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FTC & DOJ Focus on "Nascent Competition" Ignores Unique Market Dynamics in the Life Sciences

The Federal Trade Commission (FTC) and Department of Justice (DOJ) have increasingly focused on the impact that mergers and acquisitions (M&A) in the life sciences could have on "nascent competition"—competition that might eventually exist between therapies already on the market and those in early-stage development. This approach is not only highly speculative, but it also ignores complex realities and unique dynamics in life sciences research and development. By continuing to pursue this approach, the Agencies are jeopardizing a vital pathway for biopharmaceutical companies to be able to bring early-stage therapies to patients.

The Agencies articulated this new approach in their 2023 Merger Guidelines, but even before the guidelines were finalized, they sought to challenge a broad range of deals based on these flawed standards. The Agencies' aggressive stance toward more frequently opposing mergers involving "nascent competitors" strays far away from decades of balanced precedent, where economic and industry realities have been duly recognized.

> ***"The final Guidelines signal Agency intent to challenge more acquisitions where no immediate competitive overlaps exist between the merging parties under the theory that parties may nevertheless be potential future competitors...While courts have historically required the Agencies to show, at least by reasonable probability (noticeably greater than 50%), that merging parties will be future competitors, the 2023 Guidelines generally articulate a lower burden for the Agencies to show harm to future competition."***
>
> —GIBSON DUNN (2023)[1]

Legal experts have asserted that the Agencies' focus on nascent competition "at least in part, is targeted at the life science industry."[2] And the Agencies' recent approach to the life sciences industry supports this conclusion. Indeed, recent challenges brought by the Agencies suggest a new willingness to oppose deals involving investigational therapies in as early as phase 1 clinical trials.[3] These initial discoveries can be nearly a decade away from reaching the market, if at all.[4]

Unfortunately, despite clearly targeting the life sciences industry, the Agencies' focus on nascent competition ignores the unique market dynamics that define this highly competitive ecosystem.

The Agencies' approach presupposes—against long odds—that an early-stage therapy will eventually reach the market. In reality, this is far from certain. The considerable scientific, economic and regulatory headwinds present in the life sciences ecosystem mean that 9 in 10 therapies that enter clinical trials will never advance beyond the lab.[5] Importantly, by attempting to block the very deals responsible for unlocking critical resources and investment for companies to be able to overcome these pressures, the Agencies are only intensifying the already staggering challenge that companies of all sizes face in bringing new medicines to patients.

"Not every company is able to ideate and execute the myriad activities necessary to bring a drug through the research and development process to the patient. Consequently, the biotech industry has grown ever more reliant upon mergers, acquisitions and licensing agreements among both large and small companies…It follows that not only are these activities not necessarily harmful to competition, but also that they may well be pro-competitive, as they are often necessary for a product to travel the great distance from concept to approval…"

—KINCH, LEHMANN & MANTOVANELLI, LAW360 (2023)[6]

Much like passing a baton in a relay race, M&A allows life sciences companies of all sizes to connect promising innovations with the right resources, expertise and investment, at the right time, to ultimately bring new therapies to patients. In many cases, smaller companies, leveraging their specialized scientific and medical expertise and more nimble structure, lead the way in the discovery of new medicines. However, it often takes the global resources and infrastructure of a larger, more established firm to be able to conduct late-stage clinical trials, secure regulatory approval and ultimately manufacture and distribute these new therapies at scale.

The Agencies' aggressive skepticism toward M&A deals based on "nascent competition" is not only misplaced, but also sets a foreboding precedent for companies' ability to advance early-stage medicines to patients. Instead, it is vital that the Agencies consider the unique market dynamics in the life sciences and return to the balanced approach to M&A enforcement that has been a defining feature of America's life sciences industry for decades.

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

[2] Goodwin. Antitrust & Competition Life Sciences Year in Review 2023. February 2024. https://www.goodwinlaw.com/en/insights/publications/2024/02/insights-lifesciences-cldr-antitrust-and-competition-in-lifesciences-2023-yir.

[3] Law360. How Biotech Deals May Help Competition, Despite FTC View. January 2024. https://www.law360.com/articles/1791437/how-biotech-deals-may-help-competition-despite-ftc-view.

[4] BIO, Informa Pharma Intelligence, QLS Advisors. Clinical Development Success Rates and Contributing Factors 2011–2020. https://go.bio.org/rs/490-EHZ-999/images/ClinicalDevelopmentSuccessRates2011_2020.pdf.

[5] Mullard, A. Parsing clinical success rates. https://www.nature.com/articles/nrd.2016.136.epdf.

[6] Law360. How Biotech Deals May Help Competition, Despite FTC View. January 2024. https://www.law360.com/articles/1791437/how-biotech-deals-may-help-competition-despite-ftc-view.

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