Questcor to "extinguish[] a nascent competitive threat to its [Acthar] monopoly." Notably, in its complaint, the FTC conceded that there was "significant uncertainty that Synacthen, a preclinical drug, would be approved by the FDA."[28]

Like *Mallinckrodt, Illumina* involved a proposed acquisition by a company the FTC claimed was monopolist. At the time of the merger, Illumina was the leading supplier, by far, of "next generation sequencing" ("NGS") systems. Its products are based on a "short read" technology that produces very high throughput at low cost, and have been so successful that Illumina had, according the FTC, more than a 90 percent share of the NGS market. PacBio had a very small share of the market but was one of only three other suppliers of NGS systems at the time of the merger. Its products use a different technology, "long read," to provide more detailed sequencing information, but at a significantly higher cost and lower throughput. In recent years, however, PacBio had been making advancements that improved accuracy and lowered cost. According to the FTC, Illumina had been monitoring PacBio's product improvements and viewed PacBio's product and technology as a significant competitive threat. The FTC charged that the merger violated both Section 7 and Section 2, but it is clear that it was relying heavily on its Section 2 theory, perhaps to overcome uncertainty about how the market would develop. As a senior FTC official said at the time of the challenge, "[w]hen a monopolist buys a potential rival, it can harm competition. These deals help monopolists maintain power. That's why we're challenging this acquisition."[29]

IV. CONCLUSION

While it may appear the FTC is taking two distinct approaches to future competition cases, that may not be what is really happening. *Steris* demonstrated that courts can be reticent to find a firm a likely future competitor, but subsequent cases show that the Commission remains concerned about future competition cases even where there is considerable uncertainty the entry effort will be successful. The FTC's continuing investigation and challenges of these deals under both Section 7 and Section 2 may suggest that it considers the threshold requirement of a high probability of entry in future competition cases to be too stringent to capture the potential anticompetitive effects of these transactions.

This explanation would align with the agency's guidance. The *Merger Guidelines* formulation for analyzing the competitive effect of a merger involving an actual potential competitor is a function of the "market share of the incumbent," the "competitive significance of the potential

27 Mallinckrodt Ard Inc., Civil Action No. 1:17-cv-00120 (January 18, 2017), available at https://www.ftc.gov/system/files/documents/cases/170118mallinckrodt_complaint_public.pdf; Illumina, Inc. & Pacific Biosciences of California, Inc., F.T.C Docket No. 9387 (December 17, 2019) (hereinafter "Mallinckrodt Complaint") available at https://www.ftc.gov/system/files/documents/cases/d9387_illumina_pacbio_administrative_part_3_complaint_public.pdf. The FTC has used Section 2 in one other merger matter. See, Thoratec & HeartWare Int'l, F.T.C. Docket No. 9339 (July 29, 2009), available at https://www.ftc.gov/sites/default/files/documents/cases/2009/07/090730thorateadminccmpt.pdf. *Thoratec* involved an acquisition by a monopolist incumbent of a product that was in development, and the uncertainties of the clinical trial and regulatory approval process made it difficult to predict that the entry was likely.

28 Mallinckrodt Complaint ¶¶ 1, 8, 34.

29 FTC, "FTC Challenges Illumina's Proposed Acquisition of PacBio" (December 17, 2019), available at https://www.ftc.gov/news-events/press-releases/2019/12/ftc-challenges-illuminas-proposed-acquisition-pacbio.

entrant," and it "competitive threat ... relative to others."[30] The "competitive significance" of the entrant is the product of both its probability of successful entry *and* its impact if, and when, it occurs. The FTC's cases under Section 2 thus far appear to fit the category of "lower probability/high market share," as do its Section 7 pharma cases (like *BMS*), which considered probability of entry against the closeness of the competition, if it emerges. In that way, both categories hew to a "sliding scale" between the probability and competitive impact of entry implied by the guidelines.

The FTC's evaluation of future competitive effects has application beyond health care. The agency has been public about the attention it is paying to acquisitions of nascent competitors by major technology platforms.[31] A number of commenters have suggested that Section 2 may be an appropriate vehicle for challenging those types of transactions, given the limitations actual potential competition doctrine under the case law.[32] The FTC's recent work suggests that it is more likely to use Section 2 as one of its tools in tackling potential competition mergers — particularly where there is strong evidence of monopoly power, a feature that it may believe is present in some technology markets. That may provide the FTC with a possible way to circumvent the requirements of the Section 7 actual potential competition case law in litigation, but it would not be a departure from the its thinking in future competition cases as reflected in its health care actions and the Guidelines.

30 Merger Guidelines § 5.3.

31 FTC, "FTC to Examine Past Acquisitions by Large Technology Companies: Agency Issues 6(b) Orders to Alphabet Inc., Amazon.com, Inc., Apple Inc., Facebook, Inc., Google Inc., and Microsoft Corp." (February 11, 2020).

32 See, e.g. C. Scott Hemphill, *Disruptive Incumbents: Platform Competition in an Age of Machine Learning*, 119 COLUM. L. REV. 1973, 1984–89 (2019).

PRICE TRANSPARENCY: FRIEND OR FOE? HOW PRICE TRANSPARENCY MAY IMPACT COMPETITION IN THE HEALTH CARE INDUSTRY

BY DIONNE LOMAX & SOPHIA SUN[1]

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I. INTRODUCTION

The U.S. health care system is in the midst of disruptive changes designed to expand access, improve quality, and lower costs. The U.S. continually spends significantly more on health care than any other country in the world and also spends the greatest proportion of its Gross Domestic Product ("GDP") on health care.[2] For example, health care spending now accounts for 17.7 percent of the GDP, compared to 8.8 percent for the average country.[3] Moreover, total health expenditures in the U.S. have increased substantially over the past several decades. According to a study conducted by the Office of the Actuary at the Centers for Medicare & Medicaid Services ("CMS"), total national health care spending in 2018 grew 4.6 percent and reaching $3.6 trillion.[4]

Amid rising health care costs in the U.S., many have sought to find a solution. Although price transparency has been touted by some as one solution, it is now a hotly debated issue in the wake of the government's recent push for price transparency in certain sectors of the health care industry. This paper will explore the pros and cons of the government's price transparency initiative while also weighing its impact when balanced against the goals of antitrust law. Part II provides a broad overview of price transparency, discusses its pros and cons, and provides some historical perspective on price transparency initiatives generally and its limits. Part III summarizes the Administration's recent price transparency rules issued by CMS and discusses recent litigation filed to enjoin implementation of CMS' final rule regarding hospital pricing. Part IV analyzes the antitrust implications of the CMS rule and the role antitrust principles and policy play in the overall dialogue regarding price transparency in the health care sector.

This paper argues that while price transparency in the health sector is necessary, price transparency, standing alone, will not solve the problem of growing health care costs. While the notion of injecting free-market principles into health care is intuitively sound, this paper argues that if the Administration's price transparency rules are implemented as proposed, provider rates may actually increase to the detriment of consumers and thwart the rules' efficacy. Instead, legislators and industry experts should consider a more targeted approach that balances consumer preferences with antitrust principles.

II. PRICE TRANSPARENCY DEFINED

A. What is Price Transparency?

Broadly, price transparency is defined as making available to the public, in a reliable and understandable manner, information on the price of health care services, that together with other information, helps define the value of those services.[5] This includes physicians and hospitals publicizing their usual charges for particular health care services, insurers making available to their subscribers the rates they have negotiated with physicians and hospitals, and government agencies publicly reporting the average prices for common health care services.[6] Transparent health care information is useful for a variety of stakeholders, including patients/consumers (hereinafter "consumers"), employers/purchasers (i.e. payers), health plans, health care professionals, and policymakers. A recent Commonwealth Fund survey of health care leaders concluded that "transparency in health care is essential for moving towards a higher performing health care system in the United States."[7]

However, depending on who the targeted party is, the "price" of health care services can be defined as the (1) billed charge (Chargemaster data), (2) negotiated price or "allowed amount," or (3) out-of-pocket costs.[8] The billed charge is the total amount charged directly to either the

2 Emily Rappleye, *U.S. Continues to Lead in Healthcare Spending*, Becker's Hosp. Review (Nov. 7, 2019), https://www.beckershospitalreview.com/rankings-and-ratings/us-continues-to-lead-in-healthcare-spending.html.

3 *Id.* (comparing to the average Organization for Economic Cooperation and Development country).

4 Ctrs. for Medicare & Medicaid Servs., National Health Expenditures by Type of Service and Source of Funds, CY 2018 (2018), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical).

5 Ass'n of Am. Med. Coll., Price Transparency: Common Definitions 2 (n.d.), https://www.aamc.org/system/files/c/2/450000-pricetran_commondefs.pdf.

6 Am. Coll. of Physicians, Healthcare Transparency—Focus on Price and Clinical Performance 7 (2010), https://www.acponline.org/acp_policy/policies/healthcare_transparency_2010.pdf.

7 Katherine Shea, Anthony Shih, & Karen Davis, Health Care Opinion Leaders' Views on the Transparency of Health Care Quality and Price Information in the United States 1 (2007), https://www.commonwealthfund.org/publications/other-publication/2007/nov/health-care-opinion-leaders-views-transparency-health-care?redirect_source=/publications/publication/2007/nov/health-care-opinion-leaders-views-transparency-health-care.

8 Altarum Healthcare Value Hub, Revealing the Truth About Healthcare Price Transparency 2 (2018), https://www.healthcarevaluehub.org/application/files/3015/6322/4395/RB_27_-_Revealing_the_Truth_About_Healthcare_Price_Transparency.pdf.

consumer or the provider and tends to be only applicable to uninsured consumers. The negotiated rate is the amount an insurer contracts to pay for the procedures and services of the provider, and thus, is most applicable to these two contracting parties. These rates usually vary between different insurance companies but are generally lower than the billed charge. Finally, consumers tend to care the most about health care expenses that are not reimbursed by insurance. These "out-of-pocket" costs include deductibles, coinsurance, copayments, monthly premiums, and the costs of services that are not covered.

B. Price Transparency: Friend or Foe?

Those who are in favor of price transparency initiatives believe that disclosure of price data will result in a multitude of benefits for consumers and the health care industry as a whole.[9] Namely, advocates state that price transparency is instrumental to consumer protection by allowing them to make informed health care choices, judge affordability, and plan for the expense of future health care services.[10] For example, those who favor such initiatives believe that consumers will be able to use the data to identify providers who are offering services at the best price, and that providers, in turn, will be incentivized to offer the greatest value, which will also result in encouraging competitors to do the same.[11] The hope is that increased competition resulting from the implementation of price transparency initiatives will reduce price variation, decrease health care spending, and improve overall value of health care services. Moreover, price transparency advocates also assert that transparency efforts will enable policymakers to address unwarranted price variation and develop regulations to improve quality, safety, and efficiency throughout the health care system.[12] Advocates also laud price transparency for a recent study that showed, due to efforts to share critical data with consumers, increased trust in the patient-physician relationship and within health care systems.[13]

However, there are certain limits on the benefits that can be achieved from efforts to reduce information asymmetry in the industry. Retrospective studies in certain health care sectors only find minimal evidence that price transparency, alone, improves value by incentivizing consumers to shop for the best price.[14] This is likely because health care markets differ from markets for other standardized commodities and these unique characteristics inherently limit the usefulness and demand for price information. First, by its nature, health care cannot be easily standardized.[15] Different illnesses affect different people in different ways, and treatments that work for one patient cannot necessarily be replicated successfully for another.[16] Because hospitals produce many different outputs with many of the same inputs, allocating costs to particular consumers can be somewhat arbitrary—based on industry norms rather than precise economic calculations.[17]

Second, many consumers do not view doctors, hospitals, and treatments as marketplace commodities and thus, may not believe that price is the most important factor when making decisions about their health care.[18] Rather, consumers tend to believe decisions should be based on health needs and what providers recommend.[19] This belief is exacerbated by consumers having preferences for the perceived "best care," regardless of expense; often associating higher costs with better quality.[20]

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9 Am. Coll. of Physicians, *supra* note 6, at 5.

10 *Id.*

11 *Id.*

12 *Id.*

13 *Id.* (contending pricing information that is reliable and valid, transparent in its development, minimally burdensome to the reporting physician and other health care professionals, and comprehensible to the intended audience facilitates patient trust in the information and the health care system overall).

14 *See, e.g.* Anna D. Sinaiko, et al., *Association Between Viewing Health Care Price Information and Choice of Health Care Facility*, 176 JAMA Inter. Med. 1868, 1868 (2016) (finding when price information in combination with insurance benefit design that shares savings when patients choose low-cost health care facilities has led to lower spending, the impact of price information on patient choices for patients in commercial insurance without such benefit design incentives is largely unknown); Ateev Mehrotra, et al., *Promise and Reality of Price Transparency*, 378 New Eng. J. of Med. 1348, 1348 (2018) (finding limited evidence that price transparency leads to consumer shopping).

15 Congressional Research Serv., Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for Health Sector 8 (2007), https://fas.org/sgp/crs/secrecy/RL34101.pdf.

16 *Id.*

17 *Id.*

18 Altarum Healthcare Value Hub, *supra* note 8, at 2.

19 *Id.*

20 *Id.*

Third, the majority of health care services are not "shoppable."[21] Notably, only "33–43 percent of our current national healthcare spending" is used for non-urgent care that would give consumers a choice of providers and/or treatments.[22] Price and quality information is most useful where consumers can, in fact, make an informed choice. However, in many cases, health care needs are acute and patients do not have the time or—in cases of critically ill patients—even the ability to consider the relevant price and quality information.[23] Moreover, recent studies have shown that even when consumers are given the tools to engage more directly in making their own medical purchasing decisions, they either fail to use the price transparency tools and/or ignore the data the tools provide and choose to use higher priced providers over lower priced providers that were available to them.[24]

Finally, the agency relationships between consumers and insurers or providers may dampen the demand for price information.[25] Due to the inherent complexity of medical care, consumers face significant information asymmetries when it comes to determining the price and quality of their care. Information regarding health care prices and quality are often unavailable or muddled with so much jargon and detail that consumers cannot make any meaningful informed choices.[26] As a result, physicians end up serving as agents for their patients.[27] Physicians make the preliminary diagnosis, recommend which specialists will be seen, and suggest necessary medications or procedures.[28] Although ethical and professional guidelines stress that physicians must act in the best interests of the patient, they may still be swayed directly or indirectly by insurers, pharmaceutical companies, hospitals, and peers in ways that might not align with the patients' economic interests.[29]

Insurers also act as agents for consumers, negotiating contracts with providers and bearing a significant portion of the financial responsibility.[30] While public or private insurance protects consumers from the financial consequences of a hospital stay, insurance also makes consumers more insensitive to prices. Consumers tend to focus only on out-of-pocket costs, which are often a much smaller percentage of the billed charge or negotiated rate. Although consumers can obtain information about the features of different insurance plans, that information is arguably incomplete and often confusing. Consumers may also lack interest in, or familiarity with, costs borne by insurers and society as a whole.[31] Ultimately, these unique aspects of the health care industry may dilute the effects of price transparency initiatives.

III. PRICE TRANSPARENCY INITIATIVES

A. The Growing Demand for Greater Price Transparency in Health Care

The issue of price transparency is not a novel issue in health care. Many states have implemented programs designed to collect and disseminate various cost information and other data designed to control statewide health care costs and increase access to health care services.[32] For example, in 2005, New Hampshire created NHHealthCost, one of the country's first all-payer claims databases to collect and disseminate health

21 Michael Chernew et al., *Are Health Care Services Shoppable? Evidence from the Consumption of Lower-Limb MRI Scans* (Nat'l Bureau of Econ. Research, Working Paper No. 24869, January 2019) (finding that, on average, patients travel past six-lower priced providers for lower-limb MRI scans en route to where they ultimately received care).

22 Altarum Healthcare Value Hub, *supra* note 8, at 2.

23 *Id.*

24 Chernew, *supra* note 21, at 7–8 (noting that of the 50,484 lower-limb MRI scans in a sample, only in 0.7 percent of cases did patients use the price transparency tool supplied by the insurer to search for the price of MRI providers prior to receiving care).

25 Congressional Research Serv., *supra* note 15.

26 *Id.* at 10.

27 *Id.*

28 Chernew, *supra* note 21, at 9 (concluding that referring physicians heavily influence where patients receive care and referrer fixed-effects explain the largest share of the variance in the price of MRIs and "money left on the table").

29 Congressional Research Serv., *supra* note 15, at 9.

30 *Id.*

31 Altarum Healthcare Value Hub, *supra* note 8, at 2.

32 *See, e.g.* Cal. Health & Safety Code §§ 1339.55, .56, .58, .585 (West 2004); Colo. Rev. Stat. Ann. §§ 6-20-101, 10-16-133, 10-16-134 (West 2004); Mass. Gen. Laws Ann. ch. 224, § 228 (West 2014); N.H. Rev. Stat. Ann. § 420-G:11-a (2014).

care price information.[33] This database provides the median bundled prices for the thirty most common health care services.[34] Similarly, in 2018, California created the Health Care Cost Transparency Database.[35] This all-payer claims database aimed to provide greater transparency regarding health care costs, by encouraging health insurers, providers and other industry participants to use such data to develop innovative approaches and services, and inform policy decisions to reduce health care costs and increase access.[36]

1. Key Targets as One Approach for Price Transparency

When crafting price transparency initiatives, it is important to consider who the target audience is and whether or not the disclosure of certain data is likely to have a measurable impact on health care costs. A blanket reveal of health care costs may not be as useful or effective as a more appropriately targeted approach. So how do we determine what is the applicable "price" in connection with price transparency initiatives? As previously discussed, the effect of any particular price transparency initiative will depend significantly on the relevant stakeholders, the associated market conditions, the usefulness of the information disclosed, and the ability of the targeted group to act on that information.
There are numerous mechanisms that hinder price transparency.[37] Confidentiality, or "gag" clauses, and other laws prevent consumers and competing providers from knowing the rates that providers have negotiated with payers.[38] In some cases, even physicians are unaware of the true charge of their services, disincentivizing them to contain costs by reducing unnecessary tests and treatments.[39]

Some studies show that price transparency initiatives targeted at insurer-provider relationships can be useful in controlling high spending, particularly with regards to unwarranted provider price variation.[40] According to these studies, disclosing information regarding negotiated rates, or which providers are pricing outliers compared to their peers, may force insurers and providers to lower their prices.[41] One researcher studied the impact of New Hampshire's implementation of price comparisons among hospitals in 2010.[42] Until 2010, payments to New Hampshire's most expensive hospital exceeded those of its competitors by nearly fifty percent.[43] Historically, the hospital's prestigious reputation and high-earning patient population insulated it from pressure to reduce prices.[44] The introduction of price comparisons, however, led to public scrutiny over high-price providers that shifted the bargaining power towards state insurers and narrowed price variation over time.[45]

From a consumer-driven perspective, price transparency initiatives can also be implemented to provide consumers with instant, online access to an estimate of their out-of-pocket costs.[46] Insurers, having access to a plethora of historical price data, negotiated provider rates, and the consumer's current health plan, are well-positioned to provide this complete and personalized price information to consumers.[47] Equipping consumers with out-of-pocket cost data could facilitate their ability to shop around before they receive treatment for schedulable, non-emergency medical services, and as such, could directly contribute to reducing health care spending in measurable ways.

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33 Ass'n of State and Territorial Health Officials, New Hampshire Case Study All-Payer Claims Database 2 (2017).

34 *Id.* at 10–11.

35 Katherine L. Gudiksen, et al., The Secret of Health Care Prices: Why Transparency Is in the Public Interest 5 (2019).

36 *Id.* The push for price transparency has also occurred in the pharmaceutical industry. Faced with continuously increasing drug prices, state legislatures have considered a variety of initiatives, including: (1) establishing a commission to study drug pricing and identify key drivers of costs; (2) calling for CMS to negotiate reasonable prices with drug makers; (3) empowering state Medicaid agencies to negotiate drug price rebates; (4) establishing penalties on price gouging behavior by drug manufacturers; and (5) shining the spotlight on the way drug manufacturers set prices. Kaitlyn N. Dana, et al., *Drug Pricing Transparency: The New Retail Revolution*, 52 Hosp. Pharm. 155, 155 (2017).

37 *Id.* at 327.

38 *Id.* at 329.

39 *Id.*

40 Altarum Healthcare Value Hub, *supra* note 8, at 3.

41 *Id.* ("One way to incentivize change is for payers to publicly compare providers who are pricing outliers to their peers.").

42 *Id.*

43 *Id.*

44 *Id.*

45 *Id.*

46 Anna D. Sinaiko & Meredith B. Rosenthal, *Examining a Health Care Price Transparency Tool: Who Uses It, and how They Shop for Care*, 35 Health Affairs 662, 663 (2016) (reporting on the efficacy of Aetna's web-based price transparency tool that uses claims adjudication logic to provide real-time, personalized, episode-level estimates of patient's out-of-pocket expenses and total prices).

47 *Id.*

Employers represent the last target group for potential price transparency initiatives aimed at decreasing health care spending. As the leading source of health insurance in the U.S., covering approximately 149 million people under the age of sixty-five,[48] employers can substantially impact health care pricing.[49] If employers had access to both quality information on the providers included in a health plan as well as certain pricing data, they could use that leverage to demand higher value plans at lower costs.[50] Particularly, in comparison to individual consumers, employers are in a better position to not only accumulate and analyze price and quality data, but leverage their purchasing power to negotiate price.[51]

2. CMS's Price Transparency Rules

In November 2019, the U.S. Department of Health and Human Services ("HHS") and CMS issued a new proposed rule and finalized another, both with the aim of empowering health care consumers with price transparency information. The "Transparency in Coverage" proposed rule would require health plans, including employer-based plans, and group and individual plans, to inform participants, beneficiaries, and enrollees about price and cost-sharing information ahead of time.[52] Health plans will be responsible for providing this information in real time using a digital tool and may also be required to display their negotiated rates with different hospitals on their own websites.[53] The public comment period for the proposed rule closed on January 29, 2020.[54]

More significantly, CMS finalized the 2020 Outpatient Prospective Payment System & Ambulatory Surgical Center Price Transparency Requirements of Hospitals to Make Standard Charges Public (the "Final Rule"), that specifically requires all U.S. hospitals to make their standard charges publicly available. CMS defines "standard charges"—or "price"—to include the following:

- the gross charge (the charge for an individual item or service that is reflected on a hospital's chargemaster, absent any discounts);
- the discounted cash price (the charge that applies to an individual who pays with cash or a cash equivalent);
- the payer-specific negotiated price (the charge that a hospital has negotiated with a third-party payer for an item or service);
- the de-identified minimum negotiated charges (the lowest cost the hospital has negotiated with a third-party payer); and
- the de-identified maximum negotiated charges (the highest cost the hospital has negotiated with a third-party payer).[55]

This information must be made available online in a "machine-readable" format and hospitals must provide an explanation for any service codes it might use, make these lists prominent on a hospital website or web portal, ensure this information is easily accessible, and update this data at least annually.[56] Hospitals are also responsible for displaying price transparency information for at least 300 "shoppable" services, defined as services that can be scheduled in advance.[57] The pricing for shoppable services will be displayed along with charges for ancillary items and services the hospitals customarily provide as part of, or in addition to, the primary shoppable service.[58]

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48 Jaime S. King, et al., *Clarifying Costs Can Increased Price Transparency Reduce Healthcare Spending*, 4 Wm & Mary Policy Rev. 319, 338 (2013).

49 *Id.* ("At a time when employers are facing a number of long-term challenges, such as controlling costs, improving employee engagement and accountability, and determining how to comply with new healthcare reform legislation, price transparency initiatives targeting employers. . .have great potential to reduce overall healthcare costs.").

50 *Id.*

51 *Id.*

52 Transparency in Coverage, 84 Fed. Reg. 65464, 65464 (proposed November 27, 2019).

53 *Id.*

54 *Id.*

55 Medicare and Medicaid Programs: CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates. Price Transparency Requirements for Hospitals to Make Standard Charges Public, 84 Fed. Reg. 65524, 65525 (proposed November 27, 2019) (to be codified at 45 C.F.R. pt. 180) [hereinafter Final Rule].

56 *Id.* at 65555–57.

57 *Id.* at 65564.

58 *Id.* (providing examples of ancillary items and services to include laboratory, radiology, drugs, delivery room, operating room, therapy services, room and board charges, etc.).

The Final Rule strives to provide consumers, employers, clinicians, and other third parties with the requisite information to make informed decisions about their health care. CMS reiterates traditional economic theories that suggest if consumers were able to have better pricing information for health care services, providers would face pressure to lower prices and provide higher-quality care.[59] According to CMS, falling prices may, in turn, expand consumers' access to health care.[60] Particularly, CMS emphasizes that provider charge information is often either inconsistent or nonexistent, and that the lack of availability of provider charge information is one of the main obstacles limiting consumers' understanding of price information.[61] According to CMS, the Final Rule is designed to fill this information gap.

