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600 Pennsylvania Avenue, NW)
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Comments of ITIF

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Pharmaceutical Consolidation & Competition: A Prescription for Innovation

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The Information Technology and Innovation Foundation (ITIF) appreciates this opportunity to comment on the Pharmaceutical Task Force. We first caution against hasty economic analysis about a complex industry. We then envisages the optimal course of actions for antitrust agencies to achieve their stated objectives: namely, limiting market power while incentivizing pharmaceutical innovation. There is no need to radically alter antitrust doctrines and law. However, there are some actionable steps relevant to attain the stated objectives of incentivizing pharmaceutical innovation while controlling drug price increases.

INTRODUCTION

In pharmaceutical markets, more than anywhere else, “innovation is the name of the game.”¹ Innovation rather than production drives the industry’s growth.² Pharma markets are the pinnacle of “innovation markets” as defined by Richard Gilbert and as enshrined in the 1995 I.P. Guidelines.³ Because innovation requires sufficient scale, firms have often gained that scale through mergers.⁴

The FTC’s strong enforcement record in pharma mergers suffers a paradox: While more than 50 consent decrees over the last 25 years required divestitures of products as a condition for merger approval, the political pressure for stricter antitrust enforcement continues ramping up.⁵ In the year 2020 for instance, notable pharma mergers included AstraZeneca acquiring Alexion for \$39 billion, Gilead acquiring Immunomedics for \$21 billion, BMS acquiring MyoKardia for \$13.1 billion, and Johnson & Johnson acquiring Momenta for \$6.5 billion. While popular perception of the pharmaceutical industry greatly improved with its effective response to the COVID-19 pandemic, these and other pharma mergers garnered political concerns.⁶

The political pressure increased partly in response to an academic paper, “Killer Acquisitions,” by Colleen Cunningham, Florian Ederer, and Song Ma.⁷ The idea behind killer acquisition theory is that an incumbent buys an innovative nascent company developing a competing product and discontinues the competing product. The acquisition pre-empts future competition. The incumbent killed the potential rival and thereby distorted competition and stifled innovation. The antitrust implications are straightforward: Killer acquisitions go unnoticed by antitrust authorities and require a change of law and new theories of harm. In

that regard, the present call for public input fits into the perceived need that the current antitrust framework cannot catch some detrimental mergers. Cunningham et al. assert that killer acquisitions represent only a small share of mergers: 5.3 to 7.4 percent of mergers.

But does the killer acquisition theory materialize in business reality? Do incumbents ever discontinue the acquired firm's products for anticompetitive reasons? At least one study finds a similar share as Cunningham et al. and suggests that approximately 95 percent of pharma mergers are not "killer acquisitions." And within the five percent that are allegedly problematic, any discontinuation of products requires balancing against counterfactuals absent the merger. Would discontinuation of the drug have occurred irrespective of the merger due to changing market circumstances or due to different corporate strategies? The authors of the killer acquisition theory assume that these five allegedly problematic percent are all anticompetitive acquisitions. In fact, this number could very well be less.⁸ Madl qualifies the very notion of killer acquisition stating that:

The mechanism of action used in the Cunningham, Ederer, and Ma study to identify cases of overlap is not mutation-specific, meaning that two drugs targeting the same enzyme and having the same net effect (e.g., inhibition) may not treat the same patients. Accordingly, purchasing the second drug could expand the acquirer's market, rather than cannibalize sales.⁹

In other words, Cunningham et al. overlook the possible positive effects on competition and innovation of these acquisitions. The notion of killer acquisitions overly emphasizes Kenneth Arrow's concept replacement effect of innovation and overlooks the Schumpeterian aspect of innovation. In other words, the tenets of the notion of killer acquisitions rest upon the assumption that a dominant firm would acquire a rival to avoid the rival's product "cannibalizing" the dominant firm's profits. However, the acquiring firm may seek to create complementarities, thereby opening new markets. Schumpeter indeed wrote that entering new markets (through organic growth or mergers) "incessantly revolutionizes the economic structure from within, incessantly destroying the old one, incessantly creating a new one. This process of Creative Destruction is the essential fact about capitalism."¹⁰

Moreover, killer acquisitions suggest that the phenomenon of buying up nascent competitors is new and has not been addressed by antitrust agencies. The recent Illumina-Grail debacle proves the contrary: the desired acquisition of Grail by Illumina following its spinoff four years ago would generate considerable innovation and progress in the field of multi-cancer early detection tests. The merger aims at providing Grail with the regulatory and organizational capabilities necessary to commercialize its breakthrough inventions given Grail's near zero revenue. Grail is a nascent company, but not a nascent competitor to Illumina as the theory of killer acquisitions would have it. Yet, because the competitive effects of such acquisitions arguably are positive, the FTC asked a federal judge to dismiss the lawsuit, because of the high probability the federal judge would approve this beneficial merger. Beyond the antitrust agency's regrettable "gamesmanship," one cannot reasonably conclude that the FTC is unable to block acquisitions of nascent companies.¹¹ Current antitrust rules fully equip the FTC with such capability, although this ability may result in applying a misguided theory of killer acquisition to a pro-competitive enabler-acquisition.

More generally, antitrust enforcers and commentators have historically considered the acquisition of potential competitors. Indeed, in their study of pharma mergers, Balto and Mongoven consider that "an acquired firm's disappearance can have a negative impact on competition, regardless of whether or not it was producing in

the market. Potential competitors also wield market power.”¹² Antitrust agencies have traditionally considered potential competitors—referred to as “nascent competitors” in the killer acquisition’s rhetoric—as part of the merger review. For instance, in *Zeneca* where Zeneca could acquire Astra, the consent order required Zeneca to transfer and surrender all of its rights and assets relating to levobupivacaine to the firm Chiroscience within 10 business days.¹³ Zeneca was not an actual competitor to the long-acting local anesthetics, but it was a potential competitor by virtue of its agreement with Chiroscience. The FTC thus required a spinoff to address the competition concerns raised by such potential competition.

Another case is *Hoechst*. The German pharmaceutical company acquired MMD in 1995, thereby creating the third-largest pharmaceutical company.¹⁴ Dominant in four product markets (i.e., hypertension, angina, arteriosclerosis, and tuberculosis), the merged entity needed to divest either the current line of business or the potential new product to a buyer who could market the drugs. More specifically, Hoechst owned the patent for the only drug that at the time was approved by FDA for intermittent claudication, but MMD had one of the few drugs in development that could compete with Hoechst’s drug. The consent order protected potential competition by requiring Hoechst to divest its drug for intermittent claudication. The settlement also required Hoechst to maintain its research and development (R&D) efforts.

