

Comment on DOJ/FTC Request for Public Comment Regarding Making Improvements to the Premerger Notification and Report Form

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Submitted by: Partnership for the U.S. Life Science Ecosystem (PULSE)

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The Partnership for the U.S. Life Science Ecosystem (PULSE) appreciates the opportunity to provide comments in response to the Federal Trade Commission (FTC) and Department of Justice (DOJ) Request for Information regarding the Hart-Scott-Rodino (HSR) Premerger Notification Form and associated reporting requirements. We are encouraged by the administration's stated goal to ensure that any updates to the HSR framework streamline the reporting process for pro-competitive mergers and acquisitions (M&A) and other transactions. PULSE is a coalition whose members include frontline researchers, employees and leaders of life sciences companies of all sizes, who together represent the diverse and unique life sciences ecosystem across the U.S. PULSE is focused on highlighting the critical role of pro-competitive M&A in driving America's biopharmaceutical leadership.

I. M&A is Unique, Fundamental and Differentiated in the Life Sciences

The life sciences industry plays a critical role in America, supporting nearly 2.3 million jobs across every state, driving over \$3.2 trillion in economic impact and – most importantly – delivering new and groundbreaking therapies that improve and save patients' lives.¹ America's life sciences leadership depends on policies that foster the conditions required for a successful innovation ecosystem, including scientific risk-taking, capital formation, collaboration and dealmaking.

M&A is deeply and fundamentally embedded within the U.S. life sciences innovation ecosystem. M&A provides smaller and early-stage life sciences companies with access to the capital,

¹ Biotechnology Innovation Organization, *The U.S. Bioscience Economy: Driving Economic Growth and Opportunities in States and Regions* (2024), <https://bio.widen.net/s/hflmb92hwx/the-us-bioscience-economy-driving-economic-growth-and-opportunities-in-states-and-regions>

manufacturing capabilities, regulatory expertise as well as commercialization and distribution infrastructure necessary to bring new medicines to patients at scale.

Recent empirical research demonstrates that M&A is an enabling mechanism for innovation in the life sciences:²

- Drugs in development that undergo M&A are nearly twice as likely to launch as non-acquired ones.
- Novel drugs which undergo M&A are over three times more likely to launch than non-acquired ones. Novel drugs are defined as those that received an expedited review designation from the FDA, which recognizes drugs that could “fill an unmet medical need” or “demonstrate substantial improvement over available therapy.”
- Even after controlling for drug candidate and firm characteristics, there remains a large, positive, statistically significant association between M&A and new and novel drug launches.

The same research compared drugs in development which undergo M&A with a large firm (defined as those with prior experience launching a drug) to those that undergo M&A with another small firm (defined as those with no prior experience launching a drug). Drugs in development which undergo large-small firm M&A are:

- Nearly three times more likely to launch and five times more likely to launch as novel drugs, and
- Nearly 24 times more likely to launch with a new mechanism of action — representing an entirely new way of treating a disease.

The research also demonstrates that when an acquiring firm has more experience, there is a greater likelihood that an acquired drug in development will launch.

- Drugs in development are nearly twice as likely to launch, and three times as likely to launch as novel drugs when they are acquired by a firm with experience developing at least 17 drug projects, compared to when they are acquired by a firm with less experience.
- Among drug projects that are acquired within the first three years of development, when scientific uncertainty is high, those that are acquired by a large firm are 2.4 times more likely to launch, and nearly 6 times as likely to launch as novel drugs, relative to drug projects acquired by a small firm.

These data underscore why M&A is essential in the life sciences, especially when considering the significant challenges that companies must overcome:

- Bringing a single drug to market can take 10-15 years and cost more than \$2.6 billion.³
- Approximately 80% of biopharmaceutical companies operate without a profit.⁴

² Concurrences, *An Empirical Study of the Impact of Mergers and Acquisitions on Pharmaceutical Innovation* (2025), <https://www.concurrences.com/en/review/issues/no-10-2025/droit-economie/an-empirical-study-of-the-impact-of-mergers-and-acquisitions-on-pharmaceutical>

³ Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20 (Mar. 2016), <https://pubmed.ncbi.nlm.nih.gov/26928437/>

⁴ Toptal, *Biotech Valuation: A Guide for Investors* (2019), <https://www.toptal.com/management-consultants/valuation/biotech-valuation>

- Drug development is an inherently speculative endeavor, with early-stage discoveries often possessing broad potential indications that shift throughout the development process.⁵

Accordingly, in this comment, PULSE encourages the FTC and DOJ to advance a balanced and targeted approach to premerger reporting requirements – one that balances premerger screening that are known to be effective while avoiding unnecessary burdens for the pro-competitive deals that drive American innovation, competition and patient access to life-saving treatments.

