Docket No. FTC-2021-0025

COMMENTS

of

WASHINGTON LEGAL FOUNDATION

to the

FEDERAL TRADE COMMISSION

Concerning

PHARMACEUTICAL TASK FORCE, PROJECT NO. P212900

IN RESPONSE TO THE PUBLIC NOTICE
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Jason M. Blore
Cory L. Andrews
John M. Masslon II
WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Ave., NW
Washington, DC 20036
(202) 588-0302

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WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Avenue, NW
Washington, DC 20036
(202) 588-0302

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Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue, NW
Room H-113 (Annex X)
Washington, D.C. 20580

Re: Pharmaceutical Task Force, Project No. P212900, Docket No. FTC-2021-0025

Sir or Madam:

On behalf of Washington Legal Foundation, please consider this comment responding to the May 9, 2021 request for public comments. WLF appreciates the opportunity to weigh in on whether the Federal Trade Commission, and related competition enforcement agencies, should significantly alter the approach to analyzing mergers in the pharmaceuticals industry. As explained below, FTC should not abandon its established approach to antitrust enforcement.

The pharmaceutical industry is not excessively consolidated. So traditional merger analysis is enough to prevent future harm. Further, concerns that mergers reduce innovation are unfounded. Recent research shows that there is nothing unique about the pharmaceutical industry that warrants departing from the competition-based approach FTC applies to all other sectors of the economy.

I. Interests of WLF

WLF is a nonprofit, public-interest law firm and policy center based in Washington, DC, with supporters nationwide. WLF focuses on defending free enterprise, individual rights, limited government, and the rule of law. To that end, WLF often appears before federal tribunals supporting sensible, economy-

boosting antitrust rules. *See, e.g.*, *AMG Capital Management, LLC v. FTC*, 141 S. Ct. 1341 (2021); *1-800 Contacts, Inc. v. FTC*, No. 18-3848, 2021 WL 2385274 (2d Cir. June 11, 2021).

WLF also regularly submits comments to federal regulatory agencies, including FTC, on proposed policy changes. *See*, *e.g.*, WLF Comment, *In re FTC Study of Digital Technology Market Merger Review* (Nov. 19, 2018); WLF Comment, *In re FTC Investigation of Artificial Intelligence* (Nov. 14, 2018); WLF Comment, *In re FTC Informational Injury Workshop* (Oct. 27, 2017).

WLF's Legal Studies Division, WLF's publishing arm, often produces and distributes articles on a wide array of legal issues related to FTC regulations. *See, e.g.*, Steven Cernak, *FTC Lacks Statutory Authority to Lower Hart-Scott-Rodino Thresholds for Big Tech Acquisitions*, WLF LEGAL OPINION LETTER (Nov. 13, 2020); Maureen K. Ohlhausen & Anthony W. Swisher, Staples/Essendant *as a Window into FTC Vertical Merger Enforcement*, WLF LEGAL BACKGROUNDER (Apr. 19, 2019); Kevin D. McDonald & Mark R. Lentz, *Clearing up* Doryx*: Lessons from the Third Circuit's Pharma "Product-Hopping" Decision*, WLF LEGAL BACKGROUNDER (Jan. 27, 2017).

II. Recent "Blockbuster" Mergers Do Not Prove that the Pharmaceutical Industry is Too Consolidated or that Traditional, Competition-Based Antitrust Analysis Has Failed.

Recent pharmaceutical mergers and acquisitions have drawn considerable public attention. *See, e.g.*, Eric Sagonowsky, *FTC's crackdown on pharma mergers reflects 'tougher' M&A environment under Biden administration: lawyer*, Fierce Pharma (Mar. 22, 2021), https://bit.ly/3dbY5Vt. "Blockbuster" deals include Bristol-Myers Squibb's $74 billion acquisition of Celgene in 2019, AbbVie's $63 billion acquisition of Allergan in 2020, and Mylan's $12 billion payment to merge with Pfizer's Upjohn unit in 2020. *See* Agnus Liu, *The top 10 largest biopharma M&A deals in 2020*, Fierce Pharma (Jan. 19, 2021), https://bit.ly/35LQ9WU. In total, the industry has undergone hundreds of mergers over the last decade—totaling $1.6 trillion. Sagonowsky, *supra.* Although mergers "have been a staple in the pharmaceutical industry for over a century," Barak Richman et al., *Pharmaceutical M&A Activity:*

Effects on Prices, Innovation, and Competition, 48 Loy. U. Chi. L. J. 787, 788 (2020), some observers are alarmed by the size and frequency of recent deals.