Against that backdrop, should the FTC introduce novel theories of harm for reviewing pharma mergers specifically? There is no need to introduce novel theories of harm, especially if the concern is allegedly excessive drug prices. Concerning higher drug prices, antitrust authorities have seminally stated that increases in drug prices are not illegal under U.S. antitrust laws. Indeed, as recently as 2018, the FTC and the DOJ wrote for the Organisation for Economic Co-Operation and Development that “excessive pricing in pharmaceuticals by itself is not an antitrust violation under U.S. antitrust law, although soaring prices may be indicative of anticompetitive conduct.”¹⁵

Although excessive prices may support the finding of anticompetitive conduct, increasing prices per se may actually reflect innovation in the sense of the ability to develop a unique patented drug before any other competitors. U.S. antitrust agencies identify drug shortages, regulatory factors, and unilateral conducts other than antitrust violations as potential explanations for increased drug prices absent anticompetitive conduct.¹⁶ Moreover, there is strong scholarly research showing that increased drug company revenues spur more funding on research and development.¹⁷

Novel theories of harm appear to constitute a way for the FTC to block mergers otherwise lawful under current antitrust laws because they are pro-competitive and pro-innovative (as illustrated in the recent case of *Illumina-Grail*). Indeed, under current laws, anticompetitive mergers can not only be investigated but most importantly blocked whenever they are anticompetitive. In other words, it appears regrettable that the FTC wants to break its adequate compass for the sake of reaching the detrimental ends it seeks to achieve. Namely, blocking lawful and pro-competitive acquisitions in the pharma industry. To paraphrase the Supreme Court, the FTC’s desire to alter its merger review (and only regarding pharmaceutical companies) is a regrettable attempt to make the government “always wins” in challenging mergers.¹⁸ Such inconsistent policy is both detrimental—for consumer benefits and innovation purposes—and regrettable—for representing a discriminatory stance against pharma mergers without legal consistency.

Novel theories of harm can be appealing and coherent only if the diagnosis of pharma markets underpinning those proposals is correct. Unfortunately, such diagnosis is not. We demonstrate how a misguided diagnosis may lead to costly novel theories of harm.

THE DIAGNOSIS

We need to get the diagnosis right before inferring a change of antitrust laws or enforcement. The diagnosis appears erroneous on two aspects. Economic analysis does not account for the economic assumptions made, and the alleged inability of the law to investigate specific mergers appears to be an unfounded premise.

Pharmaceutical Innovation and Consolidation

Mergers and Innovation

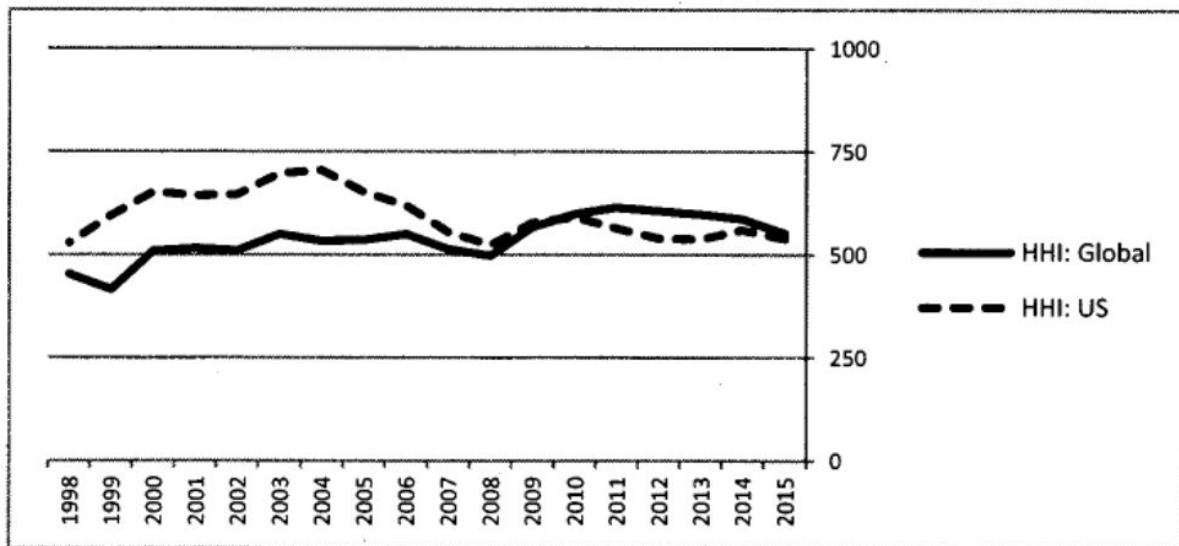
Allegedly, drug prices are too high. The view is nothing new. Drug prices “shocked” President Clinton in the early 1990s.¹⁹ A commentator notes:

In recent years, worldwide mergers have achieved record highs, and antitrust enforcement authorities are facing new challenges involving high-technology industries. Much consolidation activity has taken place in the research-based prescription drug industry...” (references omitted)

Although this situation might be thought to portray today’s situation, it was actually published 20 years ago in the *Journal of Legal Medicine*.²⁰ Citing the 1998-2000 “megamergers” between Astra and Zeneca, Hoechst and Rhone-Poulenc, SmithKline Beecham and Glaxo Wellcome, and Pfizer and Warner Lambert, the author aptly emphasizes that “the significance of innovation as a source of competition in the pharmaceutical sector suggests that merger analysis in that sector should focus not only on existing product market but also on competition over research and development.”²¹ Pharma mergers regularly sweep through the U.S. economy.²² And antitrust authorities have traditionally scrutinized pharma mergers with great vigor.²³ Nevertheless, fears of uncontrolled pharma mergers have historically emerged on an occasional basis.²⁴

Contrary to conventional wisdom, the U.S. pharmaceutical industry may deconcentrate, and historically remains as concentrated as its global rivals.