II. Future HSR Rulemaking Should Reduce Unnecessary Burdens for America’s Life Sciences Ecosystem

We are encouraged to see that the agencies’ RFI acknowledges the need to ensure that updates to the HSR form reduce undue burdens for pro-competitive transactions. It is critical that any future HSR rulemaking be true to the law’s core purpose: to serve as an efficient screening mechanism to help the agencies identify transactions that may warrant further review.

The fact is that the overwhelming majority of reported transactions do not require an in-depth investigation beyond initial screening.⁶ As a result, premerger reporting requirements should be appropriately calibrated to enable review without imposing unnecessary burdens, delays or speculative analytical requirements on transactions that are unlikely to raise competitive concerns.

As we highlighted in our comments to the DOJ/FTC’s Anticompetitive Regulations Task Force,⁷ the revised HSR form issued in November 2024 included several requirements that significantly increased the time, cost and complexity associated with preparing HSR filings – regardless of a transaction’s likely impact on competition. Indeed, by the FTC’s own estimates, the reporting requirements in the rule increased the time needed to complete required merger filings by an average of 68 hours, and up to 121 hours for nearly half of merger filings.⁸ The U.S. Chamber of Commerce further projected the cost of this increased reporting burden to be \$250 million annually.⁹

In the life sciences, the impact of these time and cost burdens must not be overlooked. Against the significant challenges and pressures inherent to life sciences innovation, such policies that needlessly delay pro-competitive transactions have significant ripple effects: eroded investment incentives, disruptions in the path to launch and, ultimately, slowed or stalled development of new treatments and cures for patients. These impacts are felt even more strongly for small and

⁵ Simon-Kucher, *Strategic Indication Selection in Early-Stage Drug Development to Maximize a Drug’s Lifetime Value*(2022), <https://www.simon-kucher.com/en/insights/strategic-indication-selection-early-stage-drug-development-maximize-drugs-lifetime-value>

⁶ Federal Trade Commission & U.S. Department of Justice. (2025). *Hart-Scott-Rodino annual report: Fiscal year 2024* (Report to Congress). https://www.ftc.gov/system/files/ftc_gov/pdf/FY24-HSR-ANNUAL-REPORT-FOR-TRANSMITTAL-TO-CONGRESS.pdf

⁷ Partnership for the U.S. Life Sciences Ecosystem (PULSE), *PULSE Comments to DOJ Anticompetitive Regulations Task Force* (2025), <https://pulseforinnovation.org/wp-content/uploads/2025/06/PULSE-Comment-to-DOJ-Anticompetitive-Regulations-Task-Force.pdf>.

⁸ 89 FR 89216 (November 12, 2024), <https://www.federalregister.gov/d/2024-25024/page-89216>

⁹ Compl. p. 64, *Chamber of Commerce of the United States et al v. Federal Trade Commission*, No. 6:25-cv-00009-JDK (May 8, 2025).

early-stage companies that must invest in significant legal resources needed to meet HSR reporting requirements. Therefore, it is critical that any updated rule avoids imposing requirements that risk delaying or deterring pro-competitive M&A in the life sciences.

Specifically, PULSE urges the agencies not to move forward or adopt the following provisions in any updated rule:

1. Required Narrative Descriptions

The agencies should avoid any requirement for companies to provide detailed narrative responses, including, but not limited to, descriptions of competitive effects, potential overlaps, deal rationale or market dynamics as part of the initial HSR filing.

As noted above, the HSR process is intended to function as a screening tool. Required narrative descriptions distort this purpose by front-loading the burden of a more substantive inquiry on merging parties, even for pro-competitive deals.