Although many commenters expressed broad support for the Final Rule, critics expressed strong concerns as to whether hospital charge disclosures would effectively reduce health care costs.[62] Those who are skeptical about the efficacy of such an approach, highlighted the impracticalities and usefulness of displaying hospital standard charges, arguing that the disclosure of hospital charges would not sufficiently permit a consumer to determine her out-of-pocket estimate as she would need additional information from insurers.[63] In addition, some commenters raised concerns that the Final Rule would encourage anticompetitive behavior among commercial insurers in an already highly concentrated industry. Due to antitrust concerns, one commenter recommended that CMS conduct a pilot study in select markets to determine the impact of the policy on negotiated prices before finalizing the Rule.[64] Further, several commenters suggested that for consumers with health insurance, insurers should be responsible for informing and educating their members on potential out-of-pocket costs, rather than hospitals.[65]

In response, CMS acknowledged the commenters' concerns that disclosure of hospital standard charges may not be sufficient "but disagree[d] that the availability of such data would be of little benefit to consumers generally."[66] Although CMS acknowledged the possibility that the Final Rule could encourage price-fixing and facilitate hospital collusion, it ultimately reiterated the standard economic theory underpinnings; holding firm to the belief that accessible pricing information will reduce health care costs by encouraging providers to offer more competitive rates.[67] CMS contended that pricing information not only benefits consumers, but also enables providers and employers to have well-informed conversations about the financial impacts of health care decisions with consumers.[68] Finally, CMS noted that the current antitrust legal framework can sufficiently address any anticompetitive practices and thus, additional testing was unnecessary prior to finalizing the Final Rule.[69]

Nonetheless, the Final Rule has led to substantial litigation. On December 4, 2019, multiple hospital associations[70] jointly filed a lawsuit against HHS, challenging the Final Rule issued by CMS that requires hospitals to make their negotiated rates publicly available.[71] While the plaintiffs endorse the Final Rule's stated goals of increasing health care cost information given to consumers, they argue the Rule actually frustrates these goals. Namely, they contend "[w]hen a patient chooses a hospital, what she wants to know is her out-of-pocket costs, not an insurer's

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59 *Id.* at 65526.

60 *Id.*

61 *Id.*

62 *Id.* at 65528.

63 *Id.*; Letter from Thomas P. Nickels, Exec. Vice President, Gov't Relation and Pub. Policy, Am. Hosp. Ass'n., to Seema Verma, Adm'r, Ctrs. for Medicare & Medicaid Servs. (September 27, 2019) (on file with CMS) (highlighting that instead of helping patients estimate their out-of-pocket obligations, the Final Rule would introduce confusion and fuel anticompetitive behavior among commercial insurers in an already highly concentrated industry); Letter from Alyssa Keefe, Vice President, Fed. Regulatory Affairs, Cal. Hosp. Ass'n, to Seema Verma, Adm'r, Ctrs. for Medicare & Medicaid Servs. (September 27, 2019) (on file with CMS) (stating the Final Rule will result in hospitals diverting resources currently devoted to informing patients of their out-of-pocket costs for health care services to providing information that will be unhelpful and confusing to consumers).

64 Letter from Kristi Sherrill, Chief Policy, Gov't and Cmty Affairs Officer, Baylor Scott & White Health, to Seema Verma, Adm'r, Ctrs. for Medicare & Medicaid Servs. (September 27, 2019) (on file with CMS) (encouraging CMS to establish a voluntary pilot program where health systems with mature pricing systems can opt-in to test alternative approaches to price transparency).

65 Final Rule, *supra* note 55, at 65528.

66 *Id.*

67 *Id.* at 65547 (citing to various studies concluding that one major barrier to fully understanding price variation is the lack of availability of negotiated charges to researchers and the public).

68 *Id.* at 65549.

69 *Id.*

70 This group includes the American Hospital Association, The Association of American Medical Colleges, the Children's Hospital Association, the Federation of American Hospitals, the Memorial Community Hospital and Health System, the Providence Health System – Southern California, and the Bothwell Regional Health Center. Complaint, *The Am. Hosp. Ass'n, et al. v. Sec'y of Health and Human Servs.*, No. 1:19-cv-03619 (D.D.C. filed Dec. 4, 2019).

71 *Id.*

'negotiated charges'," and "there is no easy way to reverse-engineer one from the other to determine what the patient's co-payment and deductible will be."[72] Further, the group states that the Rule is arbitrary and capricious, lacking any rational basis, exceeds the agency's statutory authority, and violates the First Amendment.[73]

IV. PRICE TRANSPARENCY AND ANTITRUST POLICY

The administration's plan for broad implementation of CMS's Final Rule is difficult to reconcile with traditional antitrust doctrine and policy. Under the new policy, hospitals must make certain "standard charges" publicly available. This includes, the discounted cash price, the payer specific negotiated price, as well as the de-identified minimum and maximum negotiated charges. The rates negotiated between hospitals and various payers have been closely guarded information. Indeed, such data has been deemed highly confidential by health industry participants and viewed as competitively sensitive from an antitrust perspective.

Historically, antitrust agencies have challenged providers for engaging in unlawful price fixing and otherwise sharing rate and other competitively sensitive information with competitors. In fact, agreements among competitors to raise, lower, or otherwise stabilize prices have routinely been treated by the courts as *per se* unlawful under the antitrust laws. Moreover, the Department of Justice Antitrust Division ("DOJ") and the Federal Trade Commission Bureau of Competition ("FTC") have challenged the following types of conduct as *per se* unlawful under the antitrust laws: (1) adoption and promulgation of relative value scales by medical societies or associations; (2) agreements among competing providers to establish uniform terms of sale, discount policies, or other underlying elements of price; and (3) agreements between two hospitals, through use of a common agent, to fix rates, contract terms, and conditions for the sale of various services.[74]

Under current antitrust policy, "competing hospitals, physicians, and other providers who agree among themselves on the prices that they will charge for services [and] the prices that they will pay to suppliers for goods … expose themselves to *per se* liability for price fixing, even if they enter into those agreements for what they believe to be beneficial purposes, such as controlling costs to consumers or improving quality."[75] As such, it would seem that the desire to make transaction specific data available to consumers needs to be carefully balanced against the goals of antitrust law to ensure that the disclosure of such data will not inadvertently cause prices and the cost of health care services to continue to rise.

While greater access to information is certainly viewed as important and beneficial for health care consumers, the FTC has previously noted that "[t]oo much transparency can harm competition in any market, including in health care markets."[76] In weighing in on a Minnesota legislative proposal to disclose the terms of Minnesota's public health care services contracts, the FTC stated:

> Typically, health care providers (hospitals, outpatient facilities, physician groups, or solo practitioners) compete against each other to be included on a health plan's list of preferred providers. When networks are selective, providers are more likely to bid aggressively, offering lower prices to ensure their inclusion in the network. But when providers know who the other bidders are and what they have bid in the past, they may bid less aggressively, leading to higher overall prices.
>
> We believe it is possible to give consumers the specific kinds of information they need to make better health care choices, while avoiding broad disclosures of bids, prices, costs, and other sensitive information that may chill competition among health care providers. Striking the right balance and mitigating the risk of harm to the competitive process, requires careful fine-tuning of transparency laws and regulations. As with all things, details matter.[77]

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72 *Id.* at ¶ 6.

73 *Id.* at ¶¶ 5–8 (arguing the rule runs afoul of the First Amendment by mandating speech in a manner that fails to directly advance a substantial government interest).

74 Christine L. White, ET AL., AHLA ANTITRUST AND HEALTH CARE: A COMPREHENSIVE GUIDE § 2-2(c)(1)(i) (2d ed. 2017).

75 *Id.*; When the Pharmaceutical Manufacturers Association submitted a request to the DOJ to implement a program under which member companies would agree not to increase prices faster than the rate of inflation in order to help curtail the rise in drug prices, the DOJ denied the request, noting that such conduct would be *per se* unlawful. Letter from Anne K. Bingaman, Assistant Attorney Gen., Dep't. of Justice Antitrust Div., to John R. Ferguson, Esq., Swidler & Berlin (Oct. 1, 1993) (on file with author).

76 Tara Isa Koslov & Elizabeth Jex, *Price Transparency or TMI?*, FED. TRADE COMM'N (July 2, 2015, 2:31 PM), https://www.ftc.gov/news-events/blogs/competition-matters/2015/07/price-transparency-or-tmi.

77 *Id.*

The federal antitrust agencies are not broadly opposed to the provision of fee-related information by competing health care providers to purchasers of health care services. From their perspective, the collective provision of fee-related information may yield certain procompetitive benefits stemming from an increase of information in the health care marketplace.[78] They caution, however, that such procompetitive benefits may not be realized if such information is shared without adequate safeguards in place. In Statement Five of the Health Care Statements, in order to "ensure that an exchange of price or cost data is not used by competing providers for discussion or coordination of provider prices or costs,"[79] the DOJ and FTC recommend that:

1. the collection and assembly of the fee-related information be managed by a third party (e.g. a purchaser, government agency, consultant, academic institution, or trade association);

2. while current fee-related information may be provided to purchasers of health care services, any information that is shared among or is available to competing providers furnishing the data must be at least three months old;

3. for any information that is available to the providers furnishing the data, there are at least five providers reporting data upon which each disseminated statistic is based;

4. no individual provider's data may represent more than twenty-five percent on a weighted basis of that statistic; and

5. any information disseminated must be sufficiently aggregated such that it would not allow recipients to identify the prices charged by any individual provider.[80]

Economic research supports such an approach, particularly in concentrated markets. Hypothetically, when a "well-regarded hospital contracts with two insurers and offers a lower price to Insurer 1 because otherwise Insurer 1 would steer patients to a different institution,"[81] if the hospital was required to adhere to a transparency rule that required the publication of its negotiated rates, the hospital would be "less likely to offer the low price to Insurer 1, because Insurer 2 would then pressure the hospital to lower its price as well."[82] As noted by economists Cutler & Dafny, publication of negotiated rates "would create a perverse incentive for the hospital to raise prices (on average), and as a result, its rivals could do the same."[83]

For many of these reasons, states that have already adopted and implemented price transparency initiatives have done so by adhering to certain safeguards designed to maximize the procompetitive benefits of the disclosure, while preventing the ability for such data to be used anticompetitively. "[T]o prevent potential anticompetitive use of the data, all states, to varying degrees, limit data release to specific data elements, entities or purposes."[84]

The Administration should revise its price transparency guidelines accordingly. Doing so is the best way to ensure that U.S. consumers benefit from increased information in the health care sector without being harmed by potential anticompetitive effects that could result from the dissemination of competitively sensitive data in the absence of safeguards.

V. CONCLUSION

While the goal of seeking to provide consumers with price information is laudable, it is important to ensure that the information disclosed will, in fact, help consumers make the necessary cost-effective health care decisions they need. The wholesale disclosure of sensitive data that (1) is not designed to maximize the decision-making process of consumers, and (2) is not likely to be used by consumers when making critical decisions, yet (3) can be used effectively by competing providers to reduce and/or eliminate price competition, is unlikely to have an appreciable short-term

78 U.S. Dep't Justice & Fed Trade Comm'n, Statements Of Antitrust Enforcement Policy In Health Care (1996) Statement 5.

79 *Id.*

80 *Id.*

81 Gudiksen, *supra* note 35, at 11; David Cutler & Leemore Dafny, *Designing Transparency Systems for Medical Care Prices*, 364 New Eng. J. of Med. 894, 894 (2011).

82 Gudiksen, *supra* note 35, at 11.

83 *Id.*; Cutler & Dafny, *supra* note 81.

84 Gudiksen, *supra* note 35, at 17.

effect on stifling the rising cost of health care in the U.S. In other words, the risk of the anticompetitive use of such sensitive data does not justify the theoretical benefits of the wholesale disclosure of price information without safeguards —especially when studies show consumers may disregard, or simply, not utilize the data provided.

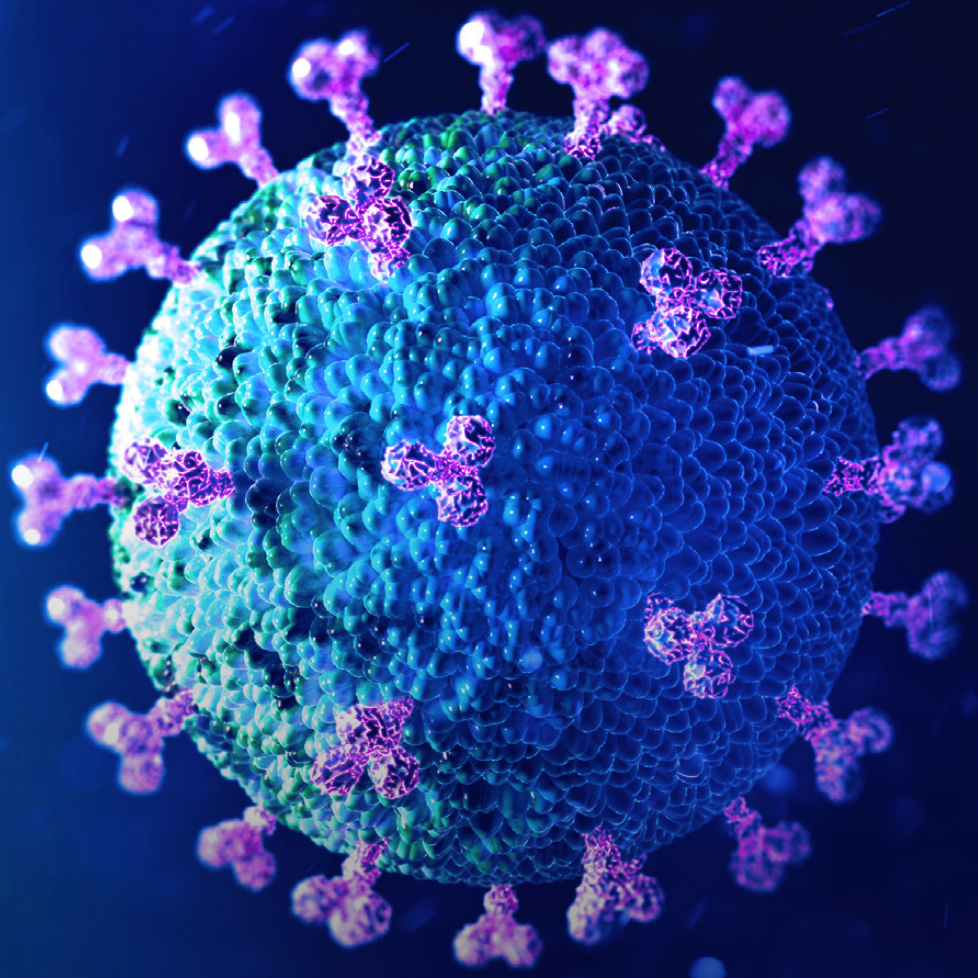
As noted by the FTC, information sharing and exchanges among competitors without the use of proper safeguards, particularly when the information shared involves specific prices or cost data, may have an anticompetitive effect. The impact of such effects is expected to be more severe in markets that are highly concentrated. "Other things being equal, the sharing of information relating to price, output, costs, or strategic planning is more likely to raise competitive concern than the sharing of information relating to less competitively sensitive variables."[85] A common refrain in antitrust jurisprudence notes that direct exchanges of information among competitors may serve as a vehicle for providers to fix prices, allocate markets, or otherwise restrain competition.[86]

Ultimately, unless a more tailored approach is adopted that appropriately employs antitrust safeguards, it is simply not possible for price transparency initiatives to effectively consider all stakeholders' interests in a way that simultaneously benefits them as health care consumers. Rather, the best approach may be to first implement transparency for those stakeholders that are in the best position to take advantage of that information (e.g. employers), followed soon thereafter by initiatives that help other stakeholders as well. If antitrust principles are ignored while crafting price transparency guidelines, the implementation of the rules, as proposed, may cause provider rates to increase to the detriment of consumers.

85 U.S. Dep't of Justice & Fed. Trade Comm'n, Antitrust Guidelines for Collaborations Among Competitors 15 (2000).

86 *Id.* at 15–16.

ANTITRUST & COVID-19 IN THE U.S.: FOUR KEY ISSUES FOR HEALTHCARE PROVIDERS



BY JOHN D. CARROLL & ALEXIS J. GILMAN[1]

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I. INTRODUCTION

The COVID-19 pandemic continues to disrupt industries around the globe, and the impact on the healthcare industry has been especially profound. Healthcare providers are working to combat the virus and treat patients while dealing with significant challenges, such as keeping their staff healthy and supplied with equipment, as well as broader issues, such as continuing operations and executing on strategic plans. The COVID-19 pandemic is not just affecting clinical and business operations, but also the legal environment in which businesses operate.

In the United States, the healthcare industry has been a primary focus of federal and state antitrust enforcement and litigation, with antitrust enforcement agencies aggressively scrutinizing provider transactions and various types of conduct (e.g. exclusive contracting arrangements). This scrutiny has continued, and will continue, during the COVID-19 pandemic, with the Federal Trade Commission (the "FTC") and Department of Justice (the "DOJ," together, the "Agencies") adopting various measures to adjust their processes—but not their standards—for investigating competitive issues. Indeed, the Agencies issued a joint statement on April 13 stating that they would be "on alert" for employers, staffing companies, and recruiters, among others, who might engage in collusion or other anticompetitive conduct in labor markets, such as agreements to lower wages or to reduce salariesbenefits or hours worked.[2]

This article provides an overview of four key antitrust issues for healthcare providers in the United States in light of the COVID-19 pandemic.

II. ISSUE 1: COMPETITOR COLLABORATIONS

Competitor collaborations have historically been subject to antitrust scrutiny, as such collaborations may lead to competitors exchanging competitively sensitive information or jointly setting prices. With that said, as articulated in the Agencies' *Antitrust Guidelines for Collaborations Among Competitors* (2000), antitrust enforcers recognize that competitor collaborations are often pro-competitive, leading to greater efficiency, increased production, higher quality, and lower prices.

More so than ever, the COVID-19 pandemic requires that healthcare providers coordinate and share information to treat their patients. But the antitrust laws remain in effect, and providers should avoid coordinating inappropriately in violation of federal or state antitrust laws (e.g. allocating markets or services, fixing prices charged to payers), including sharing information that may create an inference that such coordination is occurring (e.g. managed care rates). Still, the Agencies recognize that there are exigent circumstances.

Accordingly, on March 24, 2020, the Agencies issued guidance and outlined an expedited review process for companies seeking to work together on COVID-19-related collaborations (the "Joint Statement"), which also reminds healthcare providers and other companies that the antitrust laws still apply to ventures between competitors. The Joint Statement does not provide an antitrust exemption regarding COVID-19 collaborations, but it does acknowledge the urgency of the public health crisis by committing the FTC and DOJ to a seven calendar day turnaround, once all necessary information is received, for written guidance (DOJ Business Review letters and FTC Advisory Opinions) related to COVID-19-related collaborations. Previously, such guidance would typically take at least several months to complete, as companies or providers worked with the reviewing agency and responded to their requests in assessing competitive issues.

According to the Agencies, collaborations by healthcare providers or combinations of production capacity by businesses are examples of potentially necessary responses to the spread of the disease. The Joint Statement provides: "These sorts of joint efforts, limited in duration and necessary to assist patients, consumers, and communities affected by COVID-19 and its aftermath, may be a necessary response to exigent circumstances that provide Americans with products or services that might not be available otherwise." So long as such joint efforts are limited in duration and required to address the health crisis, the Joint Statement indicates that the Agencies will be more accommodating to such collaborations.

Finally, the Joint Statement makes clear that the Agencies will be vigilant in policing anticompetitive conduct in during the crisis, including competitor collusion and any fraudulent or illegal schemes targeting vulnerable Americans.

The Agencies' first Business Review Letter following the Joint Statement was issued by the DOJ on April 4 to several U.S. healthcare distributors of personal protective equipment ("PPE") and medications (e.g., McKesson). The Business Review Letter describes the ways in in which the requesting parties seek to cooperate and concludes that the proposed cooperation likely would not raise competitive concerns

2 https://www.ftc.gov/news-events/press-releases/2020/04/federal-trade-commission-justice-department-issue-joint-statement.

because, among other factors, the proposed collaboration is limited in scope and duration; is necessary to address COVID-19-related scarcity of supplies; will not extend beyond what is needed to make supplies more available; and is not being used to increase prices, reduce output or quality, or engage in profiteering.[3]

As healthcare providers continue to coordinate their care to enhance their ability to treat patients during the COVID-19 pandemic, they can take some comfort from the Agencies' guidance that their collaborations will not raise antitrust concerns, unless they veer into inappropriate areas, such as discussions regarding managed care rates, or extend beyond the time of the exigent circumstances of the pandemic.

III. ISSUE 2: MERGERS & ACQUISITIONS

Prior to the COVID-19 crisis, health system merger and acquisition activity remained healthy. According to Kaufman Hall, there were 92 announced hospital transactions in 2019, slightly above the number in 2018.[4] These transactions were often driven by attempts to achieve geographic scale and efficiencies, and several of these transactions combined health systems that were already financially strong. The COVID-19 pandemic is likely to change significantly the number of deals and deal rationales.

One effect of the crisis is likely to be a slow-down in the number of transactions, for a variety of reasons, including health systems and hospitals focusing on serving patients, securing critical supplies, and trying to keep their staff healthy—leaving little time for deal-making and due diligence.

On the other hand, the crisis is also likely to force some hospitals—particularly rural hospitals, small community hospitals, and those with a high COVID-19 patient population—to look for an affiliation partner for financial reasons. The COVID-19 pandemic will put many hospitals under financial pressure because relatively profitable elective procedures have been put on hold (though some loosening may soon occur in some areas), while operating costs have increased as many hospitals pay staff for overtime, hire additional staff, serve more patients with acute conditions, and pay higher prices for supplies and new equipment. Indeed, credit-agency ratings posit a negative outlook for nonprofit and for-profit hospitals.

A merger with, or acquisition by, a financially healthy partner can be a lifeline for a struggling hospital. But when it comes to such transactions, COVID-19 has not put the antitrust laws in quarantine or weakened the standard of merger review. Antitrust enforcers have made that clear.

For example, in announcing certain steps to protect the health and safety of its staff as the COVID-19 crisis deepened, the FTC said that the "the protection of competition, and the welfare of American consumers, is as important now as ever." In a March 27 blog post about merger reviews, the Director of the FTC's Bureau of Competition wrote that "[c]ompetitive concerns will be fully investigated in every case" and "[n]either the legal standards that apply to transactions nor the Bureau's investigational standards have been relaxed in light of the coronavirus pandemic."[5]

In a similar announcement, the DOJ stated that they were taking steps to "ensure that the Division can continue to review transactions efficiently and effectively" and said that the DOJ would "continue to carry out our mission to protect competition and the American consumer."[6]

The Agencies have, however, acknowledged that the crisis has changed how they are conducting their work, resulting in procedural and timing changes that parties to contemplated mergers need to consider.

For example, the FTC initially announced in mid-March that it was implementing an electronic filing system for Hart-Scott-Rodino ("HSR") premerger filings and that it would not be granting early terminations of the 30-day HSR waiting period. By the end of March, the FTC announced that early terminations would again be granted in appropriate circumstances, but noted that early terminations would be available "on a more limited basis than has historically been the case"—meaning granted in fewer cases and more slowly.

Moreover, both Agencies appear to be seeking additional time to review transactions that raise questions or potential competitive concerns. By statute, if the FTC or DOJ issues a Second Request, the parties cannot close their transaction for at least 30 days after "substantially

3 https://www.justice.gov/atr/page/file/1266511/download.

4 https://www.kaufmanhall.com/2019-healthcare-mergers-acquisitions-in-review.

5 https://www.ftc.gov/news-events/blogs/competition-matters/2020/03/resuming-early-termination-hsr-reviews.

6 https://www.justice.gov/opa/pr/justice-department-announces-antitrust-civil-process-changes-pendency-covid-19-event.

complying" with the Second Request. Often, though, the Agencies negotiate a "timing agreement" with merging parties to extend this period, often for another 30 days (i.e. 60 days post-compliance in the aggregate).

Now, however, the Agencies are seeking more time to review transactions by extending these timing agreements. In mid-March, the FTC said it was conducting a matter-by-matter assessment of investigations and litigated cases to "consider appropriate modifications of statutory or agreed-to timing." The FTC hoped merging parties would be flexible, but said that the FTC would take "affirmative action" when an unmodified time period would not allow the FTC to address competitive concerns—implying that the Agency would go to court to obtain a preliminary injunction to prevent a transaction from closing if necessary. And a recent report says that the FTC has started to seek timing agreements that would give it up to 120 days to review transactions after the parties substantially comply with a Second Request.[7]

The DOJ modified its model timing agreement in 2018 to provide a default 60 days review period after substantial compliance with a Second Request. In its March announcement, the DOJ said that it would request an additional 30 days in timing agreements—thus, a total of 90 days—to compete the review of currently pending or future mergers.