Figure 1: Concentration levels in the pharmaceutical industry.²⁵



Richman et al. demonstrate that the concentration level (i.e., the HHI index) of the U.S. pharmaceutical industry follows similar concentration patterns to those of its international counterparts. The large-scale mergers of the 1990s and early 2000s were justified by required integration at multiple levels.²⁶ Nowadays, similar justifications lead to similar outcomes. Indeed, what was true 20 years ago remains true today.²⁷ Atkinson and Ezell recently demonstrated that the 10 leading drug producers in 2019 accounted for 43 percent of global industry sales—a sharp decline from the 56 percent they accounted for in 2006.²⁸

The concerns that pharma mergers will lead to fewer drug discoveries or higher drug prices are largely unsubstantiated.²⁹ Recent empirical evidence demonstrates that “the predominant concerns over megamergers among pharmaceutical giants might be misplaced. Changes in scientific landscape of competitive innovation generated a vibrant marketplace for discovery, which megamergers do not necessarily threaten and instead might actually invigorate.”³⁰

Pharmaceutical companies compete via innovation. Rather than competing over prices in a neck-and-neck competition, pharmaceutical companies innovate to have a viable competitive edge vis-à-vis rivals.³¹ Pharma markets inherently exhibit dynamic competition given the high reliance of drug companies on patents. A temporary “monopoly” right over a new drug constitutes the main driver for R&D expenditures. In fact, the U.S. biopharma industry is the most R&D-intensive in the world.

And these sunk costs are high and increasing in part because the failure rate is high. For every 10,000 pharmaceuticals patented, about 100 may go through human trials, and less than 10 may ultimately be marketed.³² Drug development now often takes an average time of 12-14 years to bring an innovative new drug to market. These rising costs and uncertainties associated with drug innovation lead pharmaceutical companies to diversify their drug portfolios. Consequently, such diversification requires different lines of products with different patents. Mergers and acquisitions can provide a viable path toward such diversification—a crucial element for drug innovation.³³

Because of the massive R&D investments required for pharmaceutical companies to compete in the marketplace effectively, size is critical, or as Omta states: “size can be considered to be by far the most important contingency concerning performance.”³⁴ Mergers may be explained by the desire to submit more patents since “the larger firms clearly submit more patent per invested dollar than the smaller ones. This could be a clear indication of their higher innovative effectiveness. Another explanation could be that larger companies submit their patents relatively earlier than smaller ones.”³⁵

Therefore, pharma mergers can yield considerable cost efficiencies and innovation potential. But they can also lead to inferior performance. In general, “mergers reveal a pessimistic [picture]: widespread failure, considerable mediocrity, and occasional success.”³⁶ While emphasizing that correlation does not equal causality, Ornaghi found that pharma mergers between 1988 and 2004 have not necessarily increased the companies’ performance.³⁷ One possible explanation is that pharma consolidation occurs among firms with similar technology: Companies merge as a defensive move in anticipation of negative shocks or increased market competition.

The more innovative the purchased company is, the more the merger may raise more innovation concerns. Indeed, “the effects on innovation of a merger or acquisition depend on the relative capabilities of the merging partners.”³⁸ However, the removal of an innovation laggard should not generate antitrust concerns.³⁹

Without the organizational capabilities with the minimum efficient scale, the innovative firm will not reap the full benefits of the patent and consumers may not enjoy such benefits.

Indeed, Chandler wrote that, as an historical pattern, “the critical entrepreneurial act was not the invention—or even the initial commercialization—of a new or greatly improved product or process. Instead, it was the construction of a plant of the optimal size required to exploit the economies of scale or those of scope, or both fully.”⁴⁰ Larger pharmaceutical companies tend to introduce innovative drugs compared to smaller ones.⁴¹ However, this does not imply that smaller firms may not be optimally investing in a particular niche within the pharmaceutical industry.⁴²

The need to innovate and improve the quality of drugs in the face of the harsh price competition exerted by generic manufacturers also justifies pharma mergers. Generic competition brings new competitors in the pharmaceutical industry. Aggressive price competition exerted by generics challenges the traditional pharmaceutical companies’ market positions.⁴³ As a defensive move, mergers proved to be necessary to reduce costs and cope with an incredibly fierce price competition. Hence, generic competition can also justify mergers since strong price competition and high production costs justify reorganizing a consolidated entity to enhance scale and scope economies.

Generic competition spurs pharma mergers to generate cost efficiencies. For instance, Pfizer’s acquisition of Hospira was driven by the company “facing serious revenue and profit declines in the next four years as a result of generic competition and that Hospira revenues plus project \$800 million in cost savings will make the business much more attractive.”⁴⁴ The FTC should be strong advocates for mergers that generate cost savings, since this by definition, increases U.S. GDP and competitiveness.

Thanks to the Hatch-Waxman Act of 1984 (also known as the “Drug Price Competition and Patent Term Restoration Act”), a torrent of generic drug approvals followed: this Act radically simplified the procedures for approving generic substitutes for drugs without patent protection.

Before the Hatch-Waxman Act, generics represented only 19 percent of prescriptions filled in the United States. After the Act, nearly 90 percent of drug applications filled were generics.⁴⁵ Before the Act’s passing, only 35 percent of top-selling pharmaceuticals had generic competitors after their patents expired. More than 80 percent of approved pharmaceuticals have generic versions available on the market. With the Act, generics no longer wait three to five years. They enter the market immediately. Consequently, today’s drug price competition is fiercer than ever. Some legislative proposals may seek to spur generic competition, as illustrated by the three bills on the topic:

1. The Hatch-Waxman Integrity Act of 2019: This Act would support brand-name manufacturers by preventing new drug or biosimilar applicants from challenging a drug patent using the Patent Trial and Appeal Board, which has a lower standard of review and more relaxed procedural rules than traditional federal court proceedings;
2. The Blocking Act: This act would increase the number of generics on the market by preventing a generic drug manufacturer with the first approved generic from delaying the start of their 180-day exclusivity period;
3. The Creates Act: This act would allow a biosimilar or generic manufacturer to sue a brand-name drug company that refuses to make samples of a product available for testing.⁴⁶

To be sure, generic competition plays a role in reducing drug prices for consumers. But we cannot assume that generic competition, with the new entrants and strong competitive constraints it generates, may not lead to further consolidation by acquisitions.

Regardless, Hatch-Waxman does more to ensure low drug prices than antitrust lawsuits.⁴⁷ Indeed, the FTC regularly enforces antitrust laws under the Hatch-Waxman Act and advocates for courts not to renege on doing so. The recent FTC Amicus Brief illustrates this in the *Takeda Pharmaceutical Co. v Zydus Pharmaceuticals (USA)* case. The FTC legitimately urged the federal district court not to exempt lawsuits under the Act to be subject to antitrust scrutiny as potential sham litigations.⁴⁸ Not only should the Hatch-Waxman Act be appropriately enforced, but antitrust laws enforced alongside the Act should be too.