FTC and other antitrust enforcement agencies have been under increased political pressure to change their approach to analyzing pharmaceutical mergers and acquisitions. *See* Request for Comment. Proponents of greater enforcement contend that FTC should subject pharmaceutical mergers to not only stricter—but also newer and more comprehensive—forms of scrutiny. *See* Joanna Shepherd, *Consolidation and Innovation in the Pharmaceutical Industry: The Role of Mergers and Acquisitions in the Current Innovation Ecosystem*, 21 J. Health Care L. & Pol'y 1, 2 (2018). FTC has responded by signaling its own eagerness to change course and employ unconventional enforcement principles. *See* Request for Comment. Justifications range from familiar concerns, such as a merger's "effects on innovation," to yet-unnamed criteria, which FTC presumably hopes "new or expanded theories of harm" will validate. *Id.* The lack of detail exposes FTC's willingness to stray far afield from its traditional mandate for market intervention: preventing anti-competitive conduct.

FTC has "traditionally scrutinized mergers for harms to competition." Shepherd, *supra* at 12. Specifically, FTC has challenged mergers that would "substantially . . . lessen competition" while "avoiding unnecessary interference with mergers that are either competitively beneficial or neutral." U.S. Dep't of Justice & Fed. Trade Comm'n, Horizontal Merger Guidelines (Aug. 19, 2010), § 1. This can be difficult; it is challenging to accurately predict the competitive effects of a given merger. Yet economic theory and Supreme Court precedent have long supported this tight focus on competition with several important insights.

First, as "the best method of allocating resources in a free market," competition affords many significant benefits to consumers. S*ee Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 695 (1978). Competition "constrains pricing, makes companies respond to consumer preferences, and leads firms to introduce better products." Maureen K. Ohlhausen, *The Elusive Role of Competition in the Standard-Setting Antitrust Debate*, 20 Stan. Tech. L. Rev. 93, 100 (2017). Second, and perhaps unsurprisingly, a *lack* of competition typically has the opposite effect. *See id.* at 99. Weak competition

produces "higher prices, lower output, diminished quality, or compromised incentives to innovate." *Id.* (citation omitted). Third, even in a market free from competitive defects, "unfavorable market outcomes" can still occur. *Id.* at 103-04 (citing *Verizon Commc'ns v. Trinko*, 540 U.S. 398, 404, 416 (2004); *United States v. Aluminum Co. of Am.*, 148 F.2d 416, 430 (2d Cir. 1945)). Since these negative outcomes are "not [always caused] by[] a lack of competition," per se rules risk disrupting markets unafflicted by competition problems. *See id.* at 103. Such overenforcement can cause serious, long-term harms to consumers, including reduced market output. *See* Thomas A. Lambert, *The Limits of Antitrust in the 21st Century*, 68 Kan. L. Rev. 1097, 1101 (2020) (citing Frank H. Easterbrook, *The Limits of Antitrust*, 63 Tex. L. Rev. 1, 21 (1984)).

Given this dynamic, FTC should view current calls for antitrust enforcement—especially those targeted at the pharmaceutical industry—with skepticism. Too often, these demands lack any evidence of market defects. Rather, many commentators seize upon high-profile, large-scale mergers as though they were conclusive proof of excess consolidation. *See, e.g.*, Robin Feldman, *Drug companies keep merging. Why that's bad for consumers and innovation*, Washington Post (Apr. 6, 2021), https://wapo.st/2TXS4VR. Other times, a lack of competition is presumed from certain "negative market outcomes"—like increased prices—that are highly visible and easily felt by the public. *See* Ohlhausen, *Elusive Role*, *supra* at 96. These hasty appeals for antitrust intervention are unfounded. When competition defects are not the root cause of negative market outcomes, amelioration should come from other regulatory tools—like state consumer-protection laws—that can provide more targeted forms of enforcement. *See* Maureen K. Ohlhausen & Alexander P. Okuliar, *Competition, Consumer Protection, and the Right [Approach] to Privacy*, 80 Antitrust L.J. 121, 152-53 (2015). The wide availability of regulatory alternatives further bolsters the notion that competition is the proper, limited focus of antitrust. And while imaginative regulatory theories disregarding that focus abound, no evidence suggests that the pharmaceutical industry is not competitive enough.