For the life sciences industry, given the inherent uncertainty of R&D, particularly for early-stage assets, any description of the *future* competitive impact of a transaction is necessarily speculative. As a result, despite the burden they impose, these narratives are of little to no practical value to the agencies in the context of the life sciences.

2. Expansion of Potential Competition and Pipeline Disclosures

The agencies should avoid imposing broad reporting requirements related to pipeline products, early-stage research programs or competitive overlaps that *could theoretically* exist in the future.

In life sciences, pipeline assets are highly uncertain and often never reach the market. Products that may initially appear related can ultimately diverge significantly in mechanism of action, patient population, indication or therapeutic application as development progresses. As a result, broad pipeline reporting requirements risk overstating competitive concerns when the future commercial market for an asset is uncertain – and, in some cases, may not be known for a decade or more.

Particularly for life sciences companies that have numerous early-stage assets in their portfolios, a requirement to theorize on future competitive impact is at best impractical and, at worst, unfeasible without taking an overly expansive, defensive and speculative approach to pipeline disclosures in order to avoid regulatory scrutiny.

3. Broad Overlap Definitions that Mischaracterize Innovation

Any updated rule should avoid establishing overlap triggers that treat loosely related R&D efforts as competitive overlaps, including through the use of NAICS codes.

In the life sciences, these overlap definitions fundamentally misrepresent the scientific complexity and risk of life sciences R&D. NAICS codes include broad categories (e.g., research & development in biotechnology; pharmaceutical and medicine manufacturing)¹⁰

¹⁰ Office of Management and Budget, *North American Industry Classification System (2022)*, https://www.census.gov/naics/reference_files_tools/2022_NAICS_Manual.pdf

that do not differentiate between the highly specialized focus areas of many life sciences companies. As a result, overlap definitions based on these codes may identify an overlap where none exists, between companies focused on entirely different disease states, treatment modalities and/or mechanisms of action. As stated above, a company's pipeline is often a poor indicator of future competitive overlaps given the uncertainty of life sciences R&D – making any effort to identify overlap based on pipeline assets highly speculative and of little practical value.

4. Expanded Reporting Around Prior Transactions

Any updated rule should avoid expanding the requirement to report on past acquisitions beyond the current 5-year lookback window, and should avoid including exclusive licensing agreements (ELAs) as reportable past transactions.

In the life sciences, firms often pursue multiple acquisitions and licensing agreements for the express purpose of connecting promising therapies with the resources, expertise and investment needed to bring them to market. Indeed, the risk, complexity and extended time horizon of life sciences R&D often mean that a company will engage in multiple transactions at different stages of development, just to bring one new therapy to patients.

These deals are not only pro-competitive, but they also often represent the only chance of ensuring that new treatments and cures reach the patients who need them. Overly expansive past acquisition reporting requirements would risk aggregating these pro-competitive and scientifically and commercially distinct transactions into a misleading pattern of competitive harm. Moreover, any inclusion of ELA as reportable past transactions will further mischaracterize these plainly pro-competitive transactions as anti-competitive patterns; therefore, ELAs should not be treated as reportable past transactions.

5. Any Shift of the Burden to Parties to Disprove Harm

The agencies should avoid any requirement that effectively forces merging parties to affirmatively demonstrate the absence of competitive harm or provide substantive economic justifications for a proposed transaction at the filing stage.

PULSE strongly maintains that the HSR process is intended to facilitate efficient initial review, with more detailed substantive analysis occurring only where necessary through the established Second Request process. Requiring parties to provide affirmative competitive analyses at filing would fundamentally alter that framework and impose substantial burdens, even though the overwhelming majority of transactions do not raise competitive concerns.

This approach is particularly problematic in the life sciences, where additional burden or uncertainty for pro-competitive transactions can meaningfully deter investment in new therapies and obstruct a critical pathway for companies to bring new medicines to market. The future HSR framework must not a priori conclude that these transactions are anti-competitive when empirical data, as described above, clearly demonstrates the pro-competitive benefits of life sciences M&A.

III. Future HSR Rulemaking Should Support Life Sciences Innovation and Competition

PULSE appreciates the agencies' focus on ensuring that future updates to the HSR framework streamline the process for pro-competitive transactions, while ensuring that the agencies can efficiently collect the information that will meaningfully help them to assess proposed transactions. An improved and updated form that reflects the unique market dynamics of innovative industries would have substantive and significant benefits to innovation, investment and competition in the life sciences, and support America's continued global leadership.