Mergers and Vertical Competition

Historically, vertical “integration of production and distribution led to the formation of research and development units for each of the new product lines.”⁴⁹ Vertical integration may take place with chemical companies—the pharmaceutical suppliers of raw materials. Indeed, pharmaceutical companies depend on chemical companies.

The first modern pharmaceutical companies were European because they reached a sufficient size. Chandler writes:

“Even as Standard Oil was investing in its large refineries to exploit the economies of scale, the German dye makers were making still larger investments to permit them to exploit the economies of scope fully. The enlarged plants produced hundreds of dyes and many pharmaceuticals from the same raw materials and the same set of intermediate chemical compounds literally. The first three enterprises to make such investments to exploit cost advantage of scale and then those of scope—Bayer, Hoechst, and BASF—were able to reduce the[ir] price....”⁵⁰

Historically, pharmaceutical innovation took place through established companies capable of developing complex lines of diversified products. Pharmaceuticals companies could frequently diversify through mergers.⁵¹ Pharmaceutical consolidations through mergers enable the merged entities to have a steady throughput in production facilities and to benefit from more intensive use of the joint facilities and skills.⁵²

Today, the need to reach sufficient size remains acute in the global competition amongst pharmaceutical chemical makers—i.e., Contract Development Manufacturing Organizations (CDMOs).⁵³ Indeed, pharmaceutical companies increasingly seek to vertically integrate their services to best control the production line—from inventing with raw materials up to marketable drugs. Against this background, vertical mergers by pharmaceutical companies with CDMOs may result from three market rationales.

First, consolidation among CDMOs increases their bargaining power at the expense of their direct purchasers—namely, pharmaceutical companies. CDMOs increasingly appear to compete with pharmaceutical companies. Indeed, Albert Baehny, the CEO of Lonza, the market leader among CDMOs, recently recognized that the “only gap” in their portfolio is the “fill-and-finish area, where the active ingredients are mixed with other solutions to produce the finished drug and filled under sterile conditions.”⁵⁴ He added “although we offer this on a small scale, large batches are still outside our area of expertise. This is a capability we would like to have.” Asked how he thinks his company could develop such capability, Baehny categorically replied that it “can only be done through acquisitions.” The external growth of CDMOs that

compete with pharmaceutical companies puts considerable pressure on the market positions of pharmaceutical companies. These companies must in turn react to CDMOs' mergers and market entry.

Second, a vertical integration counter-balances chemicals' consolidation to recalibrate bargaining positions. Vertical integration between pharmaceutical companies and CDMOs may benefit consumers by avoiding the so-called "double marginalization problem." By minimizing transaction costs, consumers may benefit from the avoidance of the double marginalization problem. One illustration is Pfizer's recent acquisition of Hospira: While the pharmaceutical industry's reaction to the announcement was minimal, this acquisition shook the CDMO industry.⁵⁵

Finally, and most strategically, a rationale for vertical mergers between CDMOs and pharmaceutical manufacturers reverts to the urgent need to better integrate the supply chain. With the COVID-19 pandemic, supply bottlenecks for active ingredients from China prevented Western companies from having optimal supplies.⁵⁶ As a central part of the pharmaceutical industry, regulators need to allow pharmaceutical companies to achieve functioning supply chains for the benefit of citizens.

In conclusion, there are mixed effects of mergers and acquisitions in the pharmaceutical industry on innovation and efficiency. Contrary to conventional wisdom that may equate pharma mergers with anticompetitive conduct/intent, these mixed effects are obvious, as recapped by Ornaghi who analyzed pharma mergers between 1988 and 2004.

Effects of M&As on	R&D inputs	R&D output	R&D performance
Elimination of common R&D (avoid duplication of fixed costs)	-		+
Economies of scope and knowledge synergies	+	+	+
Internalization of spillovers and technology market power	+	+	+
Human capital dissipation and cultural dissonances	-	-	-
Total effect	?	?	?

Figure 2: Overall effects of pharmaceutical mergers on R&D⁵⁷

Therefore, the economics of pharma mergers reveals complex implications in terms of innovation incentives, efficiencies, and competition. Indeed, "it's hard (and somewhat futile) to say whether existing tools are fit to meet a problem without knowing whether that problem exists."⁵⁸

Consequently, the implications for antitrust enforcement and reforms suggest an inevitable complementarity between an optimal antitrust enforcement policy and other regulation areas. In so doing, the stated objectives of lowering drug prices and increasing pharmaceutical innovation may be reached by maximizing consumer benefits without deterring pharmaceutical innovation.

THE CURE

Should The Law Be Changed?

Current merger review enables antitrust authorities to challenge any merger according to policy preferences. Proposed open-textured theories of harm would conflict with case law, increase legal uncertainty, and stifle innovation due to the regulatory ambiguity of the proposal.

Antitrust approach to pharma mergers may embrace so-called “new theories of competitive harm.” As expressed in the FTC’s press release, “new or expanded theories of harm” may seem attractive to the FTC. These new and shallow theories of harm may however increase legal uncertainty, disincentivizing innovation due to non-administrable merger review in the industry. For the less than five percent of allegedly killer acquisitions, new theories of harm would ultimately harm consumers for missed reductions of drug prices with an across-the-board presumption of illegality of mergers. Antitrust laws and doctrines should not be changed. Killer acquisitions are challengeable under current antitrust laws with a straightforward generalization of the rule of reason.⁵⁹

Because the pharmaceutical industry is about human health, antitrust agencies need to carefully scrutinize the rate of innovation pre- and post-merger. Indeed, the health care industry calls for “special attention” because “diminished [health care] innovation” raises a “central antitrust question.”⁶⁰

Section 7 of the Clayton Act only condemns those mergers which “may be substantially to lessen competition.” The Clayton Act requires the merging firms to notify the FTC whenever the total assets or annual sales of the acquiring company amount to \$100 million or more, or the acquired company has assets or annual sales of \$10 million or more. Initially, Section 7 of the Clayton Act banned only mergers effected through stock transfers, and later courts further limited the ban’s scope. However, because of the government’s loss in *United States v. Columbia Steel Co* and the 1948 FTC Report, since 1950 all types of acquisitions fall within the ambit of Section 7 of the Clayton Act, provided the transaction meets the thresholds.⁶¹

To successfully challenge a merger under Section 7, an antitrust agency must show that the acquired firm “probably would have entered” the market “within a reasonable period of time” absent the merger.⁶² In addition, the Hart-Scott-Rodino Act requires merging parties above a specific size to provide advanced notice to the Antitrust Division of the DOJ and the FTC before merging. Typically, the FTC does not review sub-\$200 million acquisitions—thereby paving the way for the killer acquisition theory to unfold.