Beyond these extended deadlines, the Agencies staffs' need to conduct their work remotely, as well as the challenge of interviewing industry participants who themselves are working remotely and whose contact information may not be so readily available to staff, also add a level of inefficiency and delay to antitrust investigations. Even before the COVID-19 crisis, substantial merger investigations took, on average, approximately 10-11 months, according to available statistics. COVID-19 is likely to extend transaction timeframes.

Consequently, merging parties should be prepared for lengthy reviews if their transaction raises competitive questions or concerns. And they should be prepared for the Agencies to conduct investigations that are no less vigorous, and under standards that are no less stringent, than those prior to the health crisis.

IV. ISSUE 3: FAILING-FIRM DEFENSE

The COVID-19 crisis is putting a huge financial strain on health systems and community hospitals, with several on the brink of collapse. One hospital recently announced it would shut its doors if it didn't receive a cash infusion within days. Other hospitals have announced furloughs of hundreds of staff. Even before the pandemic, one report estimated that a quarter of all rural hospitals in the U.S. were "at a high risk of closing unless their financial situations improve," and that the pandemic and economic downturn was only going to make this worse.[8]

While merger-review standards will remain vigorous during the COVID-19 crisis, there are likely to be more hospitals that, unfortunately, will need to avail themselves of the failing-firm defense to obtain antitrust clearance and close transactions that might otherwise lessen competition. Still, there is a high standard for the defense to be satisfied, and the uncertainties of the COVID-19 crisis will pose interesting issues—and challenges—for the Agencies when evaluating the defense.

Under the Agencies' Horizontal Merger Guidelines, the elements of the failing-firm defense are that the financially troubled firm (1) be unable to meet its financial obligations in the near future; (2) not be able to reorganize successfully in bankruptcy; and (3) have made unsuccessful good-faith efforts to elicit reasonable alternative offers that would keep the troubled assets in the relevant market and pose a less severe threat to competition.

With respect to the first prong, litigated cases and agency enforcement actions show that the financial condition of the troubled firm must be severe enough to portend its imminent exit from the market. The agencies have not clearly defined the severity of the financial condition and the imminence of the exit that suffices. Prior agency officials have explained in speeches that the defense is "limited"; requires more than a temporary dip in profitability; and the mere fact that firm has been losing money does not mean that it satisfies this prong.

Certainly, the more "financial indicators"—revenues, profits, days cash on hand, discharges, capital expenditures, pension funding, etc.—that are trending steeply and consistently downward, the more likely it is that merging parties can satisfy this prong. The challenge with the current COVID-19 crisis is that no one knows how long it will last. Therefore, the Agencies may have more trouble assessing—and merging parties may have a harder time showing—whether any financial and operating declines are temporary or sufficiently dire and lasting to satisfy the first element of the defense.

7 https://www.mlex.com/GlobalAntitrust/DetailView.aspx?cid=1175932&siteid=191&rdir=1.

8 https://guidehouse.com/insights/healthcare/2020/rural-hospital-sustainability-index.

With respect to the third prong, the Agencies assess the thoroughness of the seller's search for an alternative purchaser. The Agencies require more than a cursory search for an alternative purchaser,[9] and they require that potential acquirers be given a reasonable opportunity to conduct due diligence. Merging parties can bolster their failing-firm defense by demonstrating that the seller used a consultant or investment banker to find alternative purchasers. Because COVID-19 has limited potential purchasers' ability—indeed, their capacity—to evaluate mergers and acquisitions, the agencies will have to consider how to assess the thoroughness of the seller's search for potential partners under these exigent circumstances.

The agencies have a high standard for accepting failing-firm defense, but there is also some prosecutorial discretion that the Agencies may apply, especially (at least in one author's experience) when the transaction involves a financially troubled hospital. The FTC will vigorously assess failing-firm claims by merging hospitals, but it also does not want to be responsible for blocking a transaction if it would result in a hospital shutting its doors to patients. That consideration may be particularly compelling for transactions involving a failing hospital during the COVID-19 crisis, when it is more critical than ever for hospital doors to remain open to patients.

V. ISSUE 4: PRICE GOUGING

"Price Gouging" laws, which have been adopted by approximately three dozen states, are aimed at protecting consumers by prohibiting businesses from taking advantage of emergency condition to unfairly charge artificially inflated prices for certain goods and services. These laws often carry serious civil penalties, and sometimes even criminal penalties.

The COVID-19 pandemic has already resulted in the triggering of state price gouging laws that directly control the prices that businesses may legally charge for goods and services. As businesses and consumers scramble to purchase essential products and services, state regulators are looking closely at any allegations of price gouging across supply chains. For instance, over 4,000 price gouging complaints related to the pandemic have been lodged in Texas since March 13.[10]

Healthcare providers may be victim of price gouging by medical equipment companies seeking to substantially raise the prices of masks or other medical supplies, or may themselves face allegations of price gouging if they attempt to substantially raise the rates of the medical services they are providing.

Although there is no federal price gouging statute and nothing in the federal antitrust laws prohibits charging "excessive" prices for goods or services, the Federal Trade Commission Act ("FTC Act") grants the FTC the power to prevent "unfair or deceptive acts or practices," and a number of elected officials have urged the FTC to take action. In fact, U.S. Senators Catherine Cortez Masto (D-Nev.) and Jacky Rosen (D-Nev.) recently joined a letter led by Senator Amy Klobuchar (D-Minn.) urging the FTC to protect consumers from price gouging during the coronavirus pandemic. In the letter, the senators call on the Agency to use the full extent of its authority to prevent abusive price gouging on consumer health products that members of the public need to protect themselves and their loved ones from the spread of the coronavirus. Specifically, the letter states, "Under normal circumstances, the FTC has been reticent to employ the full extent of its authority under Section 5 of the FTC Act. But these are not normal circumstances. If ever there was a time to explore the limits of the FTC's consumer protection authority, that time has come. The FTC must take urgent action to address these abuses."[11]

In addition, FTC Chairman Joe Simons released a statement outlining current enforcement efforts. Per the chairman's statement, the FTC is working with both federal and state law enforcement, as well as business and community stakeholders, to protect consumers from unfair and deceptive commercial practices and to educate the public about such practices. In short, the FTC "will not tolerate businesses seeking to take advantage of consumers' concerns and fears regarding coronavirus disease, exigent circumstances, or financial distress." The chairman added that "the FTC will remain flexible and reasonable in enforcing compliance requirements that may hinder the provision of important goods and services to consumers." While this does not give businesses carte blanche in how they advertise or market important goods and services, Chairman Simons noted that "good faith efforts undertaken to provide needed goods and services to consumers will be taken into account in making enforcement decisions."[12]

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9 See, e.g. https://www.ftc.gov/news-events/blogs/competitionmatters/2015/03/power-shopping-alternative-buyer.

10 https://www.khou.com/article/news/health/coronavirus/4000-price-gouging-complaints-have-been-filed-in-texas-during-covid-19-emergency/285-fcf921fb-7587-4463-81f4-2026ce4498f6.

11 https://www.klobuchar.senate.gov/public/_cache/files/1/1/114a671c-446c-4d89-89d2-a6a138e52fdc/D0CBBF2D657990AB0AA905FF3D11525A.2020.03.27-letter-to-ftc-re-pricegouging.pdf.

12 https://www.ftc.gov/system/files/documents/public_statements/1569773/final_chairman_covid_statement_3262020.pdf.

VI. CONCLUSION

Healthcare providers are at the front lines of the battle against COVID-19. Their services are more important than ever to meet critical patient and community health needs. The pandemic will present numerous challenges, and even some opportunities, for providers. Meanwhile, antitrust enforcers remain on the job (even if from home) and vigilant for potential violations of antitrust laws. Consequently, healthcare providers will need to assess the challenges and opportunities before them with antitrust considerations in mind. Even though antitrust standards remain strict during the COVID-19 pandemic, there remains wide scope for healthcare providers to engage in collaborations, mergers, and other transactions with competitors and other partners in the healthcare industry.

PAY-FOR-DELAY: WHO DOES THE GENERIC INDUSTRY LOBBY REPRESENT?

BY MICHAEL A. CARRIER[1]

1 Distinguished Professor, Rutgers Law School. Parts of this essay are adapted from Brief *Amicus Curiae* in Support of Appellee's Answering Brief, *AAM v. Becerra* (9th Cir. filed March 3, 2020) and Brief *Amici Curiae* of 82 Law, Economics, Business, and Medical Professors in Support of Respondent, *Impax Labs., Inc. v. FTC* (5th Cir. filed Dec. 16, 2019).

I. INTRODUCTION

The generic industry lobby, Association for Accessible Medicines ("AAM"), often represents the public interest. In the pharmaceutical industry, it challenges brand drug companies' anticompetitive conduct. It fights for lower prices for consumers. And it has built up goodwill for its work in these areas.

But there is one glaring exception. Brand and generic companies often settle patent litigation. And sometimes they do so with the brand paying the generic to delay entry. To state the obvious, generics do well when brands pay them to stay off the market. But AAM's fierce advocacy in favor of these "pay-for-delay" settlements has not received the attention it deserves.

This essay addresses this gap. It analyzes AAM's advocacy against congressional pay-for-delay legislation and its briefs in two recent cases involving a Federal Trade Commission ("FTC") challenge and California legislation. The essay concludes that in defending these blatantly anticompetitive deals, AAM does not represent the public interest.

II. DRAMA

One theme of AAM's advocacy is drama. The group constantly warns that robust antitrust scrutiny will result in fewer generic drugs and higher prices. One setting involves AB 824, California's legislation targeting pay-for-delay settlements. Lamenting that this legislation would result in calamitous consequences, AAM has sought to block it. In doing so, it has resorted to fear-mongering: AB 824 would "make it difficult, if not impossible" to settle patent litigation, "scuttle patent settlements now in the works and on the near-horizon," "dissuade generic manufacturers" from "challenging patents," and result in "fewer generic medicines on the market" and "higher prescription-drug prices."[2]

AAM also has weighed in to try to overturn the FTC's ruling against Impax. This ruling was the most thorough application of the Supreme Court's 2013 landmark decision, *FTC v. Actavis*.[3] And it offered a ringing bipartisan, unanimous (5-0) condemnation of pay-for-delay settlements. AAM nonetheless resorts to histrionics in its brief, claiming that the ruling will result in parties not having "the ability to settle patent cases," which would "thwart …" generics' "cost savings" because of "the need to litigate large patent portfolios all the way through trial."[4] Generics' inability to "pursue the same number of patent challenges" would "ultimately mean … fewer [generic] and biosimilar filings, fewer patent challenges, and fewer generics and biosimilars on the market."[5] The melodramatic argument is matched by an over-the-top style, with more than 50 bolded and italicized words in the Impax brief alone.

This is dangerous. Many associate AAM with the public interest. And its arguments do not sound frivolous on their face. So it is possible that courts and legislatures will consider this drama. The problem is that, as the remainder of this essay discusses, AAM's arguments are foreclosed by the relevant caselaw and regulatory framework.

III. PATENT SCOPE

The centerpiece of the caselaw is *Actavis*, one of the most important antitrust cases in the past generation. In the decade before *Actavis*, lower courts had immunized anticompetitive patent settlements. These "reverse payment" settlements involve patent-holder brand firms paying potentially infringing generics to *delay* entry, which differs from the typical arrangement of alleged infringers paying patentees for licenses to *enter* the market. Courts had upheld these settlements (also known as "pay for delay") on several grounds: that they fell within the "scope of the patent," benefited from a presumption of patent validity, were the "natural by-product" of industry legislation, and were supported by the public policy in favor of settlement.[6] In rejecting these arguments, *Actavis's* importance cannot be overstated. The Court held that reverse-payment settlements have the potential for "significant adverse effects on competition" and could "violate the antitrust laws."[7]

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2 Brief for Plaintiff-Appellant, *AAM v. Becerra*, at 47-48 (9th Cir. filed Jan. 30, 2020) ("California Brief").

3 570 U.S. 136 (2013).

4 Brief of the Association for Accessible Medicines as *Amicus Curiae* in Support of Respondent, *Impax Labs., Inc. v. FTC*, at 4 (5th Cir. filed Oct. 10, 2019) ("*Impax* brief").

5 *Id.* at 12.

6 See Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37, 60-67 (2009) (describing cases).

7 570 U.S. at 141, 148.

Given this roadblock to its position, AAM ignores, downplays, or mischaracterizes *Actavis* whenever it can. First, AAM takes direct aim at *Actavis's* most fundamental underpinning, which focused on the relationship between patent and antitrust law. Courts before *Actavis* had upheld reverse-payment settlements as a type of activity falling within the scope of the patent. They reasoned that payment did not "unlawfully extend the reach of the patent" since the patent holder could exclude competition based on the patent itself.[8] In other words, while the patent was still in force, antitrust had no role to play.

The Court in *Actavis* rejected this test. It reviewed the caselaw, tracing antitrust's robust role in evaluating patent arrangements back to the mid-20th century. The Court found it "incongruous" to "determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well." It made clear that "patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent." And it recognized that reverse-payment settlements had the "potential for genuine adverse effects on competition" since "payment in return for staying out of the market…keeps prices at patentee-set levels."[9]

In direct contravention of this ruling, AAM seeks to resuscitate the overturned scope-of-the-patent test. It calls "entry before patent expiration" a "procompetitive result not frequently achieved in litigation."[10] And in the *Impax* case, it claims that the settlement with Endo allowed Impax to enter "*ten years* earlier than otherwise possible" and "eight months before expiration of Endo's original patent monopoly."[11]

AAM's position is not consistent with *Actavis*, which made clear that in applying antitrust law, courts cannot simply assume that the patent is valid and infringed. Just because a generic can enter before the patent expires does not mean that a settlement automatically is procompetitive. After all, that patent might not have been valid, and in such a case, the generic's delaying entry because of payment improperly extends monopoly power.

IV. PAYMENT

Actavis was a foundational ruling not only in cementing antitrust's position but also in emphasizing the key role played by payment, which marks the dividing line between anticompetitive and procompetitive settlements. Drug companies settle cases all the time without payment. Such "patent-term split agreements" involve brands and generics dividing the remaining patent term by selecting a time for generic entry based on the patent's strength. The Court in *Actavis* thus found that settlement allowing entry before patent expiration could "bring about competition… to the consumer's benefit."[12]

The problem with payment is that the brand firm obtains more exclusivity than the patent would warrant. In other words, the brand keeps the generic off the market based on not the strength of its patent but the size of its payment. It goes without saying that potential competitors cannot divide markets through payments from one to another not to compete. That is illegal.[13] And that is what happens when a brand pays a generic to delay entry.

Payment not only distinguishes between anticompetitive and procompetitive settlements but also allows courts to avoid wading into the merits of the patent litigation to decide the antitrust case.[14] The Supreme Court found it "feasible" for a court to evaluate the antitrust effects of settlements because "it is normally not necessary to litigate patent validity to answer the antitrust question." The reason is that "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival." In fact, "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself."[15]

8 *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006); see also *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

9 570 U.S. at 147-51, 154.

10 *Impax* brief, at 12.

11 *Id.* at 2 (emphasis in original, bold omitted), 26.

12 570 U.S. at 154.

13 See, e.g. *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 48 (1990).

14 *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1315 (11th Cir. 2012) (referring to "turducken" approach of "deciding a patent case within an antitrust case about the settlement of the patent case").

15 570 U.S. at 157-58.

Payment's crucial role — and the relative infrequency today of settlements with payment — may help explain why AAM resorts to drama. For example, in arguing against AB 824, California's pay-for-delay legislation, the group relies on a syllogism: (1) generic entry lowers price; (2) settlement facilitates generic entry; (3) AB 824 bars settlements; (4) AB 824 increases price. The syllogism flows easily. And it paints a scary story. But it is not accurate. For there is a fundamental problem.

And that problem lies at the third step: that AB 824 targets all settlements. Such an assertion is completely unsupported, as AB 824 targets only the minor subset of settlements involving payment. Throughout its brief seeking to block the legislation, not one of AAM's numerous references to AB 824's effects on settlements even hints at payment. But as discussed in this section, *Actavis* drew a critical distinction between settlements with and without payment. In ignoring this holding, AAM neglects a centerpiece of *Actavis* and subsequent caselaw.

V. PREEMPTION

In its advocacy, AAM not only seeks to undercut *Actavis* but also, as discussed above, endeavors to block California's reasonable legislation targeting pay-for-delay settlements. In particular, it claims that AB 824 is preempted by the Hatch Waxman Act (Congress's landmark statute balancing competition and innovation in the pharmaceutical industry) and by patent law.

First, AAM claims that the legislation is "fundamentally at loggerheads with the Hatch-Waxman Act," as it would make it "impossible" to settle cases, "dissuade" patent challenges, and result in "fewer generic[s]" and "higher…prices."[16] Even though the Hatch Waxman Act has increased generic competition, reverse-payment settlements have undermined the legislature's goals. A central element of this subversion has been the 180-day exclusivity period that Congress created to encourage generics to be the first to certify that brand patents are invalid or not infringed.[17] This bounty, however, has been twisted from an incentive for generics to challenge and *enter* to a mechanism for preventing challenges and *delaying* entry. In fact, by settling with the first challenger, the brand firm can significantly delay other generics' entrance into the market.[18]

Such payment for delayed entry contravenes the competition goals at the heart of the Hatch Waxman Act. The drafters have said so themselves. Representative Waxman explained that reverse-payment agreements "turn…the…legislation on [its] head."[19] Waxman emphasized that the purpose of the legislation was to promote generic competition, not to allow generics "to exact a portion of a brand-name manufacturer's monopoly profits in return for withholding entry into the market."[20] Senator Hatch similarly found such agreements "appalling." And his assessment mirrored that of Waxman in making clear that "[w]e did not wish to encourage situations where payments were made to generic firms not to sell generic drugs and not to allow multi-source generic competition."[21]

AAM also claims that AB 824 "upsets the balance Congress struck in federal patent law and the Supreme Court went out of its way to protect in *Actavis*."[22] But this contention is incorrect on at least four grounds, based on antitrust preeminence, patent irrelevance, patent challenges, and exclusive licenses.

First, AAM's claim is belied by *Actavis*, which made clear that antirust plays a crucial role in the analysis of patent settlements. As discussed above, *Actavis* rejected the absolutist scope-of-the-patent approach, forging a careful equilibrium between patent and antitrust that foils any attempt to extricate antitrust from the analysis.

A second reason why patent law does not preempt AB 824, again as discussed above, is the irrelevance of the patent's merits. *Actavis's* emphasis on payment allows courts to avoid wading into the merits of the patent litigation to decide the antitrust case.

16 California Brief, at 47-48.

17 21 U.S.C. § 355(j)(2)(A)(vii).

18 See Hovenkamp et al., IP and Antitrust, § 16.01[A], at 16-10 to 16-11 (2018 Supp.).

19 Motion & Brief of Representative Henry A. Waxman as *Amicus Curiae* in Support of Petitioner at *1, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273), 2005 WL 2462026.

20 *Id.*

21 148 Cong. Rec. S7566 (daily ed. July 30, 2002).

22 California Brief, at 39.

Third, the importance of challenging invalid patents also supports AB 824. The Supreme Court made clear that the problem with payment is that it blocks the "risk of competition" on invalid patents, which "constitutes the relevant anticompetitive harm."[23] The Court also recognized the crucial "patent-related policy" of "eliminating unwarranted patent grants so the public will not 'continually be required to pay tribute to would-be monopolists without need or justification.'"[24]

Fourth, AAM contends that "whereas the Patent Act expressly confers the right to grant exclusive licenses, AB 824 deems all 'exclusive license[s]' to be presumptively anticompetitive."[25] But in *Actavis*, the Court went back decades to trace its history of finding that patent-based arrangements — *allowed under patent law* — violated antitrust law.[26] Since *Actavis*, courts have recognized that exclusive licenses are not immune from antitrust scrutiny, with the Third Circuit, for example, explaining that the exclusive license the defendant tried to defend "is not in fact a patentee's right to grant licenses, exclusive or otherwise," but "[i]nstead…is a right to use valuable licensing in such a way to induce a patent challenger's delay," conduct that *Actavis* "rejected."[27]

VI. ANTITRUST FRAMEWORK

AAM also seeks to impose its unjustified position on the type of antitrust analysis courts are to perform after *Actavis*. In offering its position, it ignores *Actavis*, citing general antitrust cases having little to do with the framework courts have applied in pay-for-delay cases in the past several years.

Although *Actavis* adopted a type of rule-of-reason analysis, this was not the "typical exhaustive consideration of a restraint's anticompetitive and procompetitive effects," but instead was a "more abbreviated analysis."[28]

The Court adopted several shortcuts favoring plaintiffs. First, it found that the "size of the payment" serves as "a strong indicator of power,"[29] which makes sense since "[a] producer in a highly competitive market would not pay anything to keep a rival out because price-cost margins are already low and keeping one firm out would not improve that situation."[30] And second, the Court found that a large and unjustified payment has the "potential for genuine adverse effects on competition" because the payment "in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed."[31]

The Court further streamlined the analysis by accepting only two of defendants' proffered justifications: (1) payments "amount[ing] to no more than a rough approximation of the litigation expenses saved through the settlement" and (2) "compensation for other services that the generic has promised to perform."[32] As a result, the settling parties are no longer able to offer reasons based on reducing risk or allowing entry before the end of the patent term. The Court confirmed this abbreviated analysis in directing lower courts to "avoid … consideration of every possible fact or theory irrespective of the minimal light it may shed on … the presence of significant unjustified anticompetitive consequences."[33] In short, "the Court appears to have all but in name adopted the presumptive illegality approach it purported to reject."[34]

The Court's recognition of only two justifications, and its rejection of the scope-of-the-patent test, precludes AAM's attempt to rewrite the rule of reason in this setting by (1) raising the bar for plaintiffs by cherry-picking (and *emphasizing* in bold and italics) individual words from

23 570 U.S. at 157.

24 *Id.* at 151 (citing *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969)).

25 California Brief, at 5.

26 570 U.S. at 148-50.

27 *King Drug v. SmithKline Beecham Corp.*, 791 F.3d 388, 407 (3d Cir. 2015).

28 Michael A. Carrier, *Payment After Actavis*, 100 Iowa L. Rev. 7, 30 (2014).

29 570 U.S. at 157.

30 Aaron Edlin et al., Activating *Actavis*, 28 Antitrust 16, 17 (2013).

31 570 U.S. at 153-54.

32 *Id.* at 156.

33 *Id.* at 159-60.

34 Thomas F. Cotter, *FTC v. Actavis, Inc.: When is the Rule of Reason Not the Rule of Reason?*, 15 Minn. J. L., Sci. & Tech. 41, 43 (2014).

unrelated antitrust cases, (2) offering as a procompetitive benefit entry before the end of the patent term, and (3) requiring balancing in every rule-of-reason case.[35] Such efforts would undermine *Actavis* and immunize pay-for-delay settlements.

AAM also urges courts to evaluate agreements "as a whole," lamenting the FTC's "cramped reading" in *Impax* that required Impax to "directly 'link' the proffered benefits to the purported payment."[36] And it criticizes the "piecemeal analysis of an agreement's individual provisions lest [courts] miss the forest for the trees."[37] But these pleas fly in the face of *Actavis*, as the Court made clear that a defendant must justify "the presence of the *challenged term* and show … the lawfulness of *that term* under the rule of reason."[38] As recognized by other Supreme Court rulings and the leading antitrust treatise, such a position is not controversial.[39]

The FTC thus was on solid ground in its *Impax* ruling when, in considering procompetitive justifications, it "look[ed] at the specific restraint, not the agreement as a whole."[40] The agency found that Impax "never attempt[ed]" to show that the provisions that involved payment "*themselves* protected Impax from the threat of patent infringement suits."[41]

As the Commission recognized, a "contrary rule would allow parties to skirt liability for anticompetitive behavior by inserting unrelated provisions into their contracts and claiming that those provisions benefited competition."[42] Remarkably, AAM's proposed approach would be more deferential than the scope-of-the-patent test by allowing settlements that blocked generic entry even *after* the patent term as long as the settling parties could point to other provisions, like a license to unrelated patents. And in fact, if the Supreme Court had adopted AAM's framework, *Actavis* itself would have come out the other way since the brand's payment would have been downplayed in comparison to the generic's entry *65 months* before the end of the patent term.[43]

AAM also ignores the possibility of at-risk entry. As discussed above, in the *Impax* case, AAM claimed that the settlement with Endo allowed Impax to enter "*ten years* earlier than otherwise possible" and "eight months before expiration of Endo's original patent monopoly."[44] This, however, ignores the possibility of generics entering the market "at risk," before a court has ruled that the patent is invalid or not infringed. After the FDA approved Impax's generic application in June 2010, the company posed a "real threat of competition," with its senior management "consider[ing] launching 'at risk'" and "tak[ing] a number of steps to prepare," including forecasting a 2010 launch, presenting such a launch to the board of directors, and obtaining approvals and manufacturing products.[45] In short, the FTC met its burden of showing the plausibility of an at-risk launch, which would have introduced generic competition before the patent litigation ended.