To that end, PULSE encourages the agencies to prioritize the following principles as part of any future rulemaking process:

1. HSR's Role as a Screening Tool

Any updated rule should ensure that the HSR process remains focused on its core statutory purpose: facilitating efficient initial review of transactions that may warrant further investigation, rather than requiring merging parties to conduct an extensive, front-loaded merits analysis as part of the initial filing.

As noted above, the overwhelming majority of HSR-reportable transactions do not raise competitive concerns or result in enforcement action.¹¹ Requiring parties to provide extensive competitive analyses, speculative market assessments or detailed substantive narratives at the filing stage would fundamentally alter the nature of the HSR process and impose substantial burdens on plainly pro-competitive transactions.

This concern is particularly significant in the life sciences, where requiring detailed upfront assessments often produces speculation rather than useful screening information, due to scientific and commercial uncertainty described above. The agencies already retain robust investigatory tools, including the ability to issue Second Requests where additional information is necessary to evaluate potential competitive concerns.

2. Revisit Scope of Required Document Reporting

The antitrust authorities should use this opportunity to streamline the existing document requests under Items 4(c) and Item 4(d) to those documents actually relied on by companies in analyzing or evaluating the proposed transaction. Today, companies are often required to include documents in their HSR filings that are sent blindly by third parties to officers or directors that may discuss a potential transaction in the context of relevant topics, but were never actually used by the company to evaluate the transaction. Replacing the language "prepared by or for" with "used by" would limit the universe of documents included with the HSR filing only to those that companies actually relied on when deciding whether to pursue a potential transaction. This modification would ensure that the companies are obligated to produce only the most relevant materials and avoid undue burdens on filers.

In the life sciences industry, where closing delays can have a significant impact on the development of innovative medicines, the additional time required to prepare an HSR filing can have significant negative consequences in addition to the cost and burden associated with

¹¹ Federal Trade Commission & U.S. Department of Justice. (2025). *Hart-Scott-Rodino annual report: Fiscal year 2024*(Report to Congress). https://www.ftc.gov/system/files/ftc_gov/pdf/FY24-HSR-ANNUAL-REPORT-FOR-TRANSMITTAL-TO-CONGRESS.pdf

the collection, review and production of documents under pre-2025 Item 4(c) and Item 4(d) obligations.

The Updated Form issued in 2024 compounded those challenges by adding, not only an additional recipient (the Supervisory Deal Team Lead) but also additional categories of documents, so-called “Plans and Reports.” Unlike those documents related to the transaction, Plans and Reports are not typically compiled by a company when evaluating a transaction and require broad and labor-intensive searches to collect them for the purpose of an HSR filing. Such Plans and Reports also will often contain many sensitive topics, not relevant to the transaction or the antitrust authorities’ investigation. Rather than a “one size fits all” approach to Plans and Reports, such document requests are better left for investigative staff that can craft appropriately tailored requests that they believe will actually inform their investigation – rather than the broad Plans and Reports requests as required by the Updated Form.

3. Prioritize Clear and Predictable Standards

Any future HSR framework should provide clear, workable and administrable standards that companies can reliably apply in practice. Ambiguous or overly subjective standards can create substantial unpredictability regarding filing obligations, timing and regulatory risk – ultimately discouraging beneficial investment and collaboration. Accordingly, the agencies should seek to ensure that future guidance:

- Avoids vague or subjective standards that invite inconsistent interpretation;
- Provides practical and administrable rules that companies can apply with confidence; and
- Reflects the distinct realities of innovation-driven industries, including the uncertainty and evolving nature of life sciences R&D.

In the life sciences industry, companies routinely structure collaborations, licensing arrangements and investment decisions across long development timelines characterized by significant scientific and commercial uncertainty. Therefore, clear and predictable standards are critical to preserve the investment environment necessary to support continued life sciences innovation in the U.S. Such standards are particularly important where filing obligations depend on subjective assessments of future overlaps or evolving R&D markets.