To help decide whether a merger will harm a market, FTC often measures that market's concentration levels. *See* Guidelines, *supra* § 5. While not always uncompetitive, "highly concentrated markets are presumed to be likely to enhance market power" and thus likely to reduce competition. *Id.* at

§ 3. FTC often uses the Herfindahl–Hirschman Index to measure market concentration. *Id.* at § 18. The HHI for a given market is calculated by identifying the number of firms in that market and then summing the squares of each firm's market share. *Id.* FTC considers markets with HHIs below 1,500 to be "unconcentrated," between 1,500 and 2,500 to be "moderately concentrated," and above 2,500 to be "highly concentrated." *Id.* at § 19. While markets exhibiting moderate or high concentration "raise significant competitive concerns" and will likely face FTC scrutiny, unconcentrated markets are "unlikely to have adverse competitive effects" and are typically left undisturbed. *Id.*

Consolidation in the pharmaceutical industry is low; the HHI fluctuates between 500 and 700. Richman, *supra* at 794-95. Concentration levels in the industry (1) are "well below" the levels FTC considers troubling and (2) have remained fairly constant for nearly two decades. *Id.* This low concentration has coincided with increases in merger activity and pharmaceutical prices that have panicked some. *Id.* at 794. This data confirms that the negative market outcomes attracting the most attention are uncorrelated with—let alone caused by—a lack of competition. Under such conditions, antitrust intervention would be misguided and likely counterproductive.

But this is not the only reason the FTC should maintain its competition-based approach. If industry-wide HHI is within the "moderately concentrated" or "highly concentrated" bands, then FTC's traditional, competition-based mandate provides ample justification to initiate antitrust action. *See* Guidelines, *supra* § 5.3. Yet FTC appears eager to adopt "new or expanded theories of harm" rather than use its current tools. *See* Request for Comment. This seems to betray a lack of confidence in the Horizontal Merger Guidelines generally.

III. Pharmaceutical Mergers are Usually Efficient and Do Not Reduce Industry-Wide Innovation.

Although large-scale merger activity does not necessarily produce an uncompetitive market, many believe that mergers cause significant harms. The most concerning of these charges is the claim that mergers reduce innovation. It is "premised on the idea that, by merging existing competitors

into one firm, consolidation will reduce incentives to develop new products in the future." Shepherd, *supra* at 2. While FTC cannot intervene in a market solely to boost suboptimal innovation levels, mergers' alleged effects on new drug development are worth examining. Diminished innovation would certainly impact the pharmaceutical industry, where consumers depend on new drugs to improve their health and even to stay alive. Understandably, then, FTC "'wants to ensure that innovation can reach patients at affordable prices.'" Sagonowsky, *supra* (quoting FTC's then acting chairwoman, Rebecca Slaughter).

Yet the current structure of the pharmaceutical industry reveals—however counterintuitively—that mergers are among the best ways to achieve innovation. Pharmaceutical companies are under increased pressure to produce new drugs more efficiently. *See* Shepherd, *supra* at 16-21. In response, the industry has developed "an innovation ecosystem" in which large companies often rely on smaller ones for research and development. *Id.* at 23; s*ee also* Roerich Bansal et al., *What's behind the pharmaceutical sector's M&A push*, McKinsey & Co. (Oct. 10, 2018), https://mck.co/362BF5j. Indeed, while occasional blockbuster mergers between two large firms draw headlines, most pharmaceutical mergers involve "bigger players acquiring smaller start-ups." *See* Feldman, *supra*. The availability of mergers during "the later stages of the drug development process" allows each firm to specialize in its areas of strength and to avoid its areas of weakness. Shepherd, *supra* at 2, 24. By allowing these companies to "concentrat[e] on their comparative advantages," mergers more efficiently bring innovative drugs to market. *Id.* at 24.

An overview of these comparative advantages illustrates the efficiency gains that mergers provide. Smaller firms are well suited to conducting early-stage research. Shepherd, *supra* at 21. They feature "a culture of nimble decision-making and risk-taking" that "facilitates discovery and innovation." *Id.* at 2, 22. This culture is reinforced by "less bureaucratic organization structure[s]" and "strict oversight by outside investment managers." *Id.* at 21-22. By contrast, the "highly bureaucratic structures" of larger firms do not allow for such flexibility. *Id.* at 21. Rather, larger companies' comparative advantages lie in the later stages of development and commercialization. *Id.* at 23. Only larger companies have the resources to efficiently guide new drugs through the long processes of regulatory approval and clinical testing. *Id.* And

larger companies are much better equipped to "organize . . . manufacturing and distribution capabilities to bring the drug to market, and mobilize . . . vast sales force[s] to quickly achieve peak sales." *Id.* at 24. They can also better withstand hefty damages awarded in litigation over established products. *See, e.g.*, Tinya Bellon & Nate Raymond, *Bristol-Myers, Sanofi ordered to pay Hawaii $834 million over Plavix warning label*, Reuters (Feb. 15, 2021), https://reut.rs/3zUn8pN (describing a Hawaii court's order that Bristol-Myers Squibb Co. and Sanofi SA "pay more than $834 million" in damages for not engaging in unconstitutional compelled-speech).