AAM also claims that the Commission "removed its burden to prove that a real, lesser-restrictive settlement option was viable," instead "fashion[ing] a wholly theoretical benchmark" and (as discussed below, taking great liberties with the opinion) "flipp[ing] the burden to Impax to demonstrate that a less restrictive settlement was impossible."[46] Real-world evidence, however, shows that brands and generics are able to settle without payment. In fact, they are overwhelmingly able to do so.

For the past 15 years, the FTC has reviewed every settlement of drug patent litigation and published annual reports detailing the number of settlements, including the number involving payment and delayed entry. In a nutshell, when the courts are applying robust antitrust scrutiny, the number of pay-for-delay settlements falls, as it did between 2000 and 2004, when 0 out of 20 settlements involved payment, and as it has

35 *Impax* brief, at 14-15, 17, 19.

36 *Id.* at 19-20.

37 *Id.* at 20.

38 *Actavis*, 570 U.S. at 156 (emphases added).

39 See, e.g. *NCAA v. Board of Regents*, 468 U.S. 85, 117 (1984) (defendants must justify the "specific restraints on football telecasts that are challenged in this case"); VII Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application ¶ 1505a, at 432 (4th ed. 2013).

40 *In the Matter of Impax Labs., Inc.*, at 32 (FTC Dkt. No. 9373, March 28, 2019) ("FTC Opinion").

41 *Id.* at 37 (emphasis in original).

42 *Id.* at 36 n.40.

43 570 U.S. at 145.

44 *Impax* brief, at 2 (emphasis in original, bold omitted), 26.

45 *FTC Opinion*, at 24.

46 *Id.* at 8 (italics and bold omitted).

since *Actavis*, when the number of pay-for-delay settlements fell from 33 (out of 140 total settlements) in 2012 to 1 (out of 232) settlements in 2016.[47] In contrast, when the courts abandon antitrust scrutiny, as they did between 2005 and 2012, the number of pay-for-delay settlements skyrockets. The Court in *Actavis* thus was on solid empirical ground when it explained that the parties could settle by allowing the generic "to enter … prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point."[48]

Despite *Actavis* and this real-world evidence, the FTC still gave Impax the chance to show that this could have been the unique case in which payment was needed for a procompetitive settlement. But Impax's lead settlement negotiator conceded that he did not recall "(1) whether Impax ever 'tried to get a date earlier than January of 2013'; (2) how Endo reacted to the prospect of an earlier date; or (3) whether Endo ever told Impax that it would 'not settle the litigation' with an entry date before 2013."[49]

In short, in advocating for an unsupported deferential approach, seeking to analyze the agreement as a whole, ignoring plausible at-risk entry, and neglecting the less restrictive alternative of settlement without payment, AAM offers an antitrust analysis having little to do with *Actavis* or subsequent caselaw.

VII. FLAWS

In addition to all of these substantive problems with AAM's positions, the group's advocacy is based on internal contradictions and misleading assertions.

First, AAM contradicts itself. As discussed throughout this essay, in litigation, AAM ominously warns that robust antitrust analysis will preclude future settlements, while suggesting that *Actavis* provided a deferential Rule-of-Reason antitrust analysis. But in seeking to block pay-for-delay legislation, AAM argues the *exact opposite*. Far from predicting the end of settlements, it concedes that "the vast majority" of settlements do not involve payment.[50] And unlike the deferential antitrust analysis it finds in *Actavis* for litigation purposes, it urges Congress not to pass legislation because "the Supreme Court prohibited 'pay-for-delay' deals."[51]

Second, AAM misleads. In advocating against legislation, the group claims that *Actavis* "recognize[d] the value of settlements and the patent litigation problem."[52] But AAM neglects to mention *Actavis's* next sentence, which made clear that "this patent-related factor should not determine the result" and that "the FTC should have been given the opportunity to prove its antitrust claim."[53]

AAM also deceives about the FTC's ruling in *Impax*. AAM twists *the company's* claim that "a no-payment settlement was impossible"[54] into an *FTC*-imposed burden on Impax "to demonstrate that a less restrictive settlement was *impossible*."[55] And it replaces accuracy with drama in claiming that the FTC "gerrymandered" and "attempt[ed] to rig" the analysis to "a *fait accompli*."[56]

Another example of misdirection is AAM's attempt to downplay *Actavis*. AAM claims that this landmark decision was confined to the "limited circumstances" presented by "large and unjustified" payments.[57] But given the Supreme Court's rejection of the scope-of-the-patent test

47 FTC Bureau of Competition, *Summary of Agreements Filed in FY 2004*, https://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/050107medicareactrpt.pdf; FTC Bureau of Competition, *Overview of Agreements Filed in FY 2016*, https://www.ftc.gov/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-fy2016 (14 additional settlements contain "possible compensation").

48 570 U.S. at 158.

49 FTC Opinion, at 41 n.43.

50 AAM, *Check the Facts on "Pay-for-Delay" Legislation*, https://accessiblemeds.org/sites/default/files/2019-05/AAM-Patent-Settlement-Fact-Sheet.pdf (last visited Mar. 21, 2020).

51 *Id.*

52 *Id.*

53 570 U.S. at 153.

54 FTC Opinion, at 41.

55 *Impax* brief, at 9 (bold and italics in original); see also *id.* at 25 (same).

56 *Id.* at 9.

57 California Brief, at 40; see also *id.* at 12 (*Actavis* "sharply restricted the scope of antitrust review of patent settlements").

and robust recognition of antitrust enforcement, that is like saying the landmark case of *United States v. Socony-Vacuum Oil* held that price fixing between rivals is *per se* illegal only in the "limited circumstances" in which there is an agreement.[58]

AAM's reliance on self-contradiction and deception speaks volumes.

VIII. CONCLUSION

For most pharmaceutical conduct, AAM represents the public interest. On "product hopping" (switching from one version of a drug to a trivially-different version), frivolous citizen petitions filed with the U.S. Food and Drug Administration to delay entry, and the denial of samples that generics need to enter the market, AAM challenges unwarranted patent monopolies and encourages market entry to lower prices and benefit consumers.[59]

Pay-for-delay settlements are different. As this essay has shown, AAM has misrepresented the law and engaged in misleading advocacy to protect generic companies that benefit from these anticompetitive agreements. Pay-for-delay settlements cost consumers billions of dollars and force patients to forgo needed medicines. Courts and Congress should keep in mind who AAM really represents when it vociferously argues against antitrust enforcement of anticompetitive pay-for-delay settlements.

58 310 U.S. 150 (1940).

59 See *Statement by Michael A. Carrier to Senate Judiciary Committee on "Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition,"* May 7, 2019, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3442650.

ECONOMIC TOOLS FOR ANALYZING VERTICAL MERGERS IN HEALTHCARE

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1 The authors are economists at Charles River Associates. The conclusions set forth herein are based on independent research and publicly available material. The views expressed herein are the views and opinions of the authors and do not reflect or represent the views of Charles River Associates or any organizations with which the authors are affiliated.

I. INTRODUCTION

The Federal Trade Commission ("FTC") and the Department of Justice ("DOJ") recently released Draft Vertical Merger Guidelines ("VMG"),[2] which describe the framework under which the federal antitrust agencies propose to evaluate vertical mergers. "Vertical" mergers involve firms that operate at different levels of the supply chain and are distinguished from "horizontal" mergers, which combine firms that compete at the same level of the supply chain. In vertical mergers, economists differentiate upstream firms, which produce an input or provide a service that may be used or relied upon by other firms, from downstream firms, which sell their products to end consumers. We use these "upstream" and "downstream" labels throughout this article.

The VMG are short — just nine pages long — and are not tailored to one industry or supply chain. While the VMG outline general principles that the agencies intend to use in evaluating vertical mergers, they lack specifics. In this article, we discuss the relevance of the VMG to healthcare mergers — where vertical transactions and investigations by the FTC and DOJ are common — and provide an overview of some economic tools that comport with the guidance offered by the VMG. While not limited to use in healthcare, these tools may be used by practitioners to quickly assess whether a vertical merger may give rise to antitrust concerns.[3]

II. RECENT ENFORCEMENT ACTIONS

Given the complex and multi-level nature of healthcare markets, vertical concerns have arisen in several contexts in recent healthcare transactions. Before discussing the economic tools that can be used to evaluate vertical effects in these mergers, we briefly describe some of these transactions to provide context to our discussion. We start by noting that as physicians increasingly move away from independent practice towards employment by hospital systems, one issue that is likely to arise in these transactions is whether such employment arrangements have the potential to disadvantage competing hospital systems. A recent example involves the acquisition of Saltzer Medical Group in Nampa, Idaho — which was at the time the largest multi-specialty physician practice in Idaho — by St. Luke's Health System. Competing systems expressed concern that after the acquisition, St. Luke's, which also operated hospitals, would block referrals from Saltzer-employed physicians to competing hospitals.[4]

Another vertical transaction involved an acquisition by Fresenius — a manufacturer of dialysis equipment and consumables for hemodialysis machines — of NxStage. In addition to its role as an upstream supplier, Fresenius was the largest operator of outpatient hemodialysis clinics in the United States. NxStage primarily sold hemodialysis equipment and consumables.[5] Although the FTC only required divestitures related to the parties' horizontal overlap in bloodline tubing supplies,[6] two commissioners also expressed concerns about the vertical effects of the transaction. The commissioners noted that NxStage also manufactured a leading home hemodialysis machine, which raised the potential for vertical harm by foreclosing Fresenius's competitors from access to NxStage's unique home dialysis equipment. In addition, one commissioner noted that the acquisition had the potential to stifle innovation in development of home hemodialysis machines because the vertically integrated Fresenius would have little incentive to purchase equipment from entrants.[7]

2 Federal Trade Commission, FTC and DOJ Announce Draft Vertical Merger Guidelines for Public Comment (2020), https://www.ftc.gov/news-events/press-releases/2020/01/ftc-doj-announce-draft-vertical-merger-guidelines-public-comment (last visited April 13, 2020).

3 The VMG describe the possibility that a merger could diminish competition by enabling or encouraging post-merger coordinated interaction among firms (coordinated effects), or that a merger may diminish competition between the merged firm and upstream or downstream competitors (unilateral effects). The Horizontal Merger Guidelines make the same distinction. We focus here on economic tools for evaluating the likelihood of unilateral competitive effects in vertical mergers as most recent enforcement action has focused on this possibility.

4 While the FTC successfully enjoined the transaction based on the horizontal overlap for adult primary care provider services, St. Alphonsus and Treasure Valley — two private hospital plaintiffs — alleged the type of vertical foreclosure concerns we described.

5 NxStage operated a very small number of hemodialysis clinics, primarily designed to test its own equipment.

6 Bloodline tubing sets are used to connect blood access devices to hemodialysis machines.

7 Dissenting Statement of Commissioner Rohit Chopra In the Matter of Fresenius Medical Care AG & Co. KGaA and NxStage Medical, Inc., FTC File No. 171-0227, (February 19, 2019), https://www.ftc.gov/system/files/documents/public_statements/1455733/171_0227_fresenius_nxstage_chopra_statement_2-19-19.pdf (last visited April 13, 2020); Dissenting Statement of Commissioner Rebecca Kelly Slaughter In the Matter of Fresenius Medical Care/NxStage, FTC File No. 171-0227, (February 19, 2019), https://www.ftc.gov/system/files/documents/public_statements/1455740/171_0227_fresenius-nxstage_slaughter_statement_2-19-19.pdf (last visited April 13, 2020).

The acquisition of DaVita Medical Group by UnitedHealth similarly raised both horizonal and vertical concerns.[8] United offers Medicare Advantage plans to seniors in the Las Vegas area; in addition, United employs physicians in Las Vegas. DaVita, on the other hand, operated a competing group of physicians in Las Vegas. Both United's and DaVita's Las Vegas physician groups contracted with insurers participating in Medicare Advantage to provide what the FTC characterized as "managed care provider organization" ("MCPO") services. MCPO services involved coordinating care, managing utilization, and controlling healthcare expenditures for Medicare Advantage plan members. The FTC alleged that United and DaVita were the two largest providers of MCPO services in Las Vegas and that the acquisition would diminish competition for MCPO services (i.e. horizontal effects). In addition, the FTC alleged that the merger would give United control over DaVita's physician group, which it saw as a "competitively significant input" for rival insurers offering Medicare Advantage plans in Las Vegas (i.e. vertical effects). As a result, the FTC alleged that United could have negotiated higher rates with or refused to contract with rival Medicare Advantage plans.

A final pair of examples can be found in the recent mergers of pharmacy benefits managers (PBMs) and health insurers: the acquisition of Express Scripts by Cigna and the acquisition of Aetna by CVS.[9] Neither matter resulted in the federal agencies taking enforcement action to alleviate potential vertical concerns, but the DOJ noted that it investigated the potential for such concerns in both matters. Specifically, in its closing statement for the *Cigna/Express Scripts* investigation, the DOJ noted that it considered whether the merger might "raise the cost of PBM services to Cigna's health insurance rivals" but ultimately concluded there was no cause for concern.[10] In the *Aetna/CVS* matter, the DOJ settlement required divestiture of Aetna's Medicare Part D individual prescription drug plan business to address horizontal overlap concerns between Aetna's and CVS's competing Medicare prescription drug plans.[11] In addition to this horizontal concern, the DOJ also considered whether the merger might give rise to a vertical concern by raising the cost of PBM services or retail pharmacy services to competitors. However, as with the *Express Scripts/Cigna* transaction, the DOJ ultimately concluded that there was no concern that *Aetna/CVS* might foreclose competing health insurers' access to either CVS's PBM or retail pharmacy network.[12]

III. FORECLOSURE & RAISING RIVALS' COSTS

With these examples in mind, the VMG discuss two mechanisms that can lead to unilateral competitive effects in vertical mergers: foreclosure and raising rivals' costs.[13] Balancing the potential for anticompetitive effects, vertical mergers may give rise to the same types of economic efficiencies that are associated with horizontal mergers. The VMG also acknowledge that, in principle, vertical mergers naturally give rise to a type of efficiency called the "elimination of double marginalization" ("EDM") which occurs when the upstream division stops selling inputs to the downstream division at a markup and instead sells to them at cost. The presence of EDM is the reason that some economists distinguish vertical mergers from horizontal mergers in terms of competitive effects. The VMG discuss when efficiencies from EDM might be large and when they might be mitigated by other factors.[14]

Foreclosure refers to a situation in which the upstream merged division refuses to supply rivals of its downstream division with an input that those rivals need to effectively compete. After a vertical merger, the upstream division may have an incentive to engage in foreclosure if the downstream division benefits from sales lost by the foreclosed downstream rivals. This conduct may increase the market power of the downstream division to the detriment of consumers.[15]

8 Complaint, *U.S. et al. v. UnitedHealth Group Inc., et al.,* No. C-4677, https://www.ftc.gov/system/files/documents/cases/181_0057_c4677_united_davita_complaint.pdf (last visited April 13, 2020).

9 In addition to operating a PBM (Caremark), CVS also operates retail pharmacies and ambulatory care centers ("Minute Clinics") in the United States.

10 Statement of the Department of Justice Antitrust Division on the Closing of Its Investigation of the Cigna–Express Scripts Merger, Justice.gov (2018), https://www.justice.gov/atr/closing-statement (last visited April 13, 2020).

11 Final Judgment, *U.S. et al. v. CVS Health Corp. and Aetna Inc.*, 1:18-cv-02340 (D.D.C. September 4, 2019), https://www.justice.gov/atr/case-document/file/1199836/download (last visited April 13, 2020).

12 Department of Justice, United States v. CVS and Aetna, Questions and Answers for the General Public (2018), https://www.justice.gov/opa/press-release/file/1099806/download (last visited April 13, 2020).

13 The VMG also discuss access to competitively sensitive information from upstream or downstream rivals as a source of unilateral anticompetitive effects in vertical mergers, but we do not discuss that issue here.

14 VMG, Section 6. The VMG appear to treat the existence of EDM with some skeptism and place the burden on the merging parties to "identify and demonstrate whether and how the merger eliminates double marginalization." That is, like a traditional efficiency in a horizontal merger, EDM is an affirmative arugment that must be made by the parties.

15 While this situation is referred to as "input foreclosure," there is also the potential for "customer foreclosure." In such a situation, the downstream division may attempt to disadvantage rivals to its upstream merged division (for example, by refusing to buy inputs from those rivals). This may provide the upstream merged division with enhanced market power. Economic analysis of customer foreclosure generally mirrors the analysis of input foreclosure that we describe below, except that the loss in profits suffered by the downstream division is weighed against the increase in profits to the upstream division that comes from disadvantaging its rivals.

Raising rivals' costs is a less extreme form of input foreclosure: rather that refusing to supply a downstream rival with an input, the upstream division of the merged firm continues to supply the input to rivals but charges more for the input. After a vertical merger, the upstream division may have an incentive to raise downstream rivals' costs because doing so makes it harder for those rivals to effectively compete. The lost sales suffered by the disadvantaged downstream rivals may benefit the merged firm but harm consumers. Compared to input foreclosure, raising rivals' costs has a smaller impact on the profits of both the targeted rival and the merging firm and, in many situations, economic models predict that raising rivals' costs is profitable even when foreclosure is not.

As we describe in more detail below, two key considerations determine whether both foreclosure and raising rivals' cost are likely to be profitable following a vertical transaction. The first consideration is whether downstream rivals have alternative input suppliers and the second consideration is the closeness of competition between the downstream division and the targeted rivals.[16] Because the same economic considerations affect the likelihood of both foreclosure and raising rivals' costs, it is the views and conduct of industry participants that will likely determine whether the agencies investigate the potential either for foreclosure or for raising rivals' cost. For example, when an insurer proposes acquiring a physician practice, if the insurer's rivals express concerns to the agencies about the acquired practice demanding higher reimbursement rates, the agencies might investigate the potential for harm from raising rivals' costs. On the other hand, if these same rival insurers express concerns that the physician practice will no longer agree to be a network provider, the agencies might investigate the potential for harm from foreclosure.

IV. MODELS AND TOOLS

Neither the VMG nor the Horizonal Merger Guidelines describe specific tools that the agencies use to evaluate a merger. Rather, these guidelines state that the agencies will utilize their "extensive experience, [and] apply a range of analytical tools … to evaluate competitive concerns in a limited period of time."[17] However, we believe that there are some tools that can be used — at least as initial screening tools — to evaluate the likelihood that a vertical merger may give rise to anticompetitive effects. Of course, any economic model is based on assumptions that may not reflect the current or future competitive dynamics of the industry, and we do not mean to suggest that the models we describe are always appropriate or always produce accurate predictions. Rather, as the FTC and DOJ state, we believe it is more informative to consider whether different economic models "consistently predict substantial price increases."[18]

A. Evaluating Foreclosure Concerns

As a concrete example of how these models might be applied to vertical mergers in healthcare, suppose that a nationwide physician practice of radiologists, Downstream Radiology Practice ("DRP"), is acquiring a manufacturer of imaging machines, Upstream Imaging Equipment ("UIE"). The merged firm would have an incentive to foreclose access by downstream rival radiologist practices to the upstream division's imaging equipment — suppose UIE had developed a state-of-the-art X-ray machine — if doing so increased the merged firm's overall (i.e. upstream and downstream) profits. To evaluate this incentive, we need to separately consider how such foreclosure would affect the profits earned by the merged firms' downstream and upstream divisions.

The downstream division's profits typically increase after *successful* foreclosure by the upstream division.[19] This is because the act of foreclosure makes the downstream division's rivals' product or service less attractive to consumers. How much the downstream division's profits increase depends on how many of the foreclosed rivals' customers switch to the merged firm's downstream division. For example, supposed that UIE refused to sell its state-of-the-art X-ray machine to radiology practices that compete with DRP. Some patients who previously received care at those competing radiology practices may choose to find another doctor, and some of the patients who switch may choose DRP. How many patients leave the competing radiology practices and switch to DRP depends on several considerations. For example, how many patients would

16 These considerations are implicit in Section 3 of the VMG. Upstream shares relate to the potential for input substitution and downstream shares relate to diversion ratios. Upstream and downstream margins also play an important role. All these factors are related to the drivers of unilateral effects in horizontal mergers, and similar intuition underlies the economic tools used to assess horizontal and vertical mergers. An example we discuss below is the vGUPPI, which measures upward pricing pressure in vertical settings, and is closely related to, and calculated with similar inputs, as the GUPPI, which is referenced in the Horizontal Merger Guidelines and measures upward pricing pressure in that setting.

17 U.S. Department of Justice & Federal Trade Commission, Horizontal Merger Guidelines Section 1 (2010).

18 VMG, Section 5.a.

19 The immediate consequence of UIE foreclosing DRP's rival is that the rival will need to obtain imaging equipment from an alternative supplier. When this happens, DRP's profits necessarily increase. It is possible that foreclosure could have additional "second-order" effects on the downstream rival that affect the profits of DRP. While these second-order effects may ultimately be important in evaluating the competitive effects of the transaction, a full model of upstream and downstream competition and repositioning would be needed to assess those effects.

switch doctors to get access to the state-of-the-art UIE machine? Can rival radiology practices buy from other equipment makers or find used UIE X-ray machines in a secondary market? Of the patients who sought a new doctor, how many would choose DRP? The answers to these questions, along with DRP's margins, will determine the downstream profit gain to DRP from foreclosing competitors' access to UIE's X-ray machines.

Economists use a common nomenclature when quantifying these effects. After the merged firm forecloses a downstream rival, some fraction of the rival's customers will stop purchasing from that firm. This fraction is referred to as a *departure rate*.[20] Typically, the more important a merged firm's input is to the downstream rival, the higher the departure rate. For example, if UIE forecloses a rival radiology practice's access to its imaging machines but there are many competing X-ray machines for sale and these machines are largely indistinguishable to radiologists and patients, the departure rate from the rival practice will be low. But if most of the rival's radiologists prefer UIE machines and there are few manufacturers of suitable alternative machines, the departure rate from the rival radiology practice will be high.

Diversion rates measure where the departing customers from the foreclosed rivals will go,[21] and determine (along with the departure rate) how many new downstream customers the merged firm will gain after foreclosing its rival.

Finally, *downstream margins* determine the profitability of the foreclosure to the merged firm's downstream operations. The product of DRP's per-patient margin and the number of new downstream patients the firm gains (which depends on the departure and diversion rates) is the downstream profit opportunity to the merged firm's downstream division from foreclosing a rival.

After foreclosure, the downstream division's increased profits are weighed against the upstream division's profit loss from a reduction in its sales. The upstream division's profits decline because the act of foreclosure causes them to lose sales to the now foreclosed downstream rivals, and their associated profits.[22] The number of lost sales multiplied by the *upstream margins* determines the size of this profit loss. If the sum of the two offsetting effects on the upstream and downstream divisions is positive, then the merged firm will find it profitable to foreclose one or all of its downstream rivals.

In summary, foreclosure is more likely to be a concern in situations in which the upstream division of the merged firm produces an important input for downstream rivals (i.e. the departure rate is high), the merged firm's downstream division and the targeted downstream rival are close competitors (i.e. diversion from the downstream rival to the downstream division is high), and the merged firm's downstream division is profitable relative to its upstream division (i.e. downstream margins are large relative to upstream margins.) Interestingly, the economic factors that determine whether foreclosure (or raising rivals' costs) is profitable are similar to those that determine if a horizontal merger is problematic: diversion ratios and margins. In both cases, high diversion ratios and substantial margins associated with diverted sales imply greater potential for concern. While the VMG provide little discussion of either consideration, a great amount has been written about estimating both diversion ratios and margins in the context of evaluating horizontal mergers, and the methods and lessons discussed in that literature can also be applied to evaluating vertical mergers.

B. Evaluating Raising Rivals' Costs Concerns

The previous section discussed the example in which the merged firm refuses to supply a downstream rival with an input. Rather than refusing to supply a downstream rival, the merged firm can instead increase the price it charges the downstream rival. For example, UIE could charge or demand 10 percent more for its X-ray machines. This price increase may not prevent competing radiology practices from buying UIE machines, but the 10 percent increase in the practices' costs may lead those practices to negotiate higher reimbursement with insurers, or to engage in quality-reducing cost reductions, potentially leading some patients to choose DRP instead.[23]

As with foreclosure, disadvantaging downstream rivals by raising their costs increases the downstream division's profits. The size of this profit opportunity depends on answers to many of the same questions as in the foreclosure analysis. Can rival radiology practices buy from other

20 For example, if the rival has 1000 customers before foreclosure and the departure rate is 50 percent, foreclosure will cause the downstream rival to lose 500 customers.

21 Continuing the previous example, suppose the diversion from the foreclosed downstream rival to the merged firm is 50 percent. Then 250 of the 500 customers that depart the downstream rival will switch to the merged firm after foreclosure.