Yet, the prospects of killer acquisitions seem relatively small: The incumbent’s desire to shut down a potential rival will arguably be the very rationale for current merger law to block a merger rather than for that merger to go unnoticed. Therefore, the prospect of challenge may be real—albeit not “easy.”⁶³ However, can we reasonably expect antitrust agencies to easily block mergers involving nascent companies which have a very limited chance of competing with the acquirer? Such prospect of easy merger opposition should instead lead to caution.

Current antitrust laws enable antitrust authorities to challenge and block mergers because that level of innovation post-merger would decline. Section 7 of the Clayton Act is flexible enough to challenge most pharma mergers as illustrated by the recent Illumina-Grail merger controversy. The only requirement is that agencies need to demonstrate that the merger may create a risk of higher prices.⁶⁴

Vigorous antitrust enforcement against pharma mergers takes place regularly. Divestitures have historically been central to a vigorous pharma merger review. For instance, the FTC required that Wellcome divest Zoming to Zeneca for Wellcome to merge with Glaxo.⁶⁵ Subsequently, both Glaxo and Zeneca continued to fiercely compete against one another, thereby illustrating the ability of the law to ensure both consolidations for innovation purposes with effective competition. Additionally, further mergers involving Glaxo also included divestitures.⁶⁶ Divestitures are standard practices and do not suggest an under-enforcement of merger law by the antitrust agencies.

Indeed, the FTC has recently found, on a unanimous basis, that a consummated merger of microprocessor prosthetic knee company was anticompetitive.⁶⁷ The FTC investigated in September 2017 Otto Bock's acquisition of FIH Group Holdings (Freedom) after the merger was consummated. Otto Bock, the leading supplier of microprocessor prosthetic knees, could not acquire Freedom because the combined firm would hold more than 80 percent of the relevant market. In December 2020, the FTC approved divestitures.⁶⁸

Another recent case illustrating vigorous antitrust enforcement on pharma mergers is provided with the *BMS/Celgene* merger.⁶⁹ The FTC required divestiture by BMS of Celgene's Otezla. Commentators have considered that the divestiture of BMS's Phase 3 oral product to treat psoriasis demonstrates vigorous antitrust enforcement with firm spinoff commitments. This divestiture accounted for \$13.4 billion, the largest divestiture ever required in a merger case.

Thus, how can we explain the current fear and claims that some detrimental pharmaceutical mergers are unscrutinized by antitrust authorities? Since Gilbert and Sunshine's article in 1995, antitrust analysis has increasingly considered the nonprice aspects of competition in merger review.⁷⁰ The argument that some mergers go unnoticed is hardly demonstrated. Parties notify mergers, and if antitrust agencies do not challenge them, it is undoubtedly because the procompetitive effects of the proposed merger outweigh its possible anticompetitive effects. Merger approvals cannot be proxies for the claims that mergers go unnoticed.

Again, current antitrust laws fully provide for adequate antitrust scrutiny among vertical and conglomerate mergers without resorting to dubious theories of harm. The Vertical Merger Guidelines (VMGs), released on June 30, 2020, have recently updated the approach on this area.⁷¹ This "long-needed revision" came to clarify how the Clayton Act applies to vertical mergers in light of the challenges brought about by today's economy.⁷² The VMGs "are intended to assist the business community and antitrust practitioners by increasing the transparency of the analytical process underlying the Agencies' enforcement decisions."⁷³ To envisage changing the approach for vertical mergers less than a year after these new guidelines were adopted would frustrate the VMGs' stated objectives of increased transparency and assistance to the business community. The VMGs provide for a coherent, administrable approach.⁷⁴

Hovenkamp considers that the "2020 Vertical Merger Guidelines are not perfect, but they are a significant step in the right direction." Indeed, by considering the upstream market and the downstream market of the vertical relationship as the "relevant market," the VMGs appraise the merging parties' bargaining power. The VMGs also address conglomerate mergers (i.e., complement and diagonal mergers) while remaining consistent with the traditional theory of consumer harm.

Vertical mergers can be anticompetitive according to either unilateral effects—namely foreclosure and raising rivals' costs—or coordinated effects—namely, post-merger collusion.⁷⁵ Also, the 2020 VMGs represent a moderate and sound approach to vertical and conglomerate mergers in general. This should apply without

special treatment to pharma mergers. Indeed, the other theories of harm mentioned in the FTC's press release—namely the theory of competitive harm applied to conglomerate mergers—would treat legitimate cost efficiencies (such as elimination of the double-marginalization problem) as presumptively unlawful. Therefore, there is no need to change the merger law for an ill-defined economic problem. Nevertheless, it does not prevent actionable steps from being adopted to incentivize pharmaceutical innovation while enhancing consumer benefits with lower drug prices.

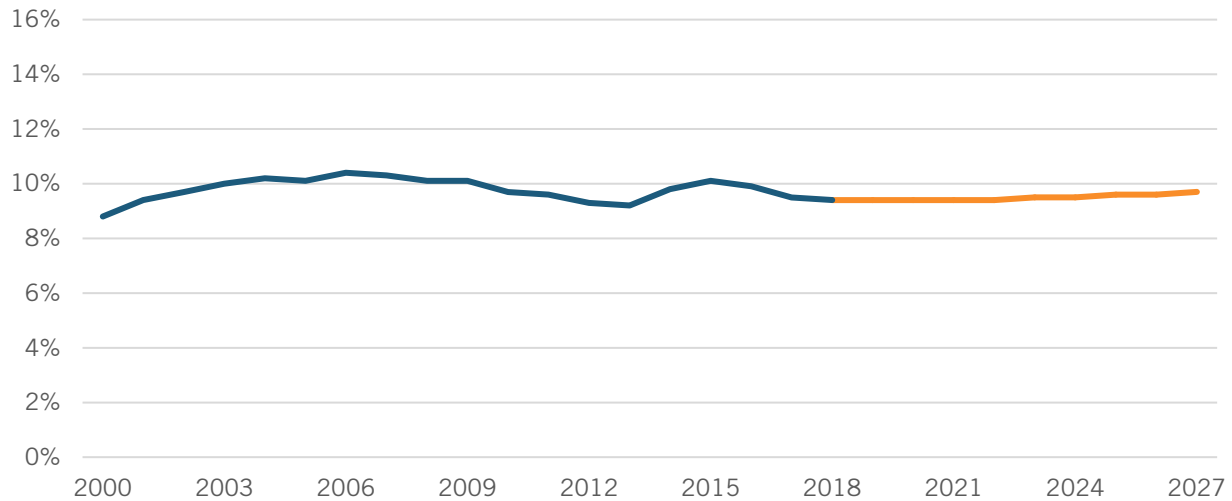
One of the most effective way to reduce drug prices is through increased generic competition; not through the prohibition (or presumed prohibition) of mergers. The Supreme Court's 2013 decision in *Federal Trade Commission v Actavis* fixed the current approach on balance between patent law and antitrust law in the context of pharmaceutical companies.⁷⁶ Agreements between generic applicants and brand-name companies may be procompetitive but may also be prone to anticompetitive effects. As noticed by the Supreme Court in *Actavis*, agreements involving “reverse payments” (pay-for-delay) by the innovator toward the generic manufacturer are primarily driven by anticompetitive purposes.⁷⁷ Prior to 2013, the courts were uncertain how to treat “patent punting strategies.”⁷⁸ Indeed, regulators and judges refused to engage in patent issues on the merits of regulating the entry of generic versions of patented drugs.⁷⁹ With the *Actavis* decision, the Supreme Court considered patent infringement action should not involve an antitrust analysis since patent provides an exception to antitrust laws.⁸⁰ This contradicts the FTC's viewpoint as expressed in its 2002 study and as outlined in the 2002 FTC Report.⁸¹