Studies claiming that mergers reduce innovation use faulty analysis. These studies begin by identifying several measurements as key indicators of a firm's contributions to innovation: the firm's total R&D expenditures, R&D projects, and new patents. Shepherd, *supra* at 12. Then the studies show that the measurements of each indicator tend to decrease after a merger. *Id.* This is shown by comparing the measurements of the combined entity (post-merger) to the sum of either the constituent entities (pre-merger) or comparable, unmerged competitors. *Id.* From these simple calculations, the researchers conclude that mergers yield less innovation. *See id.* Yet, for at least three reasons, these studies are misleading.

First, a mere tallying of total R&D expenditures, R&D projects, or new patents disregards their expected return. R&D is a risky and expensive enterprise; a high proportion of R&D dollars and projects ultimately do little to produce innovative drugs. *See* Michael Jewell, *Consolidation in the pharmaceutical industry—an outlook for 2019*, The Pharma Letter (Mar. 18, 2019), https://bit.ly/3vTPdu0. In fact, many firms merge precisely because consolidation can lead to R&D "efficiency gains." Shepherd, *supra* at 12. Mergers "allow[] firms to purchase innovative drugs that show clear potential while they are in development" and "strategically re-align their drug portfolios." Jewell, *supra*. They also "enable firms to streamline duplicative operations, reduce excess capacity, and achieve economies of scale." Shepherd, *supra* at 12 (citations omitted). This suggests that the chance of developing viable drugs improves after a merger. Further, any reduction in R&D spending may reflect efficiently abandoning redundant activities. *Id.*

Second, mergers can also benefit non-merging firms. Mergers allow consolidating firms to "sell assets . . . for which they are no longer the best owner." Jewell, *supra*. This in turn presents useful opportunities to other industry players, who can "grab these assets at very cheap prices" and develop them into their own products. Andrew Dunn, *Deal of the Year: Bristol-Myers Squibb buys Celgene*, Biopharma Dive (Dec. 9, 2019), https://bit.ly/3h32UBA (internal quotation marks omitted).

Third, internal R&D is not the only way that new drugs come to market. Shepherd, *supra* at 26. Rather, many "new drugs are externally sourced." *Id.* Critics who fixate on reductions to internal R&D activities may possess "an outdated understanding" of how innovation is generated in the pharmaceutical industry. *Id.* Since smaller companies are propelling industry-wide innovation, a crackdown on mergers would lessen the industry's chief incentive for new drug development. Small firms bear the high risks of early-stage development because they are motivated by the prospect of being bought out by a larger company. *See id.* at 2, 25. Creating a successful new drug—while enticing—is not enough incentive to innovate. This is because the smaller company would lack the resources to get even a wildly successful product approved and to market. *See id.* at 24. Rather, to reap satisfactory profits, smaller firms must depend on the late-stage capabilities of the larger, acquiring company. *See id.* The considerable benefits of mergers to small firms are likely why "data suggest that consolidation is associated with increases in aggregate innovation." *See id.* at 3.

Separately, mergers also lower small firms' capital costs. In their early stages, small companies typically lack "sizable assets to pledge as collateral for debt financing," and therefore must rely on equity financing. Adam Hayes, *Cost of Capital*, Investopedia (Apr. 12, 2021), https://bit.ly/3qo7KOj. But equity financing can become unappealing to smaller companies, especially when prolonged, by forcing them to surrender substantial equity stakes for each round of funding. Merging with a larger firm, however, allows the smaller company to access funding with fewer strings attached. Larger companies can simply contribute portions of their existing R&D budgets or turn to a commercial bank for loans. If smaller companies were prohibited from completing strategic mergers, they would likely have to relinquish additional

equity shares to secure funding for late-stage development. This would discourage many would-be entrepreneurs from even starting a new firm.

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High-profile pharmaceutical mergers have increased the pressure on FTC to abandon its traditional approach to antitrust enforcement. The voices demanding intervention are loud and confident. But many rationales for such action—particularly claims that recent mergers will harm competition or reduce innovation—lack evidentiary support. The critics also lack appreciation for pharmaceutical mergers' beneficial effects. Doubly concerning is FTC's willingness to bow to these pressures and concoct new theories to justify market intervention. Such eagerness shows a failure to recognize the risks of overenforcement. *See* Easterbrook, *supra* at 21. Before FTC tries its own hand at innovating, it should ensure that its theories do not lead to negative unintended consequences. In sum, FTC should stay the course and adhere to the tried-and-true, competition-based policy that has long served it—and American consumers—well.

Respectfully submitted,

Jason M. Blore
LAW CLERK

Cory L. Andrews
GENERAL COUNSEL & VICE
PRESIDENT OF LITIGATION

John M. Masslon II
SENIOR LITIGATION COUNSEL