22 Some of these lost upstream sales might be offset by additional sales to the merged firm's downstream division, since the act of foreclosure increases the downstream division's demand and the downstream division may need to purchase more upstream supplies to meet this demand. However, these additional sales to the upstream division will not fully offset the upstream division's losses since if they did, the upstream division wouldn't have found it profitable to sell to the downstream rival prior to the transaction.

23 This could happen because health insurers could use financial incentives to steer their members to alternative radiology providers such as DRP or because patients dislike the lower quality.

equipment makers? To what extent will rival radiology practices absorb this increase in X-ray machine costs or pass it along to their patients? How many rival practices' patients will switch doctors in response to the increased costs? And of the patients who sought a new radiologist, how many will choose DRP? The answers to these questions, along with DRP's margins, will determine the downstream profit gain to DRP from increasing the prices of UIE's X-ray machines.

To assess this incentive to raise rivals' costs, economists use a different set of tools that rely on many of the same inputs as the foreclosure calculations. These tools are related to those that investigate foreclosure because, as discussed, the economics underlying a merged firm's incentives to foreclose rivals and to increase their costs are similar. Although related, these tools answer a different question: Instead of asking *whether* the merged firm has an incentive to foreclose its rivals, they yield measures of *how strong* the merged firm's incentives to raise its rivals' costs are.

There are two commonly used tools in assessing raising rivals' costs: the first is measure of upward pricing pressure resulting from vertical mergers and the second is a measure of how bargaining dynamics might change because of a vertical merger.[24]

1. Models of Upward Pricing Pressure

The first tool we discuss is the vGUPPI, which measures the extent to which a vertical merger removes competitive constraints on upstream and downstream prices.[25] Intuitively, the upstream division's incentives to raise downstream rivals' costs are strongest when doing so drives sales to the downstream division, and when these new sales are very profitable to the downstream division. If no input substitution is possible — that is, if the downstream rival has no choice but to accept the higher price from its upstream supplier — an increase in input price should cause downstream competitors to raise their own prices by some amount (depending on the pass-through rate) to consumers.[26] The increase in the price faced by consumers causes some of them to switch to the merged firm's downstream division, which increases that division's profits.

Continuing with our previous example, if physicians affiliated with rivals to DRP are not willing to switch to alternative imaging machines, these rivals have no choice but to continue to purchase UIE's machines at the higher prices. Among other things, UIE's incentive to increase the prices charged to DRP's downstream rivals will depend on downstream diversion ratios from the targeted rival to DRP and DRP's downstream margins.

If downstream competitors can substitute away from the upstream division's input, the upward pricing pressure from a vertical merger will be mitigated. The better the substitution possibilities available to downstream rivals, the smaller is the upstream division's incentives to raise rivals' costs. Suppose, for example, that GE Healthcare made an X-ray machine that was equivalent in price and capabilities to that made by UIE. Any attempt by UIE to raise prices to downstream firms would be pointless because those downstream firms could simply purchase their equipment from GE Healthcare. The vGUPPI framework readily incorporates this form of substitution.[27]

Absent input substitution or efficiencies such as the elimination of double marginalization and assuming that downstream rivals pass through some of their cost increases, the vGUPPI method always predicts that the merged firm will have some incentive to raise its upstream prices, although the strength of this incentive depends on the model inputs. This applies to the upward pricing pressure model used in horizontal mergers as well: absent efficiencies, that model always predicts that horizontal mergers will lead to higher prices.[28] This leads naturally to the question of what the safe-harbor level of the vGUPPI might be, which is not a question that the VMG address.[29]

24 The tools used to measure incentives to foreclose rivals and raise rivals' costs typically yield results that are consistent with each other. If, for example, the agencies perform the foreclosure calculations discussed above and find that the merged firm would have a strong incentive to stop supplying downstream rivals with an input, then these tools will likely predict the merged firm has a strong incentive to raise rivals' costs.

25 Serge Moresi & Steven C. Salop, *vGUPPI: Scoring Unilateral Pricing Incentives in Vertical Mergers*, 79 Antitrust L.J. 185 (2013), http://www.crai.com/sites/default/files/publications/vGUPPI-Scoring-Unilateral-Pricing-Incentives-in-Vertical-Mergers.pdf (last visited April 13, 2020). The authors derive several measures of the effects of a vertical merger on upstream and downstream prices. Below, we focus on what the authors call the "vGUPPIu," which is most closely related to the concept of raising rivals' costs. It measures the effect of the vertical merger on the prices the upstream division charges downstream rivals.

26 When no input substitution is possible, the vGUPPI becomes very similar to the GUPPI, which is a well-known upward pricing pressure formula described in the Horizontal Merger Guidelines that measures the incentives to raise price after a horizontal merger.

27 When input substitution is possible, the vGUPPI formula requires additional considerations. In addition to information on downstream rivals' margins and pass-through rates, the elasticity of the upstream division's sales to the downstream rival with respect to input price is also required.

28 There are several additional points to be considered when evaluating incentives to increase downstream prices. For example, we have not indicated whether the upstream division is targeting the downstream division's rivals simultaneously or individually. Both scenarios can be accommodated.

29 In some circumstances, the upstream firm will increase downstream rivals' price by approximately half the vGUPPI. For example, if the calculated vGUPPI is equal to 10 percent, the upstream firm will increase downstream rivals' prices by approximately 5 percent. We emphasize that this is the increase in the price of the input, not the price to consumers of the end product.

2. Models of Negotiated Prices

Underlying the vGUPPI model is an assumption that all firms (downstream and upstream) are price-setters and all customers (including downstream firms) are price-takers. For example, a grocery store sets the price of flour, bakers can buy as much flour as they want at the store's price, and consumers can buy as many cakes as they want at the price set by the baker. In contrast to this model of sequential price-setting and price-taking, in the healthcare industry prices are often negotiated between upstream and downstream parties. In these situations, we can adapt a well-known model that was used to evaluate competitive effects in the Comcast-NBC Universal merger (the "Rogerson" model, named after a former economist at the Federal Communications Commission).[30]

The intuition of this model starts with a simple bargaining framework: independent upstream and downstream firms bargain over price and split the gains from reaching an agreement equally between them.[31] For example, suppose that pre-merger DRP and UIE negotiate over the price of UIE's X-ray machine. If DRP and UIE agree that their collective profits will increase by $10,000 if DRP purchases imaging equipment from UIE, then the bargaining model predicts that DRP and UIE will agree on a price for imaging equipment such that their profits each increase by $5,000.[32]

The Rogerson model considers how this bargaining dynamic will change for a vertically integrated firm. This dynamic changes after the merger because the gains from trade to the upstream division change. For the vertically integrated firm, the sale of a UIE X-ray machine to a downstream competitor of DRP represents an additional opportunity cost that did not previously exist. Before the merger, UIE did not consider the detrimental effect that its sales to downstream rivals had on DRP. After the merger, UIE recognizes that selling its machines to DRP's competitors will decrease DRP's downstream profits. As such, the benefits to UIE from trading with DRP's rivals decrease after a merger with DRP and UIE will ask to be compensated for this when negotiating with downstream firms.[33]

The new opportunity cost that is borne by the vertically integrated firm can be calculated from the same factors (e.g. departure rates, diversion ratios, margins) we discussed previously. The bargaining model then translates this increase in costs into a change in the price of X-ray machines that UIE charges DRP's rivals. To calculate this opportunity cost, suppose UIE stops supplying a rival downstream radiology practice with X-ray machines as we assumed above in Section 1 when discussing foreclosure.[34] The downstream radiology practice will then have to acquire equipment from its second-choice supplier, which may lead some of its physicians or patients to leave (because of a reduction in perceived quality, for example, or because the second-choice X-ray machine is more expensive and causes the competitor to raise its prices).

The opportunity cost to the merged firm from these would-be DRP customers is just the product of the number of additional customers and the per-customer profit margin. For example, if DRP typically earns $100 in profit for each radiology patient it serves and DRP would serve 15 additional patients if UIE stopped supplying a competing radiology practice with X-ray machines, then the opportunity cost (in terms of foregone profit) to the merged firm from UIE supplying DRP's competitor is $1,500. The Rogerson model predicts UIE will increase the price it charges DRP's rival for imaging equipment so that UIE's profits increase by $750.[35]

The Rogerson model can be extended to take into consideration the effect of EDM, merger efficiencies, input substitution, and so on. Absent these considerations, the Rogerson model will always predict the merged firm has some incentive to demand higher prices from downstream rivals. As with the vGUPPI model, the VMG provide no safe-harbor level of price increase for the Rogerson vertical model. However, the

30 William P. Rogerson, *A Vertical Merger in the Video Programming and Distribution Industry: Comcast-NBCU*, *in* The Antitrust Revolution 534-575 (John E. Kwoka, Jr. & Lawrence J. White 6 ed. 2014); Jonathan B. Baker, *Comcast/NBCU: The FCC Provides a Roadmap for Vertical Merger Analysis*, 25 Antitrust 36 (2011), https://dx.doi.org/10.2139/ssrn.1755683 (last visited April 23, 2020).

31 A 50-50 split of gains from reaching an agreement is most commonly assumed in economic research, but it is straightforward to allow for alternative splits (e.g. 70-30 or 30-70) to account for differences in the bargaining skill of the parties.

32 A more common situation is to assume two individuals are negotiating over the price of an automobile that is worth $15,000 to the buyer and only $10,000 to the seller. The "gains from trade" in this setting are $5,000. Under Nash bargaining with a 50-50 split, the negotiated price will equal $12,500 so that both parties "split" the gains. At a price of $12,500 the buyer is made better off by $2,500 (he pays $12,500 for something worth $15,000 to him) and the seller is made better off by $2,500 (he receives $12,500 for something worth only $10,000 to him).

33 Returning to our previous example with the automobile, suppose the value of the automobile to the seller increases by $1,000 to $11,000. Since the "cost" to the seller has increased by $1,000, the bargaining model predicts that the negotiated price will increase by $500 from $12,500 to $13,000.

34 It may seem counterintuitive to consider the effects of foreclosure to evaluate UIE's incentive to raise DRP's rivals' costs. But recall that the Rogerson bargaining model assumes upstream and downstream firms split the gains from trade. To measure the gains from trade, we need to evaluate profits in the absence of trade or, in other words, after UIE forecloses DRP's downstream rival.

35 For example, if UIE sold DRP's rival two X-ray machines, then the bargaining model predicts a price increase of $375 per X-ray machine.

output of the Rogerson model is a predicted price increase for the input good (not the final good purchased by end consumers), so at least it is readily interpretable.

V. IMPLEMENTING VERTICAL MODELS

With these tools in hand, the question then turns to measuring the inputs that determine the magnitude of incentive to foreclose downstream rivals or raise their costs. The agencies may use a combination of the parties' ordinary-course data on revenues, expenses, and sales to estimate margins. But ordinary course data may be less informative about departure and diversion rates. For example, unless UIE has in the past terminated a contract with a downstream radiology practice, it may be hard to estimate departure rates. To overcome this lack of information, the agencies may rely on economic models that relate ordinary course data (e.g. market shares) to diversion ratios and departure rates.[36] We also note that all the tools discussed here can accommodate the complex differentiated nature of today's healthcare markets. For instance, these models can distinguish between segments of customers for which departure rates and diversion ratios may differ (e.g. consumers in poor health vs. consumers in good health). Or if UIE manufactures both MRI machines and PET scanners and the alternatives (i.e. departure rates) or margins for each type of equipment differ, it is not difficult to modify these models to account for these considerations.

VI. CONCLUSION

Recent investigations of vertical transactions in healthcare and the promulgation of the VMG suggest that these deals will continue to receive scrutiny from antitrust enforcers. While the VMG set forth the general framework that the agencies will use to assess vertical mergers, they are short on details and do not address the specific issues that may arise in healthcare transactions. In this article, we described the two primary types of unilateral harm in vertical mergers — foreclosure and raising rivals' costs — and economic models that can be used to quickly evaluate the level of antitrust risk associated with a vertical transaction.

36 For example, discrete choice models estimated from customer choice data can provide estimates of diversion ratios.

NON-COMPETE AGREEMENTS: MIGHT THEY BE PROCOMPETITIVE IN HEALTHCARE?

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I. INTRODUCTION

Non-compete agreements and restrictive covenants in employment contracts have received renewed attention from policy makers and antitrust practitioners, with many raising concerns that these agreements may restrict competition and labor-force mobility.[2] For example, federal antitrust agencies have sought comments on the topic,[3] state attorneys general have voiced concern over the use of these agreements,[4] and federal and state legislatures have contemplated or enacted new laws restricting the use of these agreements.[5] Healthcare is no exception in this trend, and there has been both ongoing and renewed attention and policy concerning non-compete agreements in healthcare settings.[6]

On their face, non-compete agreements appear to be plainly anticompetitive – the very name states "an agreement to *not* compete." And yet there is a long history of recognized *procompetitive* justifications for the use of non-compete agreements where these agreements are used to facilitate another legitimate purpose (i.e. the agreement is ancillary to another goal). The economic literature outlines the benefits of non-compete agreements, and contractual restraints generally, as a means of addressing the investment hold-up problem, which arises when an investment by one party is dependent on the cooperation of another party.[7] Non-compete agreements can thereby promote greater investment and output than would otherwise exist if such agreements were prohibited. Case law tracing back centuries to English common law also recognizes the benefits of non-compete agreements along the same lines.[8] At present, most U.S. courts have recognized numerous justifications for non-compete agreements, such as protection of trade secrets, protection of customer relationships, retention of unique employees, protection of firm-sponsored training, and protection of specialized capital investment by firms.[9]

2 We will focus this article on non-compete agreements but acknowledge that other policy literature often moves fluidly between non-compete agreements and other restrictive covenants (e.g. no-poach agreements) that also potentially restrict worker mobility. Moreover, we use the term "agreement" to refer to uses of non-compete covenants in contracts generally, whether as standalone agreements or as clauses within broader agreements.

3 U.S. Department of Justice, Antitrust Division, Public Workshop On Competition In Labor Markets (September 23, 2019) ("DOJ Workshop"), available at https://www.justice.gov/atr/public-workshop-competition-labor-markets; Federal Trade Commission, Non-Competes in the Workplace: Examining Antitrust and Consumer Protection Issues (Jan 9, 2020) ("FTC Workshop"), available at https://www.ftc.gov/news-events/events-calendar/non-competes-workplace-examining-antitrust-consumer-protection-issues.

4 Karl A. Racine, Attorney General for the District of Columbia, et al., Public Comments of 20 State Attorneys General in Response to the Federal Trade Commission's January 9, 2020 Workshop on Non-Compete Clauses in the Workplace (March 12, 2020), available at https://www.regulations.gov/contentStreamer?documentId=FTC-2019-0093-0322&attachmentNumber=2&contentType=pdf; Press Release, Washington State Office of the Attorney General, Attorney General Bob Ferguson Stops King County Coffee Shop's Practice Requiring Baristas To Sign Unfair Non-Compete Agreements (October 29, 2019), available at https://www.atg.wa.gov/news/news-releases/attorney-general-bob-ferguson-stops-king-county-coffee-shop-s-practice-requiring.

5 Noncompete Agreements and American Workers: Hearing Before the U.S. Senate Committee on Small Business and Entrepreneurship, 116 Cong. (November 14, 2019), available at https://www.sbc.senate.gov/public/index.cfm/2019/11/noncompete-agreements-and-american-workers; Wash. H.B. 1450 (2019), available at http://lawfilesext.leg.wa.gov/biennium/2019-20/Pdf/Bills/Session%20Laws/House/1450-S.SL.pdf.

6 Transcript from the FTC Workshop, *supra*, n. 3 ("FTC Transcript"), Starr, 163:8-13 (There are "several bans that occurred in the late seventies and eighties of non-competes for physicians. And so there's been a recent move by several states to ban non-competes for physicians, but it's actually an old policy that was adopted in the late seventies and eighties.");.Fla. Stat. tit. XXXIII, § 542.336 (2019), available at http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0500-0599/0542/Sections/0542.336.html; Mass. Gen Laws ch. 112, § 12X (2018), available at https://www.mass.gov/info-details/massachusetts-law-about-noncompetition-agreements.

7 See generally, books by Nobel laureates Oliver Williamson and Oliver Hart, both of whom earned recognition in a large part for their work concerning restraints and investment. Oliver Williamson, Markets and Hierarchies: Analysis and Antitrust Implications (1975); Oliver Hart, Firms Contracts and Financial Structure (1995). See also, e.g. Jean Tirole, The Theory of Industrial Organization (1989), 16 ("the possibility of 'hold-up' or 'opportunism' (the confiscation of the gains associated with one party's investment by the other party) … A long-term contract must *ex post* guarantee the parties a fair return in order to *ex ante* encourage specific investment."), 23-24 ("*Ex post* trade inefficiency gives the parties incentives to contract *ex ante* to avoid or limit this inefficiency. … Some constraints (if possible, simple ones) on the second-period decision process must be contracted for."), and 29 ("This *ex ante* specification of the terms of the contract may well prevent specific investments from being expropriated."); Jean Tirole, Incomplete Contracts: Where Do We Stand?, 67 Econometrica 741 (1999), 749 ("[T]he allocation of property rights determines the bargaining powers in the ex post determination of the terms of trade and that the holders of property rights are somewhat protected against the expropriation of their specific investment. Property rights thereby boost the holders' incentives to invest.").

8 *Mitchel v. Reynolds*, 24 E.R. 347 (1711); Mallan v. May, 11 M. & W. 652 (1843); *Nat'l Soc'y of Prof'l Engrs. v. United States*, 435 U.S. 679, 688-689 (1978) ("This principle is apparent in even the earliest of cases applying the Rule of Reason, *Mitchel v. Reynolds*, supra. *Mitchel* involved the enforceability of a promise by the seller of a bakery that he would not compete with the purchaser of his business. The covenant was for a limited time, and applied only to the area in which the bakery had operated. It was therefore upheld as reasonable, even though it deprived the public of the benefit of potential competition. The long-run benefit of enhancing the marketability of the business itself -- and thereby providing incentives to develop such an enterprise -- outweighed the temporary and limited loss of competition. The Rule of Reason suggested by *Mitchel v. Reynolds* has been regarded as a standard for testing the enforceability of covenants in restraint of trade which are ancillary to a legitimate transaction, such as an employment contract or the sale of a going business.").

9 Employee Non-competes: A State- by-State Survey, Beck Reed Riden LLP (January 13, 2019), available at https://www.faircompetitionlaw.com/wp-content/uploads/2019/10/Noncompetes-BRR-50-State-Survey-Chart-20191019.pdf.

In healthcare, policy and research criticizing non-compete agreements has mostly focused on (a) potential reductions in worker mobility[10] and (b) potential reductions in access to healthcare due to reduced entrepreneurship.[11] Many states have bans on the use of non-compete agreements specific to healthcare, particularly as it concerns physicians.[12] These views and policies, however, focus mainly on worker wages or frequency of employment changes and on incomplete measures of healthcare access (e.g. counts of establishments). They generally overlook the procompetitive justifications for non-compete agreements, thereby missing many of the *investments* made by firms as a result of these agreements that may actually increase access and improve quality in healthcare.[13] To this end, more recent empirical economic research on non-compete agreements – specifically in healthcare settings – has focused on quantifying the procompetitive investments facilitated by these agreements. This literature, although still fairly nascent, has found some evidence suggesting non-compete agreements facilitate greater investment by healthcare firms.[14]

In what follows, we discuss the possible investments encouraged by non-compete agreements in healthcare. First, we observe that healthcare settings are likely to exhibit large and frequent hold-up problems. Non-compete agreements are a tool to help alleviate these problems, encouraging investment by firms that would otherwise not occur. Thus, economic theory adapted to the idiosyncrasies of healthcare suggests that (a) non-compete agreements in healthcare can often be supported by positive investment-enhancing justifications and (b) we should continue to see growth in the empirical literature demonstrating this result. Second, we should be mindful of the effects on investment caused by policies to ban non-compete agreements. In particular, there are many settings in healthcare where there are severely underserved or completely unserved markets – policies that discourage investment may further exacerbate shortages in these areas. Thus, we caution against additional policies promoting restrictions on the use of non-compete agreements in healthcare without carefully weighing the potential procompetitive benefits, like investment, against any theoretical harm.

II. POSITIVE JUSTIFICATIONS FOR NON-COMPETE AGREEMENTS

A. Economic Theory and Case Law

Economists have long recognized the investment hold-up problem. This problem generally describes a situation in which a party to a future transaction must make a relationship-specific investment prior to the transaction. Absent an agreement to protect this investment, the party may refrain from making the investment out of fear that the counterparty will expropriate the value of the investment. If left unresolved, the hold-up problem can lead to lower-than-optimal investment and, therefore, generate welfare (and competition) inefficiencies.

In the context of labor markets, non-compete agreements are a common way to help facilitate and protect investments subject to the hold-up problem, and they can promote benefits like information sharing, on-the-job training, transfer of client relationships, and costly but complementary capital investment. For example, consider a well-reputed healthcare system that is contemplating investment in a new, expensive piece of medical equipment (e.g. an MRI machine, linear accelerator, or surgical robot). Due to the complexity of the equipment, a specialized

10 FTC Transcript, Lavetti, 138:18-139:3.

11 FTC Transcript, Starr, 163:25-164:3 (Empirical results "suggesting that the non-competes were, in fact, holding down medical – the number of medical establishments in the area, that banning them would increase access to care.").

12 *Supra*, n. 9 (17 states have some form of healthcare-specific restrictions on the use of non-compete agreements); *supra*, n. 6.

13 FTC Transcript, Lavetti, 139:8-19 ("I also want to think about -- talk a little bit about the context-specific welfare tradeoffs and the extent to which the welfare effects might be heterogenous across contexts. … we might want to distinguish between research-intensive firms, manufacturing firms, and service firms, and thinking about the reasons why firms might benefit from non-compete agreements and the justification for using them in different contexts."), 147:3-6 ("There's much more fluid referral of patients across doctors within groups that use [non-compete agreements]. And these gains don't seem to occur in states that have nonenforceable [non-compete agreements] laws."), 151:2-13 ("If you were to extrapolate that to estimate what the impact would be of a national ban on the enforceability of non-competes on just physician spending alone, it would be $25 billion per year. So potentially very large consequences for consumers in terms of prices. Now, a lot of this, I want to caution, comes from the fact that we see smaller establishments. Because establishment size is shrinking, small establishments tend to have higher overhead and, therefore, higher prices, and so this is really operating through an organizational channel.").

14 Kurt Lavetti, Carol Simon, and William D. White, The Impacts of Restricting Mobility of Skilled Service Workers: Evidence from Physicians, J. Human Res. (February 7, 2019), pre-print available at http://kurtlavetti.com/UlPNC_vf.pdf, p. 1 ("These effects are consistent with [non-compete agreements] enabling practices to allocate clients to new physicians through intra-firm patient referrals, reducing a form of investment holdup."); Jessica Jeffers, The Impact of Restricting Labor Mobility on Corporate Investment and Entrepreneurship (December 24, 2019), available at https://ssrn.com/abstract=3040393, p. 3 ("I then show that investment rates increase following more enforceable [non-compete agreements]. … I find that knowledge-intensive firms drive the increase in investment rate when [non-compete agreements] become more enforceable.");Naomi Hausman and Kurt Lavetti, Physician Practice Organization and Negotiated Prices: Evidence from State Law Changes (2018), available at http://kurtlavetti.com/NCA_price_vc.pdf, pp. 2-3 ("We provide a variety of evidence on the effects of NCA law changes on physician practice organization. Changes in NCA enforceability significantly affect the rate of physician establishment job separations and the creation of new establishments, which in turn affects the distribution of establishment sizes. … The negative net relationship between concentration and prices suggests there may be important efficiency gains from physical consolidation of practices.").

team (i.e. a physician of a specific specialty and supporting technicians) is needed to operate the equipment. Moreover, significant recruiting and training costs are also associated with matching this specialized physician and team to the specialized equipment (e.g. identifying the proper candidates, training to meet the firm's standards, etc.). These many investments are financed by the firm and are highly relationship-specific, and they hold little to no value absent continued tenure by the carefully matched team of specialists. Further, once the combined investment is made (i.e. "sunk"), the physician and staff can depart with much of the value, and the firm has little or no practical means of recoupment (e.g. the firm cannot reclaim the workers' post-tenure reputation or knowledge).

Unaddressed, this situation is a classic example of the hold-up problem, since the firm faces potentially significant losses if a specialist's tenure is cut short, and the whole team is virtually always able to leave at a moment's notice due to at-will employment. Non-compete agreements mitigate this hold-up problem by preventing the team from expropriating the value of firm's investments and using the investments to directly compete against their former firm. This, in turn, better ensures the investment remains solvent, and the firm might refuse to make the investment recognizing the likelihood of the hold-up equilibrium absent the non-compete agreement. Overall, relative to the world without the non-compete agreement, consumers have access to both more medical equipment and more healthcare services.