Such reluctance by the FDA and antitrust courts to engage in these issues is problematic. Indeed, Eisenberg and Crane rightly consider that these issues relate to competition on the merits and should therefore be scrutinized more carefully.⁸² This needs to be addressed.⁸³ Drug prices may fall as a result of invalid patents unjustifiably deferring generic entry. Patent punting strategies require the application of a rule of reason, whereby a complete balancing of the multiple market considerations involved in these complex issues is considered. More than the presumed illegality of mergers, this aspect represents sensible avenues for drug price reductions without stifling innovation.

Consequently, the law adequately scrutinizes mergers in general, and pharma mergers in particular. There is no need to alter the approach toward conglomerate mergers and vertical mergers, given the uncertainty the alternative approach may generate.⁸⁴ The FTC can challenge virtually every merger, including those where no vertical or horizontal relationship exists between the firms.⁸⁵ If the FTC wants to reduce drug prices, inter-agency collaboration with the FDA would be the most effective route.⁸⁶ In that respect, the 2018 FDA's Drug Competition Action Plan deserves credit for meaningfully assessing how competition can help in lowering drug prices.⁸⁷

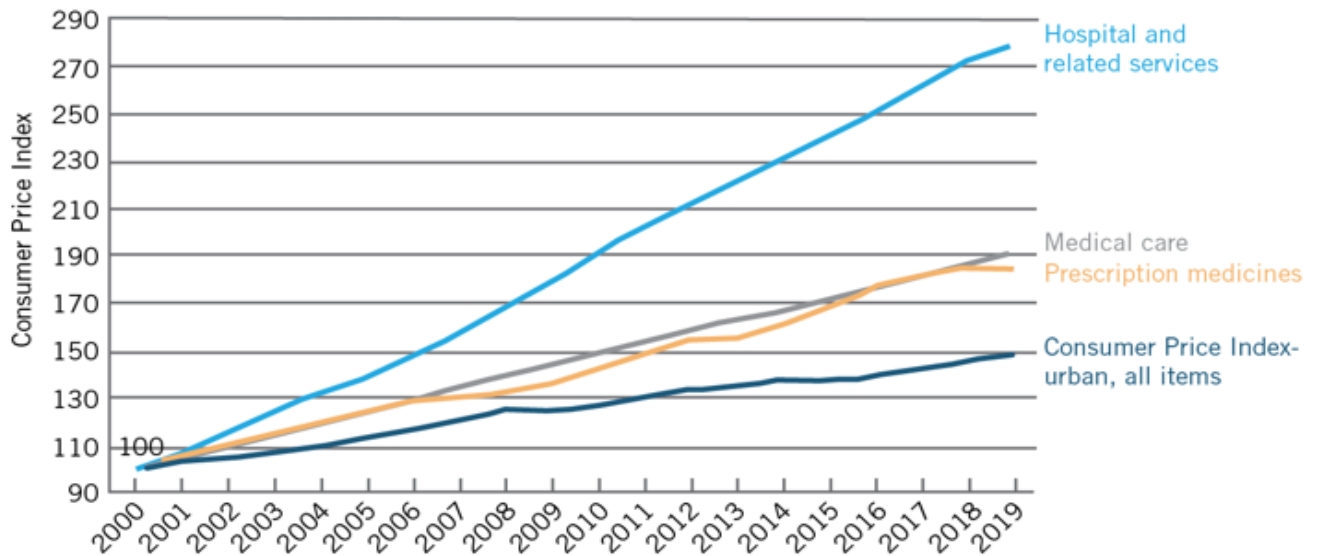
Regarding the issue of drug prices, however, the notion that drug prices are rising wildly out of line with prices in other industries is misguided. For instance, according to the Peterson Center on Healthcare and Kaiser Family Foundation, the percentage of total U.S. health care spending going toward retail prescription drugs was consistent from 2000 to 2017, at mostly under 10 percent.⁸⁸

Figure 3: Percentage of total health spending that went to retail prescription drugs, 2000–2017; projected 2018–2027⁸⁹



When examining increases in prescription medicine costs from 2000 to 2019 compared with other facets of the U.S. health care system, such as “hospital and related services” and “medical care,” the increase in prescription medicine costs has been right in line with the increase in medical care, and just slightly above the increase in the urban consumer price index, considering all items.

Figure 4: Average price levels, selected goods, and services, 2000–2019⁹⁰



Moreover, beyond enabling competitive markets, one of the most effective ways to address rising drug prices is with mechanisms to address the rising costs of developing innovative drugs, in part by working to enhance R&D efficiency. And one of the most important ways to better manage drug prices would be to enhance

R&D efficiency in drug research, in other words, to find collaborative ways to work together to make the cost of innovating new drugs less expensive.⁹¹ Most expensive for companies are candidate drugs which reach Phase III clinical trials and then fail; better success at weeding out those types of drugs earlier in the R&D process would make the entire drug discovery process more efficient and less expensive.

