PULSE
PARTNERSHIP FOR THE
US LIFE SCIENCE ECOSYSTEM

Life Sciences Mergers and Acquisitions (M&A):

Bringing Biopharmaceutical Advancements to Consumers Through Scale, Efficiency and Expertise

Consumer Benefit from M&A vs. Flawed New Approach to Merger Enforcement

Mergers and acquisitions allow life sciences companies of all sizes to bring together the resources, investment and expertise needed to develop and deliver new treatments and cures for patients.

Unfortunately, the latest merger guidelines and proposed premerger notification requirements issued by the Federal Trade Commission (FTC) and Department of Justice (DOJ) reflect a misguided approach that will prevent and deter pro-innovation M&A and disrupt our world-class American life sciences ecosystem.

Life Sciences Competition is Unique, Differentiated

America's life sciences industry reflects a dynamic, diverse and competitive market across companies of all sizes. More than **2,300 biopharmaceutical companies** are headquartered in the U.S. and hundreds more start every year in the race to discover and develop medicines for patients.[1,2] Together, the industry employs over **two million Americans across every state**.[3]

Unlike many other industries, **80% of biopharmaceutical companies operate without a profit.**[4] Between the average financial risk assumed in relation to research and development (R&D) ($2.6 billion), time (10-15 years) and manufacturing and distribution infrastructure necessary to develop and deliver a new medicine, **most companies are unable to go it alone**.[5] Even for early-stage companies that could secure the significant investment needed to bring a medicine to market, it's often the case that building full-scale, in-house capabilities would impose potentially more inefficiencies, delays and misallocation of resources.

M&A provides an essential "bridge" to advance early-stage innovations through the lengthy and resource-intensive process of clinical trials, FDA reviews, production, manufacturing and distribution, and ultimately, to the patients that depend on groundbreaking treatments and cures.

For nearly four decades, Congress has prioritized bipartisan policies that incentivize investment in innovation. The legislative foundation fueling life sciences innovation – from the *Hatch-Waxman Act* to the *Orphan Drug Act* and the *21st Century Cures Act* – has driven a diverse, dynamic and competitive U.S. life sciences ecosystem. The result for patients: a robust pipeline of medical breakthroughs from vaccines to cell and gene therapies, and other first-in-class treatments.

Patients, Innovation Depend on Life Sciences M&A

Millions of Americans, and people around the world, rely on the speed, precision and scale that are defining attributes of the U.S. life sciences ecosystem. Pro-innovation M&A has been a driving force behind groundbreaking treatments for infectious diseases – including COVID-19 – rare diseases, cancer and more.

M&A policies that allow life sciences companies to combine complementary resources and expertise are key to advancing new innovations for patients – a reality reaffirmed by our courts and other leading experts for decades. The nonpartisan Congressional Budget Office has asserted that, "*In making [an] acquisition, a large company might bring a drug to market more quickly than the small company could have or might distribute it more widely*."[6] Life sciences innovation thrives when companies of all sizes and capabilities combine, collaborate and partner.

Consider that, on the back of 10 years of increased M&A activity, the rolling five-year average of new therapies approved by the FDA more than doubled, and **there are now more than 8,000 potential new treatments and cures on the horizon** across dozens of disease areas.[7,8]

The FTC and DOJ should take a balanced and bipartisan approach towards M&A review and enforcement, acknowledging the unique, differentiated and competitive market dynamics that drive our U.S. life science ecosystem and the treatments and cures it delivers.

New Approach to M&A Enforcement Places Significant Uncertainty, Cost Burden on Life Sciences Ecosystem

The FTC and DOJ's recently finalized Merger Guidelines and proposed changes to the premerger notification requirements under the Hart-Scott-Rodino (HSR) Act form the foundation of a flawed and aggressive new approach to M&A by the agencies. Together, these developments represent a seismic shift in U.S. competition policy and illustrate a concerning hostility towards M&A. Critically, this new approach threatens to derail life sciences innovation and delay – or even prevent – innovative new treatments and cures from reaching patients.

2023 Merger Guidelines

The Merger Guidelines overhaul decades of bipartisan policy that had fostered pro-innovation, competitive M&A as a vital tool for life sciences companies of all sizes. While the guidelines do not have the force of law, the agencies can use the guidelines to review and litigate M&A transactions.

As one analysis from legal experts noted:

"The 2023 Merger Guidelines provide a window into the expanded and more aggressive antitrust enforcement characterizing Agency review of mergers under the Biden Administration… ***merging parties should expect aggressive enforcement action by the Agencies that seek abandonment of mergers through lengthy investigations, procedural delay, and more frequent court challenges."***[9]

With the latest Merger Guidelines, the **FTC and DOJ have introduced unclear standards of competition** that create uncertainty and inconsistent barriers to pro-innovation M&A. They suggest that even *theoretical and speculative impacts* on competition could be used to deem a deal unlawful – drawing arbitrary lines for the agencies to litigate against. For life sciences innovators, this substantial **added uncertainty and risk could upend the already high-stakes process of bringing new treatments and cures to patients.**

Proposed HSR Premerger Notification Rule

The FTC and DOJ's **proposed changes to the HSR premerger notification requirements would subject merging companies to heightened scrutiny and immense costs of compliance by default** – even though more than 97% of HSR-reportable transactions don't warrant an in-depth investigation and more than half are so "nonproblematic that the Agencies can clear them on cursory review," according to a Foley & Lardner analysis.[10]

By dramatically increasing the amount of information that merging parties must report before completing an M&A deal, the FTC is **ignoring an important reality: the majority of M&A transactions are affirmatively pro-competitive.** Despite this fact, antitrust experts in a recent survey estimated that the expanded reporting requirements would:[11]

- Increase the time to prepare required HSR filings by **an additional 241 hours over 22 days**; and
- Cost merging parties **more than $234,000 in fees from outside counsel alone**, not including the costs of internal labor and other administrative costs.

These costs could have particularly grave consequences for innovation in the life sciences ecosystem. In their comments to the FTC on the proposed rule, the Biotechnology Innovation Organization (BIO) notes:

"The scope and the nature of the revisions ***send a clear message that all dealmaking will be subjected to greater scrutiny. Unfortunately, this includes the innovation-driving M&A activity on which the biotech sector depends****… Burdensome premerger reporting requirements that impede such transactions will stymie, if not overtly thwart, innovation."*[12]

Together with the uncertainty created by the new Merger Guidelines, these burdensome reporting requirements threaten to upend decades of balanced competition policy and obstruct a critical path to advancing innovative life-changing medicines.

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