Case law recognizes many possible forms of relationship-specific investments that firms may make and that risk being undercut by hold-up without protection from non-compete agreements. These benefits include protection of trade secrets, customer relationships, unique employees, employee training, and capital investments.[15]

Protection of trade-secrets is often cited as a justification for enforcing non-compete agreements. *Gallagher Healthcare Ins. Serv. v. Vogelsang* is one such example of a court recognizing this justification.[16] Gallagher Healthcare Insurance Services ("GHIS") acquired a firm and the services of its employee, Vogelsang, whose responsibilities included building strong personal relationships with clients. Due to his job function, Vogelsang had access to confidential information, including client lists, business practices, and product pricing, all of which GHIS incurred substantial costs to gather and develop. A Texas appeals court found that the confidential information shared with Vogelsang was worthy of protection and that his non-compete agreement was enforceable.[17]

Customer relationships are another common justification for non-compete agreements. In *Healthcare Servs. of the Ozarks, Inc. v. Copeland*, non-compete agreements were enforced to protect a healthcare firm's customer relationships.[18] Two employees resigned their employment with a home health service firm in order to work for a direct competitor. The Supreme Court of Missouri found that the non-compete agreements the two signed were enforceable because the firm's patient base was a protectable interest "just as customers are protectable in a business context."[19]

"Unique" employees are yet another recognized justification for non-compete agreements in industries with highly specialized workers, such as healthcare, technology and entertainment industries.[20] In *Karpinski v. Ingrasci*, an oral surgeon, Karpinski, successfully grew his referral networks through legitimate efforts and decided to open a second office.[21] He hired the a second surgeon, Ingrasci, as an employee, who at the time just finished his oral surgery training. Karpinski paid for office rent and equipment and supported Ingrasci as the practice grew. After a few years, Ingrasci left to open his own practice, taking patients from Karpinski's practice with him, and forcing the eventual closure of Karpinski's practice. A New York appeals court concluded that the employer, Karpinski, had a "rightful interest" in the practice that he built over many years,

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15 *Supra*, n. 9.

16 *Gallagher Healthcare Ins. Serv. v. Vogelsang*, 312 S.W.3d 640 (Tex. App. 2009), available at http://www.search.txcourts.gov/SearchMedia.aspx?MediaVersionID=df-52cf11-5140-4af0-a7b8-adacc8f7bddc&coa=coa01&DT=Other&MediaID=42751d45-db7c-4486-9b16-7d71d431b9da.

17 *Id.*, 20-21 ("According to its summary judgment evidence, GHIS's confidential information (1) took years to acquire; (2) is only shared with employees and agents of GHIS on a 'need to know basis'; (3) is not 'readily ascertainable by its competitors'; and (4) gives GHIS 'a valuable competitive advantage in the insurance brokerage industry.'… We conclude that GHIS presented summary judgment evidence to show that its confidential information was an interest worthy of protection.") (Internal citations omitted).

18 *Healthcare Services v. Copeland*, 198 S.W.3d 604 (Mo. 2006), available at https://scholar.google.com/scholar_case?case=9744857035705482206&hl=en&as_sdt=2006.

19 *Id.*, 613. See also, Lavetti, Simon, and White, *supra*, n. 14 ("Firms that provide skilled services face unusual difficulty controlling their assets, the most valuable of which are often the relationships that exist between their workers and clients. … [I] n many cases such as medicine there may be legal restrictions to writing a contract that even implicitly assigns a price to patient referrals.").

20 *Reed, Roberts v. Strauman*, 40 N.Y.2d 303, 308 (1976) ("[I]njunctive relief may be available where an employee's services are unique or extraordinary and the covenant is reasonable. … This latter principle has been interpreted to reach agreements between members of the learned professions (e.g. Karpinski v Ingrasci, 28 N.Y.2d 45)."), available at https://scholar.google.com/scholar_case?case=6906663183339910981&q=Reed,+Roberts+v.+Strauman&hl=en&as_sdt=2006.

21 *Karpinski v. Ingrasci*, 28 N.Y.2d 45 (1971), available at https://scholar.google.com/scholar_case?case=7561492754060308676&q=Karpinski+v.+Ingrasci&hl=en&as_sdt=2006.

and the court enforced the non-compete agreement to protect against the loss of the practice.[22]

Employee on-the-job training is another justification frequently upheld by courts. In *Community Hosp. Group v. More*, the Supreme Court of New Jersey enforced a non-compete agreement to protect investment in costly training that an employee received on the job. The court found that the firm made a substantial investment in training its employee, Dr. More, and that training, generally, is a legitimate protectable business interest that justifies a non-compete agreement.[23]

Lastly, employers may make costly and specialized capital investments that are complementary to specific employees. In *Reddy v. Community Health Foundation of Man*, the Supreme Court of West Virginia found that a clinic's investment to provide equipment and supporting staff to its physicians – so that the physicians could engage in medical practice without undertaking a substantial financial risk from owning a practice – was a legitimate business interest to be protected by a non-compete agreement.[24]

As these examples illustrate, there are many settings and many courts in which the relationship-specific investment facilitated by non-compete agreements might outweigh the restrictions imposed by the same agreement.

B. Applied to Healthcare

As any experienced antitrust practitioner will readily admit, whether the benefits to investment from a non-compete agreement outweigh the costs rests on the facts of each individual case. And yet some generalization is nonetheless possible: many healthcare settings suffer from significant investment hold-up. In healthcare, we are likely to see investments that depend on *two or more* of the above justifications *at once*. As the following examples illustrate, healthcare is an industry characterized by its highly specialized and hard-to-replace workforce, frequent dependency on client relationships, and costly, upfront, specialized capital investments and training.

Consider the decision to open a new dialysis clinic and hire specialist physicians to oversee and work within the clinic. Opening a dialysis clinic requires enormous relationship-specific investment that is made up-front and is dependent on the ongoing tenure by the physicians hired to work within the clinic. To start, a new clinic requires specialized *capital investment*, such as hemodialysis machines, that have little use outside of their intended purpose. Then, specialized "*unique*" staff must be recruited, notably, at least one specialized physician to oversee the clinic. On top of that up-front investment, the clinic's success is dependent on the firm's investment in its reputation and operations (i.e. *trade secrets* that are responsible for the brand's recognized success), building provider-patient trust (i.e. *customer relationships* that the firm helps to grow but cannot "own" due to regulatory and moral constraints in healthcare), and extensive ongoing *training* of its physicians and other staff.

Not only does this example demonstrate *all* the above, recognized, legitimate justifications for the use of a non-compete agreement, but also the confluence of *all* those justifications at once demonstrates the significance of the hold-up problem. The firm stands to lose not one but a plethora of investments simply by the departure of one of its complementary inputs – its carefully recruited, matched, hard-to-find workers. Non-compete agreements are a means to protect against that possibility, incentivizing firms like these to further make investments.

Many other settings may not necessarily exhibit as many justifications for non-compete agreements at once. For example, manufacturing cars generally requires significant specialized capital investment and trade secrets in developing and streamlining the assembly line and operations, but it is not also simultaneously dependent on personalized customer relationships nor does it involve unique employees so intimately in its production process. As another example, car repair is dependent on reputation, customer relationships, and specialized know-how, but despite this, its workforce is not as unique nor does it require the same level of specialized capital investment. And the same can be said in other instances: e.g. retail services, such as restaurants and plumbers, are dependent on customer relationships and reputation but lack

22 *Id.*, 53 ("The hardship necessarily imposed on the defendant must be borne by him in view of the plaintiff's rightful interest in protecting the valuable practice of oral surgery which he built up over the course of many years… In sum, then, the plaintiff is entitled to an injunction barring the defendant from practicing oral surgery in the five specified counties and to damages actually suffered by him in the period during which the defendant conducted such a practice in Ithaca after leaving the plaintiff's employ.").

23 *Community Hosp. Group v. More*, 869 A.2d 884, 887 (2005) ("In this case, the evidence established that JFK made a substantial investment in Dr. More by giving him the opportunity to accumulate knowledge and hone his skills as a neurosurgeon. Indeed, Dr. More acknowledges that it 'takes years of education, practical experience and accumulated skills and knowledge, as well as an innate talent, for a doctor to reach [his] level of practice.' ") (Internal citations omitted), available at https://scholar.google.com/scholar_case?case=8303630126937898778&q=Community+Hospital.+Group+v.+More&hl=en&as_sdt=2006.

24 *Reddy v. Community Health Foundation of Man*, 298 S.E.2d 906, 919 (W. Va. 1982) ("In the case before us the employer urges that its provision of equipment and supporting staff to Dr. Reddy made it possible for the doctor to engage in a medical practice in Man and gain the good will of sufficient patients to allow him to undertake his own practice without substantial financial risk…[Physicians] enjoyed the benefits of building a practice in a risk-free environment where all costs of their acquiring patient good will are borne by others. The covenant is thus a response to the unjust enrichment of doctors that would be the result of the Foundation's labors if the clinic were left unprotected."), available at https://scholar.google.com/scholar_case?case=2321770070398239230&q=Reddy+v.+Community+Health+Foundation+of+Man&hl=en&as_sdt=2006.

capital intensity; or the telecom industry is capital intensive and specialized but is not dependent on personalized customer relationships. Most healthcare settings, particularly healthcare provider settings, are like the dialysis example above and exhibit a vast array of investments that each might justify a non-compete agreement.

Research undertaken by pharmaceutical and medical device firms, as another example in healthcare, also requires many simultaneous and large investments that can create a hold-up problem. For instance, developing a novel drug takes significant investment up-front, with the likely time to see pay off measured in years or decades. Like all research-driven industries, pharmaceutical firms face a hold-up problem concerning their intellectual property (i.e. *trade secrets*). In addition, highly specialized clinicians and a large amount of situation-specific capital investment – both products of the complex discipline and extensive regulatory hurdles – are needed to bring a product to market. Thus, pharmaceutical and other healthcare research firms face a significant hold-up problem, a general result of the winner-take-all nature of research, but also a result that is compounded by the specialization and regulatory burden that is particular to healthcare.

The above are but two examples of the holdup problem healthcare. Due to the specialized, capital-intensive nature of healthcare and the complementarity of healthcare capital and labor, hold-up is a significant problem in many healthcare settings. As a result, non-compete agreements are an important and commonly used tool to incentivize investment in healthcare.

III. SETTINGS WHERE GREATER INVESTMENT CAN PROMOTE WELFARE

To be clear, non-compete agreements present a trade-off, both in terms of competition over time, and ultimately, in terms of welfare. On the one hand, non-compete agreements incentivize and make possible up-front investments that would otherwise not occur. And yet, on the other hand, non-compete agreements do indeed have potential to restrict future competition by preventing workers from becoming future competitors to their former firm. In any specific case, key facts can be vetted and a rule of reason analysis can be used to determine, in the context of a particular non-compete agreement, whether the benefit of investment is greater than the cost of future restrictions on workers.

The above discussion of investment-promoting effects of non-compete agreements in healthcare is not a total welfare analysis. But the analysis need not be "total" in order to nonetheless present some important and tangible settings where non-compete agreements are likely to provide an overall positive effect. In healthcare, it seems there are enough settings with potential investment hold-up that policy makers and regulators might reconsider views that condemn all non-compete agreements without more closely looking at the effects to investment from such bans.

In particular, there is extensive literature highlighting underinvestment and shortages in healthcare in many areas, especially in rural communities and vulnerable populations. Bans to non-compete agreements risk discouraging investment and, therefore, risk further exacerbating supply shortages in these settings. Consider these examples to illustrate some settings with potentially significant underinvestment in healthcare:

- There are currently 1,388 geographic areas that face a shortage of primary care. Those areas account for roughly 80 million people in the United States.[25]

- A large number of rural communities do not have a local hospital and face significant travel distances to obtain hospital care.[26] This is an increasing problem as the United States has seen a wave of recent hospital closures.[27]

- There continue to be thousands of rare but untreated diseases, despite the success of pharmaceutical programs like the U.S. Orphan Drug Act.[28]

25 As of March 31, 2020, 1,388 counties or parts of counties were designated as a Primary Medical Health Professional Shortage Area. Bureau of Health Workforce, Health Resources and Services Administration, U.S. Department of Health & Human Services, Designated Health Professional Shortage Areas Statistics: Designated HPSA Quarterly Summary, as of September 30, 2019, available at https://data.hrsa.gov/topics/health-workforce/shortage-areas (accessed April 6, 2020).

26 Pew Research Center, How Far Americans Live From The Closest Hospital Differs By Community Type (December 12, 2018), available at https://www.pewresearch.org/fact-tank/2018/12/12/how-far-americans-live-from-the-closest-hospital-differs-by-community-type/.

27 United States Government Accountability Office, Rural Hospital Closures: Number and Characteristics of Affected Hospitals and Contributing Factors (August 2018), available at https://www.gao.gov/assets/700/694125.pdf.

28 Aarti Sharma, et al., Orphan Drug: Development Trends and sSrategies, 2 Journal of Pharmacy and Bioallied Sciences 290 (2010).

In these instances, competitive forces are struggling to supply even the requisite output to the market. There are, of course, many factors contributing to shortages in these settings, so it is not to say that promoting the use of non-compete agreements is the cure-all. But that does not diminish the corollary observation – more comprehensive bans to non-compete agreements may further reduce already low investment in these settings.

IV. CONCLUSION

The ability of non-compete agreements to incentivize investment suggests that we need a balanced approach that assesses the welfare implications to both workers and firms. Proponents of restrictions on non-compete agreements generally focus only on the potential limitation of worker mobility, and they typically fail to consider the beneficial effects to investment from these same agreements. This is especially true in healthcare, where labor specialization and specific, upfront, complementary capital investment are inherent. Furthermore, there are potentially many settings in healthcare in which underinvestment is an acute problem. Policy seeking to ban non-compete agreements should be mindful of exacerbating shortages in these settings. Developing empirical research appears consistent with these views that, in healthcare, there are net potential benefits from non-compete agreements through their ability to promote investment. Even without more research, however, there is a clear basis in healthcare to look at overall effects of non-compete agreements.

FIRST OF ALL, DO NO HARM: NEW DIRECTIONS IN EU ANTITRUST ENFORCEMENT REGARDING PHARMACEUTICALS

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I. INTRODUCTION

As parting shots across the waters to and from the UK, the recent *Paroxetine* and *CMA v. Pfizer/Flynn* cases respectively affirm the EU approach to pay-for-delay and establish a workable approach to excessive pharmaceutical pricing. We will first look at these two cases. Next, we briefly examine relevant peculiarities of pharmaceutical markets, and outline the history of EU antitrust enforcement in that sector. This sets the scene for identifying the new directions currently developing in EU antitrust enforcement with regard to pharmaceuticals. We conclude by exploring what this means for firms and antitrust authorities. In summary: first of all, do no harm.

II. THE WATERSHED

A. Pay for Delay

On January 30, 2020, judiciously timed one day before Brexit, the CJEU handed down its preliminary ruling on a referral by the UK's Competition Appeals Tribunal ("CAT") in the *Paroxetine* pay-for-delay Case.[2] In a Transatlantic echo of the U.S. Supreme Court *Actavis* Case (2013),[3] and following the line set out by its Advocate General Kokott, in *Paroxetine* the CJEU confirmed the approach taken by the European Commission to pay for delay. In essence, it found that substantial value transfers in the context of patent settlements from originators to generic producers that lack an objective justification form by object restrictions of competition between (at least potential) competitors. It is assumed such agreements intend to delay market entry and carve up the spoils at the expense of consumers. This position is in line with the EU's General Court rulings in *Lundbeck* (2016),[4] and *Servier* (2018),[5] and forms a strong indication of where the pending appeals to the CJEU in these cases are headed. In addition, the CJEU found in *Paroxetine* that it is possible for a strategy of exclusion-based pay for delay deals to qualify both as cartel infringements under Article 101 TFEU and as an abuse of dominant position under Article 102 TFEU. (In this context too however, there is room for a defense based on objective justification.)

In our view, the *Paroxetine* ruling conclusively establishes the bottom line regarding pay for delay cases throughout the EU. It that sense it forms the "end of an era" where some doubt remained in this regard. It simultaneously frees up capacity for the pursuit of new directions in antitrust enforcement regarding the pharmaceutical sector.[6]

B. Excessive Pricing

Excessive pricing, nonexistent as an abuse in U.S. competition law, has long been a contested theory in EU antitrust.[7] In the *AKKA/LAA* Case (2017) Advocate General Wahl even asked the question whether there is such a thing as an excessive price – although answering in the affirmative.[8] This view has meanwhile been confirmed by the highest relevant courts in the EU at national level regarding pharmaceuticals pricing in Italy, Denmark, and most recently (and in our view importantly) in the UK. On March 10, 2020 in its *CMA v. Pfizer/Flynn* judgment,[9] the Court of Appeals reversed, on the principles applied, a 2018 CAT judgment. The CAT had transposed the standard two steps for excessive pricing set out in the *United Brands* Case (1974)[10] – excessive returns in relation to costs and unfair prices – into an eight-pronged test, notably adding a

2 Case C-307/18 *Generics et al. v. CMA*, judgment of January 30, 2020, ECLI:EU:C:2020:52, para 140. Opinion AG Kokott January 22, 2020, Case C-307/18, ECLI:EU:C:2020:28. See [2018] CAT 4, *Generics (UK) Limited et al. v. CMA*, March 18, 2018.

3 *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013). See Athanasiadou, *Patent Settlements in the Pharmaceutical Industry under US Antitrust and EU Competition Law* (Kluwer Law International, 2018).

4 Case T-472/13 *Lundbeck v. Commission*, Judgment of September 8, 2016, ECLI:EU:T:2016:449. Barazza, "*Pay-for-delay agreements in the EU pharmaceutical industry: Patent law and competition law in the light of Lundbeck*," (2017) 1 *European Pharmaceutical Law Review* 3-21.

5 Case T-691/14 *Servier v. Commission*, Judgment of December 12, 2018, ECLI:EU:T:2018:922. See Buttigieg, "The Servier judgment - the GC's evolving case law on 'pay-for-delay' patent settlement agreements," *Journal of Antitrust Enforcement* 7 (2019) 279–289.

6 MLex March 5, 2020, "GSK's pay for delay judgment could mark 'end of an era' for antitrust enforcement, EU official says."

7 Abbott, "Excessive pharmaceutical prices and competition law: doctrinal development to protect public health" (2016) 6 *UC Irvine Law Review* 281-320.

8 Opinion of AG Wahl, April 6, 2017, ECLI:EU:C:2017:286 in Case C-177/16, *AKKA/LAA v.* Konkurences padome, Judgment of September 14, 2017, ECLI:EU:C:2017:689. See Wahl, "Exploitative high prices and European competition law – a personal reflection," in Konkurrensverket (Swedish competition authority), *The pros and cons of high prices* (Stockholm 2007) 47-66.

9 [2020] EWCA Civ 339, *CMA v. Pfizer/Flynn*, March 10, 2020.

10 Case 27/76, *United Brands Company and United Brands Continentaal BV v. Commission*, Judgment of February 14, 1978, ECLI:EU:C:1978:22, paras 248-253.

separate requirement of establishing economic value.[11]

In *CMA v. Pfizer/Flynn* the CAT was found to have misinterpreted EU law in doing so. It had been wrong to require more than a cost-plus calculation to determine whether the drug prices that dominant companies Pfizer and Flynn had increased virtually overnight by multiples between 7 and 27 were excessive. The Court of Appeals also found that the UK competition authority ("CMA") need not establish a hypothetical benchmark price or economic value *per se*, and enjoyed a degree of freedom in selecting its methodology and use of evidence to prove excessive pricing.[12]

Significantly, these findings by the Court of Appeals were in line with the rare *amicus curiae* intervention by the European Commission that occurred in this case, and can therefore be seen as the most up-to-date statement of EU law on the issue of pharmaceutical pricing – albeit for now at national level. It is also important to note that phenytoin sodium, the generic medicine involved, served a significant captive UK patient population as an epileptic cure, but was already in use for this purpose since before the Second World War. Hence, *CMA v. Pfizer/Flynn* sets a practicable standard for excessive pricing, yet in a factual context where innovation, intellectual property and regulatory exclusivity were absent. These aspects are relevant for the future directions we identify based on this approach.

III. THE CONTEXT: PHARMACEUTICALS MARKETS

Pharmaceutical markets account for 20 percent of health care spending in Europe.[13] The prices of pharmaceutical products vary widely, with cheap generic medicines on one end of the spectrum and expensive patented drugs of over €100.000 per patient per year on the other end. Patent protection and regulatory exclusivity strongly influence the intensity of competition and consequently the ability to charge high prices. Exclusivity rights combined with high ability and willingness to pay can lead to high prices in the context of private producers and public payers. After patent expiry, prices normally drop as a consequence of generic entry, because firms' strategies shift from product differentiation and marketing to price competition. Yet low prices may also be a concern where they lead to vulnerable supply chains and shortages, a risk that is evident during the current COVID-19 pandemic.

Exclusivity rights are meant to stimulate innovation. The EU pharmaceutical industry is innovation rich with 15 percent of sales invested in R&D versus 4 percent across all major industries.[14] Yet a notable development in this context is that the largest pharmaceutical companies ("big pharma") appear to be on a path to further specialization into all the regulatory elements of bringing a drug to market – clinical studies, market registration, reimbursement, sales and marketing –leaving R&D more and more to publicly funded institutions and small and mid-size biotech firms.

In view of the above, it is important to note that the EU competition and intellectual property rules apply in parallel.[15] This is firm case law since the landmark *Consten/Grundig* ruling of the CJEU in 1966,[16] as well as its early case law regarding pharmaceuticals.[17] Competition is key both to promoting innovation and controlling prices. The protection of intellectual property rights promotes *competition for new markets* (innovation) while also limiting the scope for *competition in existing markets* that could reduce prices. Holding a patent as such constitutes enjoying a temporary exclusivity, but does not by definition imply dominance in a particular relevant market (although it may sometimes lead to such dominance), let alone an antitrust abuse.[18] Yet restrictions of competition may be found illegal even in the presence of a patent, as we have seen

11 [2018] CAT 11, *Pfizer Inc. and Pfizer Limited v. Competition and Markets Authority*, June 7, 2018. Abbott, "The UK Competition Appeal Tribunal's misguided reprieve for Pfizer's excessive pricing abuse," *IIC - International Review of Intellectual Property and Competition Law* 49 (2018) 835-853.

12 Although the CMA's fines were not reinstated, such fines may now be re-imposed by the CMA in accordance with the Court of Appeal's ruling, notably after taking into account comparable products.

13 European Federation of Pharmaceutical Industries and Associations ("Efpia"), The Pharmaceutical Industry in Figures: Key Data 2019 https://www.efpia.eu/media/413006/the-pharmaceutical-industry-in-figures.pdf.

14 *Ibid.*

15 See Case T-472/13 *Lundbeck v. Commission*, Judgment of September 8, 2016, ECLI:EU:T:2016:449; Case C-170/13 *Huawei v. ZTE*, Judgment of July 16, 2015, ECLI:EU:C:2015:477; Case C-457 *AstraZeneca v. Commission*, Judgment of December 6, 2012, ECLI:EU:C:2012:770.

16 Joined cases 56 and 58-64 *Consten/Grundig v. Commission*, Judgment of the Court of July 13, 1966, ECLI:EU:C:1966:41, at p. 345.

17 Case 24/67 *Parke, Davis v. Probel, Reese, Beintema-Interpharm and Centrafarm* Judgment of February 29, 1968, EU:C:1968:11; Case 15/74 *Centrafarm v. Sterling Drug*, Judgment of October 31, 1974, EU:C:1974:114, paras 9, 39.

18 Fonteijn, Akker & Sauter, "Reconciling competition and IP law: the case of patented pharmaceuticals and dominance abuse," in: Muscolo and Tavassi (eds), *The interplay between competition law and intellectual property: An international perspective* (Kluwer Law International, Alphen a/d Rijn 2019) 411-425.

in the pay for delay cases.[19]

IV. PAST AND PRESENT EU ANTITRUST ENFORCEMENT REGARDING PHARMACEUTICALS

A. Exclusion

Regarding pharmaceuticals, as elsewhere, the two basic categories of EU antitrust enforcement (exclusion and exploitation) have been pursued sequentially. Initially, the focus was on protecting the process of competition. It has shifted only more recently to protecting consumers directly.[20] The exclusion dimension came out clearly in the first generation of cases under Articles 101 and 102 TFEU, where pharmaceuticals producers used various methods of blocking parallel trade.[21] This form of arbitrage exploits differential pricing related to the differences in purchasing and bargaining power between the EU Member States by directing medicines from "cheap" to "expensive" Member States. These practices are protected under the competition rules as a matter of principle due to the EU's focus on unhampered cross-border trade. However apart from a degree of price competition in "expensive" Member States the parallel trade of pharmaceuticals may also have deleterious health effects if it leads to shortages for essential medicines in the "cheap" Member States from which supplies are diverted.

