

A Timeline of the FTC & DOJ's Flawed Approach to Life Sciences M&A

In recent years, the Federal Trade Commission (FTC) and Department of Justice (DOJ) have taken an increasingly aggressive approach toward life sciences mergers and acquisitions (M&A). This new approach not only represents a substantial pivot away from the Agencies' own long-standing precedent of balanced antitrust policy, but also risks obstructing the many complementary relationships that M&A fosters, which are responsible for bringing innovative new treatments and cures to patients.

Throughout the long and costly journey to bring a new medicine to patients, life sciences companies of all sizes rely on pro-innovation M&A to combine their unique skills and resources and ultimately innovate more efficiently. As recently as 2020, the Agencies acknowledged the importance of a balanced approach to M&A review and enforcement:

"Mergers are one means by which firms can improve their ability to compete. It would be illogical, then, to prohibit mergers because they facilitate efficiency or innovation in production."

—POLICY STATEMENT, FTC (2020)¹

Unfortunately, the Agencies have recently failed to acknowledge the unique competitive dynamics that shape the life sciences industry. Instead, the Agencies have taken steps to broadly deter pro-innovation M&A across the life sciences ecosystem:

2021 • MARCH

FTC & DOJ announce Multilateral Pharmaceutical Merger Task Force:

Made up of antitrust enforcers from the U.S. and abroad, the Task Force launched with the stated goal of retooling the Agencies' approach to M&A review and enforcement in the life sciences. Unfortunately, as commenters noted in their remarks to the Task Force, such a goal is entirely inconsistent with the economic reality in America's life sciences industry. In fact, "eliminating or restraining the opportunity for mergers and acquisitions will severely impede the ecosystem that has catapulted the U.S. life sciences and biomedical innovation ecosystem into its current leadership position in the world" (Biotechnology Innovation Organization).²

2022 • JUNE

FTC & DOJ host "Public Workshop on the Future of Pharmaceuticals: Examining the Analysis of Pharmaceutical Mergers":

Despite cautions from the industry about potentially disrupting the world-class U.S. life sciences ecosystem, this workshop "made clear that the FTC has every intention of making changes to the way it reviews pharmaceutical mergers" (Buchanan).³ Although workshop panelists did not commit to any particular policy stance, the Agencies' aggressive new approach to life sciences M&A began to take shape within the year.

2023 • JUNE

FTC introduces proposed Hart-Scott-Rodino (HSR) premerger notification rule:

This proposed rule would dramatically increase the amount of information that merging parties are required to disclose before completing an M&A deal. Importantly, in this proposal, the FTC ignores a key dynamic: the vast majority of transactions subject to these reporting requirements are plainly pro-competitive.⁴

2023 • JULY

Agencies introduce Draft Merger Guidelines:

The Draft Merger Guidelines foreshadowed a significant overhaul of the Agencies' approach to competition policy, suggesting that even theoretical and speculative impacts on competition could be used to deem a deal unlawful. Although the merger guidelines do not hold the force of law, the unclear standards of competition proposed in the draft guidelines opened the door for the Agencies to challenge a broad array of potentially pro-competitive deals.

• DECEMBER Agencies finalize 2023 Merger Guidelines:

Despite nominal revisions, the final guidelines remained largely unchanged from the July draft. In fact, as one analysis noted, the finalized guidelines served mostly as a formal acknowledgement of “many developments already seen at the Agencies”⁵—in other words, a marked shift toward more aggressive M&A enforcement. For life sciences companies, this shift has introduced greater uncertainty to an already high-stakes ecosystem, and risks upending a key path to bring new medicines to patients.

2024 • OCTOBER

FTC releases finalized HSR premerger notification rule:

Despite some revisions from the proposed rule, the final rule imposes substantial costs of compliance from increased reporting requirements on merging parties by default. Given that 80% of life sciences companies already operate without a profit,⁶ these costs may be enough to stop many pro-competitive M&A deals intended to bring new treatments or cures to patients.

Thanks to decades of balanced competition policies,⁷ the U.S. life sciences industry has emerged as among the most competitive in the world, with more than 2,300 companies,⁸ operating in all 50 states, working to revolutionize our approach to treating disease.

Now, with more than 8,000 potential new treatments and cures in the pipeline,⁹ it is vital that the FTC & DOJ reconsider their approach to life sciences M&A enforcement, and return to a balanced approach that recognizes the unique and fundamental role of M&A in fueling innovation, competition and growth in America's life sciences industry.

¹ The Antitrust Division of the U.S. Department of Justice and the U.S. Federal Trade Commission. Policy Statement: Conglomerate effects of mergers. June 4, 2020. https://www.ftc.gov/system/files/attachments/us-submissions-oecd-2010-present-other-international-competition-fora/oecd-conglomerate_mergers_us_submission.pdf

² Comment from Biotechnology Innovation Organization - Carlo Passeri. FTC Notice for Multilateral Pharmaceutical Merger Task Force. <https://www.regulations.gov/comment/FTC-2021-0025-0013>

³ Buchanan. FTC, DOJ Pharma Taskforce Takes Aim at Pharmaceutical Mergers in Push to Reform Merger Review. August 1, 2022. <https://www.bipc.com/ftc-and-doj-pharma-taskforce-takes-aim-at-pharmaceutical-mergers-in-push-to-reform-merger-review>

⁴ U.S. Chamber of Commerce, Business Roundtable, American Investment Council, Longview Chamber of Commerce. Civil Action No. 6:25-cv-009. Complaint for Declaratory and Injunctive Relief. <https://www.uschamber.com/assets/documents/Complaint-Chamber-of-Commerce-v-FTC-E.D.-Tex.pdf>

⁵ Gibson Dunn. U.S. Antitrust Agencies Release Revised 2023 Merger Guidelines Designed to Increase Scrutiny of Deals. December 21, 2023. <https://www.gibsondunn.com/us-antitrust-agencies-release-revised-2023-merger-guidelines-designed-to-increase-scrutiny-of-deals/>

⁶ Rottgen, R. Biotech Valuation Idiosyncrasies and Best Practices. <https://www.toptal.com/finance/valuation/biotech-valuation>

⁷ Partnership for the U.S. Life Science Ecosystem. The Pro-Competition Policies Driving Life Science Innovation. <https://pulseforinnovation.org/the-pro-competition-policies-driving-life-science-innovation/>

⁸ Citeline. Pharma R&D Annual Review 2023. https://images.intelligence.informa.com/Web/InformaUKLimited/%7B1e2824e9-0137-4cb4-9ef5-b8643c2243cc%7D_13575_Citeline_R_D_White_Paper_V6.pdf

⁹ PhRMA. In the Pipeline. <https://phrma.org/en/Scientific-Innovation/In-The-Pipeline>