One important step in this regard is the Prescription Drug User Fee Act (PDUFA). By putting in place mechanisms that allow drug developers to have frank conversations with regulators about the technical and scientific expectations for a drug to clear certain clinical trial hurdles, it has streamlined the drug review process to some degree and helped drug developers make better decisions about the likelihood of candidate drugs passing the clinical trial gauntlet. Congress's 2017 reauthorization of PDUFA (PDUFA VI) also placed greater focus on supporting rare diseases and breakthrough therapies, including continued application-fee waivers and advanced reviews for medicines that can treat rare diseases, as well as prioritizing the development of breakthrough medicines for patients with life-threatening diseases.⁹²

Further, the advent of new technologies such as artificial intelligence and big data are likely to facilitate the drug-discovery process, helping to better identify biomarkers or to apply high-performance computing to analyze chemical and structural of proteins and molecular compounds that may lead to cures.⁹³

Will The Law Be Changed?

Lawmakers and enforcers appear determined to change merger law, especially for pharmaceutical markets. Pharmaceutical companies allegedly engage in “product hopping” (i.e., abusing patent laws to extend drug patents terms) or “evergreening” (i.e., preventing generics from entering the market). These accusations, if substantiated, should be a concern for the application of patent law. It may not necessarily involve antitrust enforcement unless the enforcement of patent laws is assumed to be deficient.

Antitrust enforcement should remain at an adequate level without twisting well-experienced approaches to antitrust and the need for legal clarity. However, current legislative proposals may change merger law, primarily with the proposed extensive (yet inappropriate) use of presumptions and a reversed burden of proof. On February 4, 2021, Senator Amy Klobuchar (D-MN) introduced S.225, the Competition and Antitrust Law Enforcement Act (“CALERA” Bill). If enacted, this legislative proposal would likely shift the burden of proof for megamergers, including pharma mergers.

The bill purports to change the legal standards that courts use to determine whether an acquisition is anticompetitive. The CALERA bill suggests modifying the Clayton Act by The CALERA bill revising the standard to “create an appreciable risk of materially lessening competition, or to tend to create a monopoly or a monopsony.” This change would give antitrust enforcers and judges broader discretionary power since the mere hypothetical risks may invariably be included in the analysis. Broadening the scope and discretion could lead to legal uncertainty and abuse.

Also, the bill purports to shift the burden of proof to the merging parties, requiring they demonstrate the benefits of the transaction outweigh the potential risks in certain circumstances. Under current law, antitrust agencies bear the burden of proof since any violation of the law needs to be substantiated to be deemed credible. With the CALERA bill, the shift of the burden of proof means that merging firms presumptively violate the Clayton Act unless they can demonstrate otherwise. The CALERA bill enumerates the circumstances under which the burden of proof is shifted.

Moreover, the CALERA Bill addresses the perceived problem of “killer acquisitions.” Indeed, a merger review would take place for acquisitions of small companies of more than \$50 million even if those companies are not competitors and are unlikely to become competitors in the future. This proposal may expand the reach of the antitrust authorities’ ability to review mergers involving start-ups.

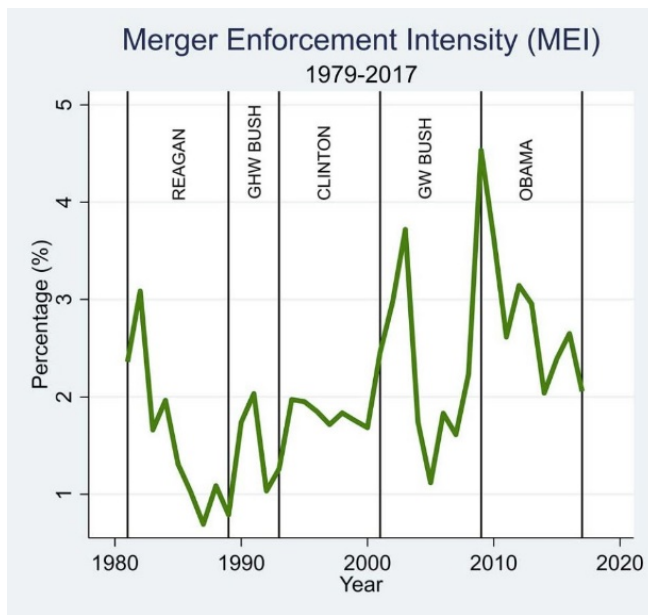
It is probable, given the political environment, lawmakers will reform the Clayton Act. Small firms may find it more challenging to acquire larger ones, and presumptions of illegality combined with broad discretion make it all-the-more difficult, if not impossible, to meet the shifting burden of proof. The preservation of the market structure justified by new and unclear theories of harm may take precedence over consistent application of the current approach as encapsulated in the 2020 VMGs. And yet, current enforcement procedure is more effective than legal reforms to adequately satisfy merger control considerations.

Enforcement Effectiveness

Should vertical merger enforcement be “reinvigorated,” this requirement should be applicable to all mergers (thus not unfairly discriminating pharma mergers specifically), and such aggressive merger control can be best achieved through enforcement, not by changing laws.⁹⁴ Indeed, contrary to the narrative pushed forward by the proponents of the killer acquisition theory and more generally by those arguing that merger review currently suffers lax enforcement, Macher and Mayo empirically demonstrated the lack of evidence for this narrative.⁹⁵

Macher and Mayo elaborate a merger enforcement intensity (MEI) index computed by a ratio of annual merger enforcements to annual reportable mergers under the Hart-Scott-Rodino Act. The MEI ratios reveal that peaks of intensity match at periods of economic recessions—namely, 1982, 2003, and 2009. In that regard, the current economic crisis following the COVID-19 pandemic unsurprisingly leads to the contestation of mergers.

Figure 5: MEI Ratios⁹⁶



The authors' next important question is: "why has the enforcement policy evolved as it has?"⁹⁷ A prime factor in explaining the evolution of merger enforcement is not a change of political environment and administrations but rather the increase of agency budgets. The authors find that the change in 2000 of the filing thresholds under the Hart-Scott-Rodino Act played a considerable role. They indeed conclude that "with limited financial and investigative resources, this shift to focus on large mergers has likely contributed to the increase in measured merger challenges as larger mergers are more likely, *ceteris paribus*, to provoke anticompetitive concerns than smaller mergers."⁹⁸

In other words, agencies focused their efforts on more extensive mergers after 2000.

Because more giant mergers are presumed to be more problematic for antitrust purposes, the ratio of challenges of mergers stabilized over the last 20 years. Consequently, increasing agencies' budgets and more administrative capacities may be more effective than any change of policy and be conducive to more merger challenges.