The next generation of exclusion cases followed in the wake of the DG COMP Sector inquiry that took place in 2008-2009, and fueled a 10 year enforcement effort, broadly up to the Commission's Report on competition enforcement regarding pharmaceuticals in 2019.[22] The 2019 Report states that in the EU, over an eight year period, the 28 national competition authorities (NCAs) plus the Commission jointly pursued over 100 pharmaceuticals cases. Of these, 29 led to antitrust decisions, including five binding commitment decisions and 21 fining decisions for over one billion Euros in total.[23] Twenty cases were recorded as still ongoing.

Starting with its *Fentanyl* Decision,[24] the Commission itself notably launched a number of then groundbreaking pay for delay (also dubbed reverse payments) cases already cited above, where generic producers settled patent suits with originators, effectively staying out of the market in exchange for consideration. In our view the *Paroxetine* Case settles the Commission's approach as good law, marking the end of an era. In addition, during this period the Commission prosecuted exclusion in abuse of patent procedure in *Astra Zeneca*, that was confirmed by the CJEU (2010).[25] At the national level decentralized enforcement of the EU competition rules regarding exclusionary practices in the pharmaceutical sector took off,[26] branching out into novel abuses such as disinformation and disparagement regarding off-label use and generic products.[27]

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19 See also Directive 2004/48/EC of the European Parliament and of the Council of April 29, 2004 on the enforcement of intellectual property rights, DIRECTIVE 2004/48/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the enforcement of intellectual property rights (Text with EEA relevance) DIRECTIVE 2004/48/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the enforcement of intellectual property rights (Text with EEA relevance) OJ 2004, L157/45, recital 12: "This Directive should not affect the application of the rules of competition, and in particular Articles 81 and 82 [now 101 and 102] of the Treaty. The measures provided for in this Directive should not be used to restrict unduly competition in a manner contrary to the Treaty."

20 Hancher & Sauter, "A dose of competition: EU antitrust law in pharmaceuticals," *Journal of Antitrust Enforcement* 4 (2016) 381-410.

21 Art. 102 TFEU e.g. Joined Cases C-468/06 to C-478/06 *Sot. Lélos v. GlaxoSmithKline*, Judgment of September 16, 2008, EU:C:2008:504. Art. 101 TFEU e.g. Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKline Services Unlimited v. Commission*, Judgment of October 6, 2009, EU:C:2009:610.

22 The Commission's Final Report concerning the pharmaceutical sector inquiry of July 8, 2009 is to be found at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf. The follow up at EU and national (NCA) level is found in the Commission's Report on Competition enforcement in the pharmaceutical sector (2009-2017) of January 18, 2019, at http://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/report_en.pdf.

23 The Commission also examined over 80 pharmaceuticals mergers during this period and demanded remedies in 19 of them, notably regarding competition for generics in *Teva/Allergan* (Decision 7746 in 2016) and biosimilars in *Pfizer/Hospira* (Decision M.7558 in 2015).

24 Case AT.39685 – Fentanyl, Decision of the European Commission of December 10, 2013 based on Article 7 of Regulation 1/2003, https://ec.europa.eu/competition/antitrust/cases/dec_docs/39685/39685_1976_7.pdf.

25 Case T-321/05 *AstraZeneca AB and AstraZeneca plc v. Commission*, Judgment of 1 July 2010, ECLI:EU:T:2010:266.

26 See Thill-Tayara & Provost, "Dominance in the pharmaceutical sector: An overview of EU and national case law," *e-Competitions Pharma & Dominance*, Art. N° 88025 (*Concurrences*, November 21, 2019). https://www.concurrences.com/en/bulletin/special-issues/pharma-dominance-en/dominance-in-the-pharmaceutical-sector-an-overview-of-eu-and-national-case-law-en.

27 Notably in France, but also in Spain and Italy. At EU level see Case C-179/16 *F.Hoffmann-La Roche v. Autorià Garante della Concorrenza e del Mercato*, Judgment of January 23, 2018, EU:C:2018:25.

B. Exploitation

Toward the end of the abovementioned time-period, exploitation cases affecting consumers directly were taken up, initially by competition authorities at national level: in Italy (*Aspen*, 2016), the UK (*Pfizer/Flynn*, 2017), and Denmark (*CD Pharma*, 2018), based on applications of the *United Brands* test that have now all been confirmed at the highest judicial level in the respective jurisdictions.[28] The Commission itself has meanwhile opened a wide-ranging excessive pricing investigation covering now 26 Member States, following on the 2016 Italian Aspen case.[29] All these excessive pricing cases concerned extreme price increases for long established generic products with locked-in populations and no credible innovation context. The UK Court of Appeal's recent *CMA v. Pfizer/Flynn* ruling – with Commission *amicus curiae* advice – sets out a workable approach for the standard of proof in such cases. It may be based on a cost-plus analysis, provided defenses such as objective justifications raised by the undertakings involved are addressed in a credible manner. This leaves considerable discretion to the competition authorities. The next question is how to deal with cases regarding high prices for pharmaceuticals where intellectual property and regulatory exclusivity do play a role – which brings us to the new directions in this field.

V. NEW DIRECTIONS IN SUBSTANCE

A main strength of competition enforcement is its flexibility, as the relevant rules are simple and may be applied to all types of competition issues in very different settings. The challenge for NCAs and the European Commission alike is focusing their resources on those problems where competition enforcement can make a difference. Below, we highlight three substantive trends in this respect: (i) increasing scrutiny of biosimilar markets; (ii) excessive pricing as a permanent feature; and (iii) the increasing importance of digital services related to drug provision.

A. Increased Scrutiny for Biosimilar Markets

The first trend is in line with the traditional concern for speeding up (or combating delays in) the transition to generic markets. Although biological medicine is not novel from a medical perspective, antitrust's involvement with it is relatively recent. Several anti-inflammatory drugs with high levels of turnover, notably TNF-alpha inhibitors, have faced generic entry since 2015. The TNF-alfa inhibitor Remicade (with the active substance infliximab) faced antitrust scrutiny from the CMA for their volume-based rebate scheme. In its no grounds for action decision, the CMA pragmatically concluded that the rebate scheme had not worked as impact of clinical caution turned out to be less strong than had been envisioned by MSD. The Romanian competition council was the first to fine an originator producer for delaying entry of competitors, by strategically using the Romanian public procurement rules.

Crucial differences from a competition perspective between biosimilar competition and traditional generic competition are that for the former (i) entry is more expensive and riskier and (ii) the contestable share of the market is often smaller.

Regarding entry, biologicals are "alive," far more complex in structure, much larger in size and therefore less stable than synthetic drugs. The production process itself is demanding, generally takes more than six months, and fewer companies are able to develop and produce biosimilars than synthetic drugs. Crucially, unlike generics which can simply rely on the data of the original product, registering a biosimilar requires new clinical studies to prove equivalency. Hence, bringing a biosimilar to the market is more risky and costly than doing so for traditional generic drugs. To achieve and maintain a healthy market structure it is therefore important to maintaining the investment incentives for biosimilar producers. Especially for drugs aimed at smaller populations, it remains to be seen if the incentives to invest into biosimilars are sufficient.

The second crucial difference is the often smaller contestable share. Even though clinical caution for switching patients to biosimilars has decreased significantly,[30] hospitals are unable to switch all their patients for certain types of drugs – especially those administered subcutaneously. In some cases there are medical reasons for this, but caution on the side of patients themselves remains an important factor.[31] At the same time, clinical caution from doctors has far from disappeared and there is a general consensus that switching more than once every so many years is undesirable. Switching barriers in biosimilar markets affect the type and duration of anti-competitive behaviors. Using rebates on locked

28 Colangelo & Desogus, "Antitrust scrutiny of excessive prices in the pharmaceutical sector: A comparative study of the Italian and UK experiences," *World Competition* 41 (2018) 225–254.

29 *Antitrust: Commission opens formal investigation into Aspen Pharma's pricing practices for cancer medicines*. Commission press release IP/17/1323 (May 15, 2017).

30 The so called Norswitch study played an important role in decreasing clinical caution. Jørgensen et al., "Switching from originator infliximab to biosimilar CT-P13 compared with maintained treatment with originator infliximab (NOR-SWITCH): a 52-week, randomised, double-blind, non-inferiority trial," *The Lancet* 389 (2017) 2304-2316.

31 On the nocebo effect: Colloca et al., "The clinical implication of nocebo effects for biosimilar therapy," Frontiers in Pharmacology 10 (2019) 1-11 https://doi.org/10.3389/fphar.2019.01372.

in patients to strengthen the originator's position on the contestable markets share may be anticompetitive. As buyers are likely to choose for a product for two years or longer such rebates can have a long-lasting effect.

We expect NCA's and the European Commission to be vigilant on biosimilar markets as the traditional concern for the transition to generics is combined here with vulnerable incentives to develop biosimilars.

B. Excessive Pricing is Here to Stay

The direct concern with consumer exploitation through excessive pricing has developed from an antitrust rarity to an instrument that may well be applied regularly. The often-cited argument that regulation and buying power should be the preferred tools to correct very high prices and not competition policy is making way for a for more nuanced view. Although alternative solutions may exist in theory, action against excessive pricing does have a role in a world where regulation can never be perfect. Additionally, compensating buying power for monopolistic drugs is limited because denying patients an effective drug is close to impossible.

So far, the excessive pharmaceuticals pricing cases that have been successful all concern old drugs that regressed from once competitive markets or price regulated markets to free pricing in relatively small and non-competitive markets. The price increases involved generally followed a transfer of ownership or distribution rights – used in Pfizer-Flynn case to bypass price regulation. The transfer of such rights can also be part of a strategy to avoid reputational damage. Switching barriers, size of the market and acquisitions may all contribute to the monopoly position of the drug.

In the *Pfizer/Flynn* case, a loophole in the NHS' price regulation scheme facilitated the price hike. A new type of concern has arisen regarding the EU orphan drug regulation, which grants a ten-year exclusivity for rare diseases.[32] It is meant to stimulate the development of drugs for small patient populations. A clear shortcoming of this regulation is that it can be gamed, creating opportunities for charging high prices for long existing drugs even when used for well-established practices. The recent successful application of Gilead for orphan status in the U.S. (which provides similar protection) for a potential COVID-19 vaccine likewise suggests gaming of orphan drug regulations.[33]

In this context, the application of excessive pricing can be a further lock on the door, even if prevention would be preferable. An excessive pricing case would ideally serve the dual role of correcting an excess while pointing at ways to prevent similar future cases arising. Yet our view is that the excessive pricing cases are here to stay as prevention is not always feasible and new loopholes may always be found. Especially in a context of patents and regulatory exclusivity, this means incentives for innovation should be taken on board in an appropriate manner. A suitable topic for a separate paper, it appears likely that this would involve taking an investment perspective into account, including in a cost-plus context.[34]

C. "Beyond the Pill"

The third trend parallels issues that come up in the digital economy and that is the development towards pharmaceuticals not only providing drugs, but also related (digital) health services. Such services could consist of self-monitoring devices, tools to improve patient compliance, diagnostic devices, and platforms with information or help from specialists or nurses. Technology firms from outside the pharmaceutical industry are often involved jointly with a pharmaceutical company.

Those services – which are sometimes labelled as "beyond the pill" – have obvious advantages for patients and health care systems. At the same time, such services also have the potential to lock in patients and prescribers. Neither may elect to switch to a competing drug if that means losing certain services, having to get used to new apps or devices or losing personal data. Additionally, prescribers may not want to work with different platforms and different services for different patients. Lastly, control over data itself may lead to dominance that can then be transferred to drug provision.

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32 Regulation (EC) No 141/2000 of the European Parliament and of the Council of December 16, 1999 on orphan medicinal products, Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products OJ 2000, L18/1.

33 Public outrage made Gilead withdraw their application. The FDA takes the current number of patients into account for deciding on orphan status applications.

34 This could involve taking a life cycle approach, and integrating the probability of success when assessing investments in innovation, as well as comparing the internal rate of return ("IRR") and the weighted average cost of capital ("WACC").

For a future healthy competitive environment, it is essential that switching remains possible and that either a wide array of companies is able to offer integral packages of medicines and services, or that platforms provide access to competing drugs. Portability of data across platforms and interoperability between platforms are essential here.[35] Antitrust enforcement will likely focus on deliberate efforts to hinder switching.

VI. NEW DIRECTIONS IN ENFORCEMENT

Having explored topics for future antitrust enforcement regarding pharmaceuticals, in this final section we address the need for an ability to act quickly, the role of purchasers, and the relationship to regulation.

A. The Need for Speed

Swift action can be crucial for preserving competitive markets and incentives. Producers may be deterred from developing new biosimilars by successful strategies from originator companies to keep them out. Similarly, lack of access to the essential platforms or raw materials may already discourage competitors as early as the pipeline stages. The need for speed contrasts with the average duration of antitrust investigations. Therefore, we believe there may be a structural need for using interim measures and injunctions more frequently.

When the heat is turned up solids liquefy – see the Commission's April 2020 guidance regarding pharmaceutical cooperation in the context of the COVID-19 epidemic. It reached back to the future by producing within days its first comfort letter in the 17 years since antitrust modernization under Regulation 1/2003.[36] The current public health crisis may yet lead to new views on the need for planning and coordination between market parties in the healthcare sector. Conversely it may also lead to fresh perspectives both on what is required and feasible in terms of speeding up antitrust intervention.

B. An Active Role for Purchasers

Another way to speed up is in the hands of purchasers. This works in two ways. First and most obviously, with early warning signs from within the sector itself some competitive damage could be prevented rather than cured. Especially when it comes to bundling health care services and drug provision, early warnings may prevent the transfer of dominance from services to drugs or vice versa. Equally important however is the responsibility that purchasers have in avoiding or addressing problems in the market, such as by ensuring all competitors all have a fair chance in tender procedures, and taking the effects on market structure into account in their purchasing decisions.

Purchasers may also contribute to enforcement and deterrence. Follow-on actions, private damages suits predicated on antitrust infringements established in public enforcement proceedings, have already been pursued by public health authorities, for example in the UK.[37] Now the standards for the pursuit of pay for delay and standard excessive pricing cases have been established, public enforcement is more likely to be successful. At the same time private enforcement in the EU is coming into its own.[38] Consequently private health insurers and public health authorities are increasingly likely find their way to court to claim damages. This may change the calculus for anticompetitive behavior.

C. The Relationship with Regulation

Especially prior to the expiration of intellectual property rights and regulatory exclusivity, the relationship between antitrust and regulation is likely to remain complex. In our view, win or lose, competition authorities in the EU should at least attempt enforcement at all stages in order to develop the requisite experience and track record. Even if lost, a case may be useful to trigger regulatory action and/or reform.[39]

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35 Portability of data was also an important element in the merger decision of the EU in the joint venture between Sanofi and Google. Case M.7813 - *SANOFI / GOOGLE / DMI JV* 2016.

36 Communication from the Commission, Temporary Framework for assessing antitrust issues related to business cooperation in response to situations of urgency stemming from the current COVID-19 outbreak, April 8, 2020; and *Antitrust: Commission provides guidance on allowing limited cooperation among businesses, especially for critical hospital medicines during the coronavirus outbreak*, Commission press release, IP/20/618 (April 8, 2020).

37 Bourke, Chapter 16 "United Kingdom," in Kobel, Këllezi & Kilpatrick (eds), *Antitrust in pharmaceutical markets and geographical rules of origin* (Springer, 2017), at 310-311.

38 Rodgers, Sousa Ferro & Marcos, "A panacea for competition law damages actions in the EU? A comparative view of the implementation of the EU Antitrust Damages Directive in sixteen Member States," *Maastricht Journal of European and Comparative Law* 26 (2019) 480-504.

39 An example from telecommunications is the EU regulation of mobile call termination and roaming, which was based on market definition principles and the need for a remedy that were established in failed dominance abuse cases.

The need for such reform is already obvious. The EU orphan drug regime could make the criteria for admission – either prevalence or demonstrable lack of profitability – fully cumulative requirements instead of alternative options. If a would-be orphan product could potentially be profitable by itself, why provide 10 years of regulatory exclusivity? If not, then let's see the evidence. Likewise, introducing a common methodology for health technology assessment at EU level would enhance consistency and predictability for pharmaceutical producers and purchasers alike. This would be useful even if the relevant thresholds – what a society is willing to pay for an added quality adjusted life year – remain the province of national decision making.

Finally, antitrust and regulatory relief alike may come to rely more frequently on compulsory licensing under Article 31 TRIPS, including test data access.[40] This could liberate captive patient populations by adding a competitor to the market, and therefore allow pricing problems to be resolved by competition, not detailed price regulation.

VII. CONCLUSION

"First of all, do no harm": in the present context, this Hippocratic adage is a double-edged sword.[41] It applies to pharmaceutical firms and antitrust enforcement regarding such firms alike. For antitrust authorities this means foremost taking account of the balance between safeguarding innovation and access to affordable medicines while applying the antitrust rules in an equitable manner. This involves looking at both static and dynamic effects. For firms it means competing on merit – and to be seen doing so – not gaming the system to entrench their market power and maximize profits. In other words, for both sides the interests of patients and consumers must come first.

40 't Hoen et al., "Medicine procurement and the use of flexibilities in the agreement on trade-related aspects of intellectual property rights, 2001–2016," *Bulletin of the World Health Organization* 96 (2018) 185–193.

41 "ὠφελέειν ή μὴ βλάπτειν" in the Hippocratic treatise on Epidemics (Book I part 2, para 5); "In illnesses one should keep two things in mind, to be useful and at least cause no harm." Ratsis, "First do no harm: the impossible oath," *British Medical Journal* 179 (2019) 366; https://doi.org/10.1136/bmj.l4734.

RETHINKING PHARMACEUTICAL PRODUCT REFORMULATIONS

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1 Legal Counsel, Dr. iur. The opinions expressed in this article are those of the author alone and do not reflect the official positions of any of the corporations to which the author is or was affiliated.

I. INTRODUCTION

Product reformulations are not *per se* problematic from an antitrust perspective. Introducing a new reformulated version of a pre-existing drug is not in itself anticompetitive. Brand-name manufacturers may legitimately design their product life-cycle management strategies and have serious economic and strategic incentives for focusing on pharmaceutical products which have already been successful in the treatment of patients. Knowing how risky, costly, time-consuming and uncertain an endeavor pharmaceutical R&D is, it is not surprising that brand-name manufacturers invest resources in developing further versions of successful products and in expanding existing technology and know-how.

The main thesis of this piece is that in order to preserve innovation incentives for pharmaceutical companies, such product reformulations should be examined by antitrust enforcers irrespective of whether they are deemed – in their view – to be superior or "genuine" innovations which substantially improve pre-existing products. Rather, enforcers should focus on the company's overall conduct and strategy around such product reformulations. Some product reformulations may be highly problematic, as part of so-called "product-hopping" strategies, aiming to prevent the substitution of the new version of a brand-name drug with generics.[2] Such product-hopping occurs when a brand-name drug manufacturer seeks to switch the demand from a drug product A, whose patent protection is about to expire, to a drug product B, which is usually a modified version of drug product A, but enjoys a longer term of remaining patent protection, thus "killing" the demand for generic versions of product A.[3]

The main goal of anticompetitive product-hopping strategies is to block generic substitution and to prevent demand shifting from the brand-name pharmaceutical product – which is no longer patent protected – to its generic equivalents. The combination of product-hopping strategies with patent settlements or other types of agreements between originators and generic manufacturers have the potential to lead to the elimination of any meaningful competition even *post* generic entry.[4] Generic substitution is the substitution of brand-name pharmaceutical products by therapeutically equivalent and cheaper generic drug versions, which is designed to correct a type of agency problem: the market failure arising from the prescription drug system, namely the disconnect between the physician who chooses to prescribe a specific drug and patients and/or insurers who pay for it.[5]

II. HARD vs. SOFT PRODUCT SWITCHES AND GENERIC SUBSTITUTION

Product switching strategies are roughly divided in antitrust literature in two broader categories: "hard" product switches, where the brand-name manufacturer introduces pharmaceutical product B and in parallel withdraws product A from the market, and "soft" product switches where the brand-name manufacturer does not withdraw the product A but continues to market it, shifting however all of its promotion and marketing efforts to drug product B.[6] Courts have rightly followed a more lenient approach when analyzing soft product switches, finding that they do not necessarily amount to consumers' coercion but merely offer them a new product choice.[7] A soft switch comprised of launching a new product without withdrawing in parallel the product's previous version from the market - and absent a gaming of the regulatory system by the brand-manufacturer - represents substantially lower antitrust risks.[8] Nevertheless, the distinction between hard and soft product switches is not always clear-cut. For instance, a brand-name drug manufacturer may not withdraw product A from the market but may instead increase its price to prohibitive levels, practically removing it from the market by making it unaffordable;[9] such strategy would likely have the effect of a "hard" switch, even if formally

2 See Shadowen Steve D., Leffler Keith B., Lukens Joseph T., "Bringing Market Discipline to Pharmaceutical Product Reformulations," 42:6 IIC 698, (2011), pp. 698-704.

3 Ginsburg Douglas H., Wong-Ervin Koren W. & Wright Joshua D., "Product Hopping and the Limits of Antitrust: The Danger of Micromanaging Innovation," 12 CPI Antitrust Chronicle 1, (December 2015), p. 2; Cheng Jessie, "An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry," 108 Col. Law Rev. 1471, (October 2008), p. 1488.

4 See for instance Carrier Michael A., "A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product-Hopping," 62 Florida Law Review 1009, (2010), pp. 1033-1036.

5 FTC, *Amicus Brief, Mylan Pharms. v. Warner Chilcott*, 2015, pp. 25-26.

6 Shepherd Joanna, "Deterring Innovation: NY v. Actavis and the Duty to Subsidize Competitors' Market Entry," 17:2 Minnesota Journal of Law, Science and Technology 663, (2016), pp. 668-672.

7 *Walgreen Comp. et al. v. AstraZeneca Pharms. et al.*, 534 F. Supp. 2d.146, 148-152 (D.D.C. 2008).

8 Hovenkamp Herbert J., Janis Mark D., Lemley Mark A. & Leslie Christopher R., *IP And Antitrust: an Analysis of Antitrust Principles Applied to Intellectual Property Law*, Wolters Kluwer, 2nd ed. 2015, 15-78.3 – 15.80, arguing that in such cases if the generic has lost any market share this was most probably due to the desirability of the patent owner's new product.

9 Shepherd Joanna, "Deterring Innovation: NY v. Actavis and the Duty to Subsidize Competitors' Market Entry," 17:2 Minnesota Journal of Law, Science and Technology 663, (2016), pp. 668-672, noting that this tactic would be generally considered as a soft switch, but have the same effect as a hard switch.

categorized as a "soft" one. Reducing the price of the new drug product is another option which may lead to a successful product switch.[10] However, both of these strategies presuppose that the regulatory framework on prices would accord such broad freedoms to the brand-name drug manufacturers, without imposing limits or caps that could effectively prevent such abuses. The following sections briefly present three product reformulation strategies which nicely illustrate the complexities of their antitrust analysis.

A. Hard Product Switches and Coercion of Patients

In *New York v. Actavis PLC, Forest Labs LLC* (hereinafter the "*Namenda*" case), the brand-name drug manufacturers allegedly attempted to switch Alzheimer patients from Namenda IR – a drug which was reaching the end of its patent exclusivity in July 2015 – to the newer version of the drug Namenda XR before generic versions of the former entered the market.[11] This could have been a legitimate life-cycle management strategic decision; however, it was combined with the planned withdrawal of Namenda IR from the market,[12] in a hard product switch. The envisioned removal of the older version of the drug from the market prior to the release of generics, and the "forced switch" of patients were criticized for going far beyond mere attempts to minimize the impact of new competition and for having severe effects on consumer welfare in the form of fewer drug choices and diminished price competition.[13] The New York State filed a complaint alleging that the drug's withdrawal from the market would violate antitrust laws; the complaint led to a preliminary injunction barring the brand-name manufacturers from restricting patients' access to Namenda IR prior to the entry of generic IR versions.[14] As affirmed by the 2nd Circuit, the envisioned hard product switch would likely impede generic competition by precluding the generic substitution through State drug substitution laws.[15] Generic manufacturers were deprived of the most cost-efficient means of generic distribution: generic substitution.[16] This was not the first time a court found that preventing generic substitution through allegedly manipulative and unjustifiable formulation changes is a restriction on competition.[17]

B. Product-Hopping Combined with No-AG Commitments

Another interesting case is *FTC v. Endo*, in which no-authorized generic ("no-AG") commitments[18] and side-deals on development and co-promotion were combined with alleged product-hopping. On March 2016, the FTC sued Endo Pharmaceuticals Inc. and generic pharmaceutical companies for allegedly violating antitrust laws by concluding a set of reverse payment settlements concerning two of Endo's most important drugs: Opana ER and Lidoderm.[19] Facing the threat of generic entry when the end of the patent term was approaching, Endo had been working on a reformulated version of Opana ER (a crush resistant formula of the drug marketed as Opana ER CRF), allegedly aiming to prevent automatic generic substitution. The generic manufacturer Impax was the first generic challenger to file a paragraph IV Abbreviated New Drug Application

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10 Ho Cynthia M., "Should All Drugs Be Patentable? A Comparative Perspective," 17 Vand. J. Ent. & Tech. L. 295, Winter 2015, pp. 317-321.