4. Prioritize Speed and Reliability in the Review Process

Any future revisions to the HSR framework should preserve a filing process that supports a timely transaction review (~30-day notification period) and minimizes unnecessary uncertainty for merging parties.

In life sciences, transactions frequently occur at pivotal moments when emerging companies need timely access to resources such as financing, clinical development support, manufacturing capacity and commercialization expertise. Delays associated with unnecessarily burdensome filing requirements can therefore have meaningful ripple effects on innovation and investment. Such delays also add significant and unnecessary regulatory uncertainty to the parties in a transaction, as well as key external stakeholders such as investors.

Maintaining an efficient review timeline for transactions that do not raise competitive concerns will also allow the agencies to focus their limited resources on transactions that may warrant closer scrutiny while preserving the predictability necessary for companies to pursue pro-competitive transactions and partnerships.

5. Preserve Early Termination for Clearly Pro-Competitive Transaction

The agencies should preserve Early Termination as a pathway for transactions where the initial HSR filing demonstrates that no further competitive review is necessary.

Early termination has historically served as an important mechanism for reducing unnecessary delay and uncertainty for transactions that do not raise competitive concerns. Preserving this process is particularly important in the life sciences industry, where prolonged uncertainty surrounding transaction timing can disrupt financing, research and commercialization efforts, as discussed above.

Early termination also promotes more efficient allocation of agency resources by allowing the agencies to focus investigative efforts on the relatively small number of transactions that may require additional scrutiny.

6. Consider Updated Treatment of Exclusive Licensing Agreements

As part of any future review of the HSR framework, the agencies should revisit the reporting requirements for pharmaceutical ELAs.

Pharmaceutical ELAs are frequently used to facilitate the development and commercialization of innovative therapies by enabling companies to combine complementary expertise, capital, manufacturing capacity and commercialization capabilities. Many exclusive licensing arrangements are collaborative and developmental in nature, rather than transactions involving consolidation of existing commercial competitors. These arrangements often serve pro-competitive and innovation-enhancing purposes, particularly where smaller firms lack the resources necessary to independently develop and commercialize a product.

Nonetheless, there has been an industry-specific requirement for life sciences companies to report ELAs via the HSR form since 2013 – a 13-year period during which we are aware of only one enforcement action against a proposed licensing deal out of dozens, if not hundreds, completed each year. In light of the burden created by this requirement – and the limited enforcement value it provides – we recommend reverting to the pre-2013 framework that excluded pharmaceutical ELAs from required reporting.

7. Clarify Required Reporting on Foreign Subsidies & Covered Nations Products

PULSE encourages the FTC and DOJ to adopt clear, administrable definitions that limit reporting obligations to subsidies and foreign relationships that are commercially significant and relevant to the agencies' competitive analysis of a transaction.

While PULSE recognizes the statutory obligation under the Merger Filing Fee Modernization Act of 2022 to collect certain information regarding foreign subsidies, the law currently does not fully define the term “subsidy” – serving as a source of significant uncertainty for filing parties.

Further, the requirements to report on products produced, in whole or in part, by “covered nations” – as included in the 2024 HSR rule – failed to account for the highly global and interconnected nature of the life sciences supply chain. American leadership in the life sciences increasingly relies on companies competing in a global marketplace, with complex networks of suppliers, manufacturers, research collaborators and other third-party partners across multiple jurisdictions. As a result, supply relationships are often dynamic, multi-tiered and not easily ascertainable through available business records – making comprehensive reporting operationally burdensome.

Accordingly, PULSE encourages the FTC and DOJ to clarify these requirements as part of any future updates.

IV. Conclusion

PULSE appreciates the opportunity to provide input on potential updates to the HSR premerger notification framework.

As our comments have highlighted, America’s global leadership in the life sciences is fueled in no small part by the many pro-competitive partnerships between researchers, academics and life sciences companies of all sizes. Ensuring that any future updates to the HSR form reflect this reality and the recommendations noted above are critical to ensure that America’s life sciences ecosystem remains the most innovative and competitive in the world.

We thank you for your attention to this important issue and look forward to continuing to work with the agencies as part of potential future rulemaking. Please do not hesitate to reach out if we can provide additional information, input or clarification.

Sincerely,

Partnership for the U.S. Life Science Ecosystem (PULSE)