CONCLUSION: A PRESCRIPTION TO INNOVATION

At the heart of the issue of pharmaceutical mergers is the debate about the goals of antitrust. Should the major goal of antitrust regarding the drug industry be reduced prices or increased innovation? If the goal is prices, then perhaps more aggressive antitrust enforcement might be warranted. If the goal is innovation, then we should be wary of more aggressive antitrust enforcement. Given the massive benefits to the United States and the world from drug innovation, antitrust policy regarding the industry should put advancing innovation at the center.

In 2019, the U.S. Committee on Finance held a hearing titled "Drug Pricing in America: A Prescription for Change."⁹⁹ Our comments demonstrate that more than change, we need a "prescription to innovation" in order to lower drug prices and to enhance pharmaceutical innovation. The following actionable steps address the FTC's questions to carve out a pathway for lower drug prices and increased drug innovation:

1. Adopt FTC Guidelines on pharma mergers: Because of the ambiguous (and generally procompetitive) effects of pharma mergers in innovation and consumer benefits, a rule of reason on these mergers should be adopted. Presumptions of legality or presumptions of illegality prove inadequate with the fact-finding exercise and balancing of arguments necessary for judges to appraise the net competitive effects of the envisaged mergers;
2. Refrain from adopting an unclear new theory of harm: The current theory of harm—namely, consumer harm—remains a workable, sufficiently clear legal standard by which virtually every merger can be challenged;
3. Increased enforcement: Should the FTC want to increase its scrutiny on pharma mergers, reform of enforcement—not of existing policies—is sufficient, as empirical evidence demonstrates.

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- ⁸⁴ J. Thomas Rosch and Darren S. Tucker, “*Emerging Theories of Competitive Harm in Merger Enforcement*”, *The Antitrust Source*, (October 2011):1-7, https://www.ftc.gov/sites/default/files/documents/public_statements/emerging-theories-competitive-harm-merger-enforcement/1110mergerenforcement.pdf (noting that “antitrust counsel are likely to be more comfortable with challenges to potential vertical mergers than to conglomerate mergers.”)
- ⁸⁵ J. Thomas Rosch and Darren S. Tucker (referring to Commissioner Rosch concurrent statement in 2008 about the challenge of Lundbeck’s 2005 acquisition of Indocin from Merck).
- ⁸⁶ For example, in his article where he discusses how to reduce prices without depressing innovation, Stephen W. Salant does not identify antitrust and merger control as a tangible way to reach this objective. Rather, he identifies 1) international referencing pricing to insure that Medicare pays the price negotiated by foreign governments, 2) legalization of commercial arbitrage, 3) creation of an FDA whitelist of foreign pharmacies where U.S. patients can safely fill prescriptions. See Stephen W. Salant, “*Reducing Drug Prices without Depressing Innovation*,” (January 15, 2019), <https://lagv2019.sciencesconf.org/247191/document>
- ⁸⁷ FDA, *FDA Drug Competition Action Plan*, (May 2018), <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/fda-drug-competition-action-plan>
- ⁸⁸ Rabah Kamal, Cynthia Cox Twitter, and Daniel McDermott, “*What are the recent and forecasted trends in prescription drug spending?*” (Peterson Center on Healthcare and Kaiser Family Foundation, February 20, 2019), <https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/#item-start>.
- ⁸⁹ Ibid.
- ⁹⁰ PhRMA, “*Biopharmaceuticals in Perspective: Fall 2020*” (PhRMA, December 2020), 106, <https://www.phrma.org/en/Report/Chart-Pack-Biopharmaceuticals-in-Perspective-Fall-2020>.
- ⁹¹ Stephen J. Ezell, “*Testimony Before the Before the United States House of Representatives, House Committee on Government Oversight and Reform: HIV Prevention Drug: Billions in Corporate Profits After Millions in Taxpayer Investments*” (ITIF, May 2019), <https://www2.itif.org/2019-house-oversight-drug-price-testimony-ezell.pdf>.
- ⁹² Stephen J. Ezell, “*How the Prescription Drug User Fee Act Supports Life-Sciences Innovation and Speeds Cures*” (ITIF, February 2017), <https://www2.itif.org/2017-pdufa-life-sciences-innovation.pdf>.
- ⁹³ Joshua New, “*The Promise of Data-Driven Drug Development*” (ITIF, September 2019), <https://itif.org/publications/2019/09/18/promise-data-driven-drug-development>.
- ⁹⁴ Steven C. Salop, “*Invigorating Vertical Merger Enforcement*,” *The Yale Law Journal*, 127 (2018):1962-1994, <https://www.yalelawjournal.org/feature/invigorating-vertical-merger-enforcement>
- ⁹⁵ Jeffrey T. Macher and John Mayo, “*The Evolution of Merger Enforcement Intensity: What Do The Data Show?*” *Journal of Competition Law & Economics*, (2021):1-20, <https://doi.org/10.1093/joclec/nhaa037>. This section builds on Macher and Mayo’s findings. The two authors also argue elsewhere that judicial standards have not favored lax

merger enforcement over time, quite the contrary. See Jeffrey T. Macher, John W. Mayo, David E.M. Sappington, Mark Whitener, “The Evolution of Judicial Standards: Evidence from Litigated Merger Trials, (March 2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3809174 (demonstrating that “contrary to the current narrative, judicial standards have shifted in favor of the Agencies over time...We find no statistically significant evidence that the outcomes of antitrust merger cases vary according to whether the judges involved were appointed by Republican or Democratic presidents”).

⁹⁶ Jeffrey T. Macher and John Mayo, “The Evolution of Merger Enforcement Intensity: What Do The Data Show?” *Journal of Competition Law & Economics*, (2021):1-20, 18 <https://doi.org/10.1093/joclec/nhaa037>

⁹⁷ Jeffrey T. Macher and John Mayo, “The Evolution of Merger Enforcement Intensity: What Do The Data Show?” *Journal of Competition Law & Economics*, (2021):1-20, 18 <https://doi.org/10.1093/joclec/nhaa037>

⁹⁸ Jeffrey T. Macher and John Mayo, “The Evolution of Merger Enforcement Intensity: What Do The Data Show?” *Journal of Competition Law & Economics*, (2021):1-20, 20 <https://doi.org/10.1093/joclec/nhaa037>

⁹⁹ U.S. Committee on Finance, “Drug Pricing in America: A Prescription for Change, (January 29, 2019), <https://www.finance.senate.gov/hearings/drug-pricing-in-america-a-prescription-for-change-part-i>