11 *New York v. Actavis PLC, Forest Labs LLC*, 787 F.3d 638, 642-643, 647-648 (2nd Cir. 2015). Namenda IR and Namenda XR have the same therapeutic effect and the same active ingredient; the medical difference between the drugs is that Namenda IR is administered twice a day since it is released immediately in the bloodstream and Namenda XR is administered only once, since it is released gradually.

12 *New York v. Actavis PLC, Forest Labs LLC*, 787 F.3d 638, 654 (2nd Cir. 2015).

13 ASPE Issue Brief, Department of Health and Human Services, "Some Observations Related to the Generic Drug Market," (May 16, 2015), pp. 5-7. Available at https://aspe.hhs.gov/sites/default/files/pdf/139331/ib_GenericMarket.pdf. (last accessed on April 23, 2020).

14 See also *The People of New York v. Actavis PLC, Forest Labs LLC*, No. 14 Civ. 7473, (S.D.N.Y. 2014), at 104-109, discussing the anticompetitive conduct of the defendants; at 117-123, granting the preliminary injunction.

15 *New York v. Actavis PLC, Forest Labs LLC*, 787 F.3d 638, 654 (2nd Cir. 2015).

16 *New York v. Actavis PLC, Forest Labs LLC*, 787 F.3d 638, 655-656 (2nd Cir. 2015); *United States v. Microsoft Corp*. 253 F.3d 34, 63 (D.C. Circuit 2001), finding that barring competitors from the cost efficient means of distribution constitutes an antitrust violation; *United States v. Dentsply International, Inc.*, 399 F.3d 181, 191 (3rd Cir. 2005), ruling that the test for a Section 2 violation of the Sherman Act is not total foreclosure but whether a substantial amount of rivals is barred or the market's ambit is severely restricted. See however *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 13-MD-2445, (ED. Pa. 2016), at *20, arguing that the *Namenda* decision did not hold as a matter of law that automatic generic substitution is the only cost-efficient means of generic competition in every pharmaceutical antitrust case.

17 *Abbott Labs. v. Teva Pharms. USA Inc.*, 432 F. Supp. 2d. 408, 423 (D. Del. 2006).

18 A "No-AG commitment" is a promise not to launch an authorized generic drug, made by the brand-name manufacturer as part of a settlement with a generic competitor. For a detailed analysis of no-AG commitments and their antitrust implications see further Athanasiadou Amalia, "Patent Settlements in The Pharmaceutical Industry under US Antitrust and EU Competition Law," International Competition Law Series, Wolters Kluwer (2018). pp. 176-194.

19 FTC, Complaint, *FTC v. Endo Pharmaceuticals et al.*, 2016. See also FTC Press Release, *FTC Sues Endo Pharmaceuticals Inc. and Others*, 2016.

("ANDA")[20] for Opana ER on December 2007; as a result, Endo would not have sufficient time to obtain FDA approval for the reformulated Opana ER before Impax's generic entry. The brand-name manufacturer and the generic challenger subsequently concluded a settlement and license agreement and a co-development and co-promotion agreement. One month after this settlement with Impax, Endo filed a New Drug Application for the reformulated Opana ER CRF, with which generic drug versions of Opana ER were not automatically substitutable.[21] Within two years, and pursuant to Endo's marketing efforts, 90 percent of sales had moved to this new Opana ER CRF version.[22]

The FTC alleged that as part of this settlement, Endo committed not to launch an authorized generic version, granting Impax an absolute generic monopoly during the 180-day exclusivity period that the first generic challenger is accorded in the U.S. In order to ensure the generic manufacturer's supra-competitive profits promised by the settlement, Endo undertook to pay Impax if its reformulation strategy succeeded, and resulted in the devaluation of the no-AG commitment. The FTC alleged that this was indeed the case, leading Endo to make an additional payment of more than $102 million to Impax.[23] Second, Endo had agreed to pay Impax $40 million purportedly for an independent co-promotion and development deal concerning another drug, which the FTC claimed was a side-deal constituting a concealed reverse payment.[24] Endo agreed to settle the FTC charges,[25] but Impax is litigating with the FTC before the 5th Circuit at the moment of this writing.[26]

C. Servier's Hard Product Switch to Second Generation Perindopril

Controversial drug product reformulation strategies are not of course exclusive to the U.S.; however, there have not been many enforcement decisions of the European Commission examining them. An exception is the product reformulation strategy employed by Servier, scrutinised as part of the *Commission v. Servier* decision in 2014.[27] In an effort to extend the lifecycle of its blockbuster drug perindopril, Servier arguably developed and introduced a second generation product which had – according to the Commission's assessment – no superior medical effect, but served as its "principal weapon" against generic entry.[28] This reformulated version of perindopril was based on a replacement of salts in the second generation product, which generated new patent protection for Servier until 2023, and also involved a shift in the drugs' dosages.[29]

The Commission found that Servier's launch of this second generation product was linked to the regulatory framework on generic substitution: pharmacists could not substitute a drug with one salt for a drug with another salt in certain European Member States, nor could they substitute medicines with different dosages.[30] It was argued that Servier carefully planned the timing of the product switch from the first to the second generation of perindopril, with the parallel withdrawal of the first generation drug from the market. The main objective of Servier's product switch was allegedly to block generic substitution due to the different salt and the different dosages of its new drug product.[31] According to the Commission, it proved to be almost impossible for generics to enter markets where Servier had already successfully switched to the second generation drug before generic entry occurred, such as Belgium, Ireland, and Denmark.[32] In its *Servier* judgment, the General Court of the European

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20 The paragraph IV ANDA is a mechanism introduced by the Hatch-Waxman Act and now found in 21 U.S.C. § 355(j)(5)(B)(iv). Paragraph IV ANDAs aim to challenge and eliminate weak or invalid patents blocking the entry of lower cost generic drugs. Generic manufacturers wishing to enter the market before the expiration of the brand-name manufacturer's patents in the U.S may file a paragraph IV certification, arguing either patent invalidity or non-infringement of the brand-name drug by their generic drug.

21 *In re Opana ER Antitrust Litigation*, 162 F. Supp. 3d 704, 714 (N.D. Ill. Feb. 10, 2016).

22 *In re Opana ER Antitrust Litigation*, 162 F. Supp. 3d 704, 714 (N.D. Ill. Feb. 10, 2016).

23 FTC, Complaint, *FTC v. Endo Pharmaceuticals et al.*, 2016, pp. 17-20.

24 FTC, Complaint, *FTC v. Endo Pharmaceuticals et al.*, 2016, p. 3.

25 *FTC v. Allergan et al.*, Case No. 17-cv-00312 (N.D. Cal.), FTC File No. 1410004, Joint Motion for Entry of Stipulated Order for Permanent Injunction, January 23, 2017.

26 See further, *Impax Laboratories Inc. v. FTC,* (5th Cir.) FTC Brief, 19-60394, (date filed: 12.10.2019).

27 CASE AT.39612 – Perindopril (Servier), Commission Decision of 9 July 2014, relating to a proceeding under Article 101 and Article 102 of the Treaty on the Functioning of the European Union, C(2014) 4955 final, Brussels, 9.7.2014, [cited as: EU Commission Decision, Servier, 2014].

28 EU Commission Decision, *Servier*, 2014, paras 217-228. See especially *idem* paras 225-226, citing internal document of Servier and Teva, mentioning the replacement of the erbumine with the arginine salt lacked added therapeutic benefits but was likely to impede or block generic entry.

29 EU Commission Decision, *Servier*, 2014, para. 8. Due to the different molecular weight of the new salt, this second-generation drug was sold in different dosages. See also *idem*, paras 223-228, arguing that the second version of perindropil did not have superior medical effects when compared to the first version of the drug.

30 EU Commission Decision, *Servier*, 2014, paras 233-234, citing Servier's internal documents.

31 EU Commission Decision, *Servier*, 2014, para. 242.

32 EU Commission Decision, *Servier*, 2014, para. 240-241, mentioning the UK as an exception where generics entered the market after Servier's product switch.

Union did not address in detail the Commission's arguments regarding Servier's hard product switch;[33] it will be interesting to see whether the Court of Justice of the European Union proceeds in such an analysis when ruling on the pending appeals.[34]

III. ANALYSING PRODUCT SWITCHES FROM AN ANTITRUST PERSPECTIVE

A. The Timing of Drug Product Reformulation

The cases above make it evident that the *timing* of a product reformulation is a key element which raises controversy, since it may serve as one of the main criteria in determining whether such a reformulation is abusive from an antitrust perspective. A certain number of arguably problematic product reformulations may occur near the end of the drug's patent life and concern changes which may be seen as anticompetitive and principally designed to impair generic competition.[35]

In order to provide for legal certainty regarding the timing of product reformulations that could be unproblematic, two U.S. antitrust experts have proposed time-based safe harbors and antitrust immunity for reformulations occurring within a four-year window, starting eighteen months before the first generic ANDA is filed.[36] The rationale behind this proposal was that within eighteen months, a generic applicant should have sufficient time to reformulate its generic drug version and submit a new ANDA for the reformulated brand-name drug.[37] However, this position does not seem to take into consideration that reformulated brand-name drug versions are often protected by a number of new patents, covering for instance new ways of producing or administering a drug's active ingredients. Even though often mentioned in antitrust literature as "secondary," these patents may have strong exclusionary potential. Letting aside the scientific and regulatory difficulties of reformulating a generic pharmaceutical product in such a short time-frame, it is also unlikely that generic applicants would be successful in their attempts to reformulate their generic versions without infringing these secondary patents and facing patent infringement litigation. The second safe harbor proposed concerns product reformulations that occur after generic versions enter the market.[38] Even though this makes good sense regarding soft product switches, hard product switches *post* generic entry can also have a devastating impact on generic substitution rates if the reformulated version of the brand-name drug and the generic drug are not deemed therapeutically equivalent, so that granting them automatic antitrust immunity may not be ideal.

Even though it is of paramount importance, the timing of a product reformulation alone should not be the sole criterion of antitrust analysis. Providing for strict safe harbors regarding the timing of product reformulations could lead to abuses and further gaming of generic substitution schemes. The overall context in which the product switch occurs and its combination with parallel strategies or other side-deals is much more important, especially since the legal standard under which such strategies are to be evaluated is the rule of reason in the U.S.[39] and a case-by-case analysis of their object or effect in potentially preventing, restricting or distorting competition in the European Union.[40]

B. Overall Conduct and Combination with Other Strategies

Stating that the overall context of a product reformulation is the one that should be decisive in determining whether it constitutes an abuse or not, is of course easy to claim but very hard to implement. However, there are a number of indications that may make this assessment easier for antitrust authorities. For example, the combination of a product reformulation with the parallel revocation from the market of the older – yet

33 Judgment of the General Court of December 12, 2018, *Servier SAS and Others v. European Commission*, Case T-691/14, EU:T:2018:922.

34 See further Appeal brought on 22 February 2019 by the European Commission against the judgment of the General Court (Ninth Chamber, Extended Composition) delivered on December 12, 2018 in Case T-691/14, *Servier and Others v. Commission*, (C-176/19 P); Appeal brought on February 28, 2019 by Servier SAS, Servier Laboratories Ltd, Les Laboratoires Servier SA against the judgment of the General Court (Ninth Chamber, Extended Composition) delivered on December 12, 2018 in Case T-691/14, *Servier and Others v. Commission*, (Case C-201/19 P).

35 See indicatively, Ho Cynthia M., "Should All Drugs Be Patentable? A Comparative Perspective," 17 Vand. J. Ent. & Tech. L. 295, Winter 2015, pp. 317-321; Hughes D., & Ferner R., "New Drugs for Old: Disinvestment and NICE," 340 BMJ (formerly the British Medical Journal) 690, (March 27, 2010), p. 691; Shadowen Steve D., Leffler Keith B. & Lukens Joseph T., "Bringing Market Discipline to Pharmaceutical Product Reformulations," 42:6 IIC 698, (2011), pp. 701-704.

36 Carrier Michael A. & Shadowen Steve D., "Product Hopping: A New Framework," 92:1 Notre Dame Law Review 167 (2016), pp. 206-208.

37 *Ibid.* pp. 206-208.

38 *Ibid.* pp. 209-210.

39 *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2236-2237 (2013).

40 Article 101, TFEU.

commercially successful version – that happens to be near the end of its patent life is a clear red flag, especially if combined with a settlement with the potential generic entrant that has elements of a pay-for-delay deal. The dichotomization of product reformulations to "hard" and "soft" product switches where the former are almost *ipso facto* deemed to be anticompetitive and the latter tolerable, could however prove to be problematic. Therefore, antitrust analysis should look beyond these two labels, which should not be used without further consideration of the product reformulation at issue and the impact any such reformulation has on the competitive landscape – and most importantly on patient and physician choice, public health schemes and ultimately on consumer welfare.

IV. LIBERAL ECONOMIES AND INNOVATION INCENTIVES

A. Antitrust Liability for Product Portfolio Changes?

Even though this may often be ignored by antitrust enforcers, it remains true that monopolists and successful pharmaceutical companies have no general duty to facilitate their competitors' entry into the market,[41] or to continue selling a particular product.[42] As stated above, merely introducing a new product to the market – irrespective of whether this product is superior or not therapeutically – does not itself amount to exclusionary conduct. Additionally, withdrawing a drug product from the market should not be deemed anticompetitive *ipso facto*. Such a withdrawal could make economic or commercial sense (e.g. if a drug no longer has profitable sales or no longer fits into the portfolio of the brand-name manufacturer) and could be unproblematic from an antitrust perspective, if it is not combined with other types of anticompetitive strategies.

In free market and liberalized economies, there is merit to brand-name manufacturers' arguments that they should not be held liable for taking a commercial decision to stop the marketing or promotion of a drug product.[43] At the end of the day, pharmaceutical companies are private corporations that are operating for profit and their behavior in the market – as well as the life cycle management strategies they adopt – are mainly driven by the goal of maximizing their profit margins. Antitrust enforcement does of course play a central role in shaping these strategies, by creating sticks to deter anticompetitive behavior and the adoption of abusive monopolization strategies. It seems that the case law has successfully managed to create such a "stick" regarding hard product switches, which are rightly deemed anticompetitive if combined with wrongful conduct such as disparaging the previous version of the drug product, raising false safety concerns, coercing consumers, or reducing the market's ambit.[44]

B. Who Should Determine What Constitutes Genuine Innovation?

The FTC has argued that even though innovation concerns are important, they should not bar *ipso facto* antitrust liability, especially in the pharma industry where the potential for anticompetitive product redesign is high.[45] While there is merit to this view, it is important that courts, regulators and antitrust enforcers bear in mind that the preservation of incentives to innovate is crucial. Nonetheless, such a preservation of innovation incentives cannot be achieved by lawyers and economists that arbitrarily deem certain product reformulations as "superficial," "marginal" or "fake innovation." First, evidently, lawyers and economists do not have the necessary scientific expertise to evaluate the merits of such innovations from a medical and therapeutic perspective. Second, it has to be borne in mind that even innovations that may be deemed "incremental" have the potential to save human lives and be beneficial for patients – if not for all, at least for some.

The relationship between innovation incentives and antitrust enforcement is already quite a thorny one, where the right balance is difficult to strike. The differentiation of positions in the matter of product hopping has been quite stark. Some commentators argued that product-hopping should be *per se* lawful and be scrutinized under antitrust law in hard switches only when there is objective evidence of sham innovation

41 See for instance Cheng Jessie, "An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry," 108 Col. Law Rev. 1471, (October 2008), pp. 1500-1503, arguing that brand-name manufacturers are not under the duty to "serve as the sales force of generic manufacturers" and that antitrust law should not condemn product-hopping merely on this ground.

42 Hovenkamp Herbert J., Janis Mark D., Lemley Mark A. & Leslie Christopher R., *IP And Antitrust: an Analysis of Antitrust Principles Applied to Intellectual Property Law*, Wolters Kluwer, 2nd ed. 2015, p. 15-78.

43 *Ibid.* p. 15-78.

44 *In re Suboxone Antitrust Litigation*, 64 F. Supp. 3d. 665, 682 (E.D. Pa. 2014); *United States v. Grinnell Corp. et al.*, 86 S. Ct. 1698, 1704, (Jan. 13, 1966), condemning a behavior under Section 2 of the Sherman Act which was "plainly and explicitly" for the single purpose of willfully acquiring and maintaining monopoly power; *United States v. Microsoft Corp.* 253 F.3d 34, 65 (D.C. Circuit 2001), finding that "[j]udicial deference to product innovation, however, does not mean that a monopolist's product design decisions are per se lawful."

45 FTC, *Amicus Brief, Mylan Pharms. v. Warner Chilcott*, 2015, pp. 27-28.

leading to zero or negative consumer welfare effects.[46] This approach seems rather radical and would require antitrust enforcers to provide an assessment on the merits of a product reformulation and to determine with confidence the lack of any positive effects for patients – a burden that would likely be nearly impossible to carry. On the other extreme, economic models under which product reformulations overall should be prohibited were examined, albeit recognizing the detrimental effects such a ban could have had on *ex ante* innovation incentives.[47] Even though they are extreme opposites, both these approaches have a common – and highly problematic – element: they entail an often arbitrary determination of what constitutes a genuine innovation, which is rarely backed up by scientific, medical and therapeutic data. The burden of proof should be higher for enforcers and antitrust authorities to prove that the innovations at issue in a product reformulation are shams or unimportant. This assessment should be done by medical researchers, biologists, doctors and other healthcare professionals who are in a much better position to judge the importance (or lack thereof) of any scientific improvements.

V. CONCLUSION

Laws governing generic substitution generally prohibit the substitution of brand-name drugs by generic drugs which are not "therapeutically equivalent." Nevertheless, there is no single definition of "therapeutic equivalence."[48] It seems there is a great margin to improve the regulatory frameworks for generic substitution, which could have a much greater and holistic impact on generic penetration, than time-consuming, expensive and fragmented antitrust enforcement in a handful of cases. For instance, broadening or at least clarifying in a uniform way the concept of therapeutic equivalence, could potentially have a much more extensive and effective impact in facilitating generic substitution, without arguably having an adverse effect on the innovation incentives of pharmaceutical companies. Antitrust enforcement is of course a useful tool to remedy market failures, but it is no panacea; a robust regulatory framework that has the reflexes to quickly adapt to the ever-changing life-cycle strategies of the pharma industry is much more likely to prove successful against abusive product reformulations and effectively protect patients and healthcare schemes.

Attaining a balance between antitrust scrutiny of product reformulations while preserving essential innovation incentives is not an easy endeavor. Given the complexity and sophistication of drug product reformulation strategies and the difficulty of making a distinction between hard and soft product switches, a rule of reason analysis should take into consideration the factual specificities of each case. First, it is crucial to examine the *timing* of a product reformulation and its connection to an imminent threat of generic entry. Second, a parallel withdrawal of an older version of the relevant drug from the market could be a potential red flag, especially if this specific version of the relevant drug is expected to face imminent generic entry and there is evidence that the main reason behind such withdrawal is to prevent generic entry and substitution. A third important criterion would be the examination of the overall conduct of the brand-name drug manufacturer and the broad context of its strategies. This is of paramount importance because any parallel strategies aiming to abuse the regulatory framework or to illegitimately delay generic entry would shed a different light on an accompanying product reformulation.

On the flipside, courts and antitrust authorities should be cautious when examining and determining whether specific drug product reformulations are scientifically important, as part of their antitrust inquiry. Since neither courts nor enforcement authorities have the necessary scientific background to objectively determine whether a new drug product is innovative or not, they should generally refrain from setting the bar for what constitutes a "genuine innovation" or a "marginal improvement." Even incremental changes in a drug product have the potential to benefit patients and innovation incentives should not focus exclusively on quantitative criteria: a manifest example of this are the incentives that are provided for R&D targeting orphan diseases that only affect small parts of the population. When scrutinizing product reformulation strategies, extra caution should be exercised so as to ensure that the innovation incentives of originators are preserved also with regard to product reformulations, which should not be automatically considered to amount to lower quality innovation that does not benefit patients or scientific progress.

46 Ginsburg Douglas H., Wong-Ervin Koren W. & Wright Joshua D., "Product Hopping and the Limits of Antitrust: The Danger of Micromanaging Innovation," 12 CPI Antitrust Chronicle 1, (December 2015), pp. 693-707, criticizing the decision and arguing that product-hopping is "the predictable legal response to the incentives created by patent law and state substitution laws," while product shifting frustrates generic manufacturers because they can no longer rely on the marketing efforts of the brand-name drug manufacturers.

47 Lemus Jorge, Okzul Olgu, "Product Hopping and Innovation Incentives," paper presented in the 14th International Conference on Competition and Regulation of CRESSE (2019).

48 *New York v. Actavis PLC, Forest Labs LLC*, 787 F.3d 638, 644-646, (2nd Cir. 2015). See also Jesse Vivian C., "Generic Substitution Laws," U.S. Pharmacist (2008). Available at: http://www.uspharmacist.com/content/s/44/c/9787 (last accessed on April 23, 2020).

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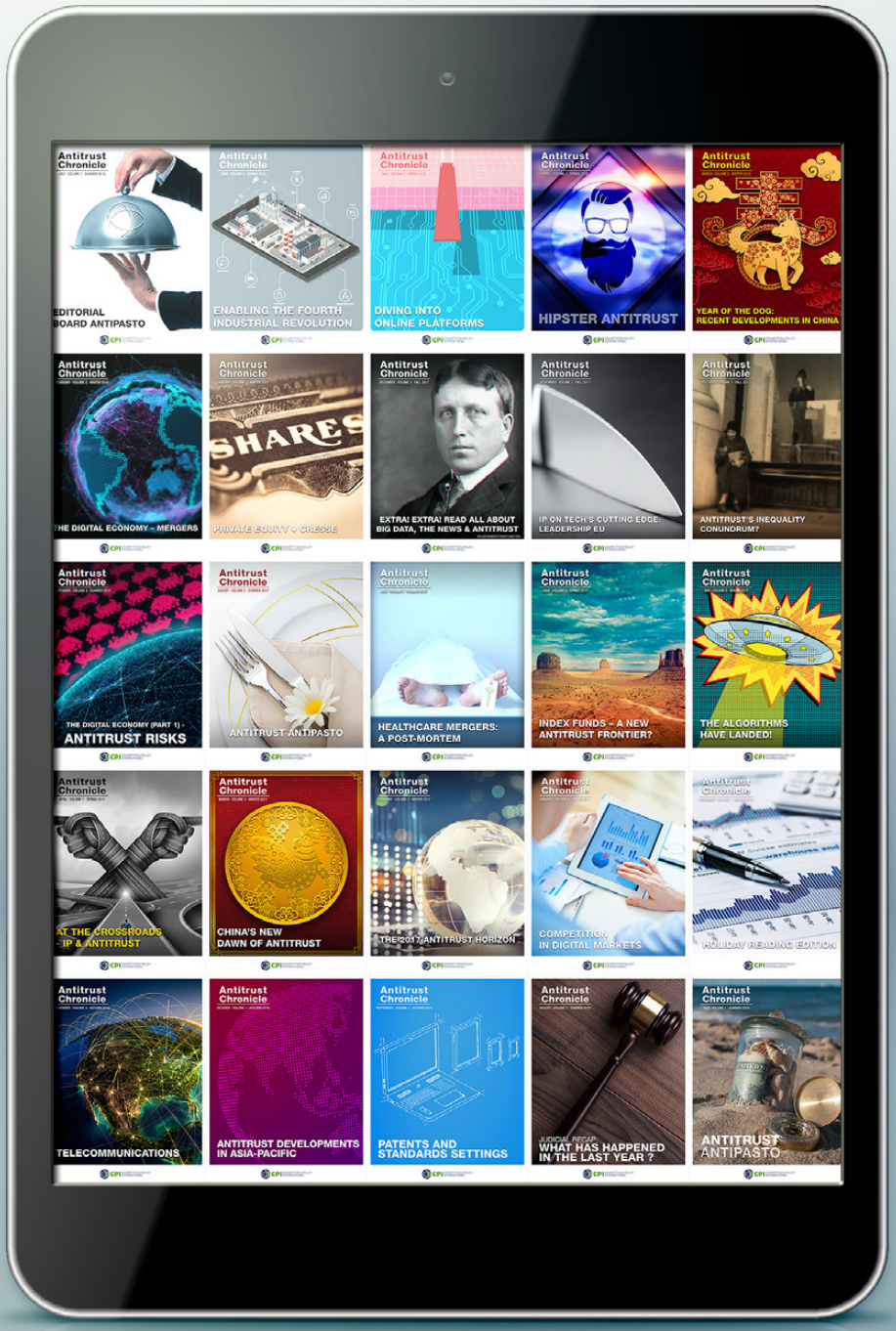


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