Response to OMB RFI on Deregulatory Recommendations – Docket No. OMB-2025-0003

Submitted by: Partnership for the U.S. Life Science Ecosystem (PULSE)
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The Honorable Russell Vought
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The Partnership for the U.S. Life Science Ecosystem (PULSE) appreciates the opportunity to submit these comments in response to the Office of Management and Budget's (OMB) request for information (RFI) issued on April 11, 2025. We strongly support the OMB's efforts to examine regulations that are stifling American innovation and burdening American businesses.

The Unique and Fundamental Role of Life Sciences M&A

PULSE's members represent frontline researchers, employees and leaders of life sciences companies of all sizes that support a diverse, vibrant life sciences ecosystem at the national level and in local communities. We are focused on promoting and supporting the unique and vital role that pro-competitive mergers and acquisitions (M&A) and other collaborations play in sustaining America's leadership in biomedical innovation.

Breakthrough treatments and cures are rarely the work of one actor alone. Rather, they are often the result of a collaborative process, where early-stage biotechnology firms advance promising research and development (R&D), investors contribute significant funding against high risks and more established companies contribute the substantial regulatory expertise, technical capabilities and infrastructure needed to bring medicines to patients at scale. By ensuring a broad and efficient allocation of resources and investment across the life sciences ecosystem, pro-competitive M&A is the lifeblood of that process.

Life sciences M&A uniquely allows companies of all sizes to specialize in what they do best, and partner to combine complementary capabilities and advance new medicines from the lab to patients. It's why we support fair and balanced antitrust enforcement and believe that the policies supporting our competitive markets should foster – rather than undermine – the unique dynamics of the life sciences ecosystem.

However, we are concerned that the recently finalized changes to the Hart-Scott-Rodino (HSR) premerger notification requirements are imposing an excessive and unnecessary burden on America's life sciences ecosystem. Our recommendations are designed to help the HSR requirements better recognize and reflect the unique market realities of the life sciences industry and support America's leadership in bringing new medical breakthroughs to patients in need.

The U.S. life sciences ecosystem is not just a driver of innovation, it is a cornerstone of our national competitiveness. America leads the world in new drug development and biopharmaceutical exports, thanks in large part to a dynamic ecosystem that rewards early-stage risk-taking and facilitates downstream collaboration. This ecosystem includes more than 2,300 biopharmaceutical companies across every U.S. state,[1] with hundreds more starting every year,[2] advancing over 8,000 potential new treatments and cures across a wide range of diseases.[3] Pharmaceutical manufacturers directly employ an estimated 291,000 U.S. workers and indirectly support an additional 1.5 million jobs across the country.[4] Per employee, the biopharmaceutical industry contributes more to America's economy than the average of all other industries.[5]

However, this leadership is not guaranteed. Biomedical innovation is becoming more and more of a global race as U.S. companies compete with firms from abroad to develop the next generation of treatments, as asserted by the National Security Commission on Emerging Biotechnology's April 2025 report to Congress.[6] Flawed merger enforcement policies risk undermining the world-class U.S. life sciences ecosystem by chilling investment, pushing away talent and even leading U.S.-based startups to relocate to other jurisdictions.

Without clear and efficient merger review regulations, we risk losing both a vital economic engine and our global leadership in developing life-saving treatments. We thank the OMB for its leadership in launching this important RFI and stand ready to support its work to reduce barriers to American innovation and dynamism.

Reconsider the HSR Requirements to Promote Predictability and Efficiency

As the OMB evaluates opportunities for reform, we urge reconsideration of the recent changes to the HSR premerger notification process. The final rule issued by the Federal Trade Commission (FTC) in October 2024 imposes a significant burden on the life sciences industry, and particularly for early-stage companies, while doing very little to enhance competitive outcomes.

As PULSE and other leading stakeholders have emphasized, the final HSR rule nearly doubles the time and cost burden of completing required premerger filings. Importantly, this burden applies broadly to all proposed mergers, despite the FTC's own data showing that 98% of mergers pose no risk to competition.[7] In the life sciences industry, this rule threatens to impede a critical pathway to bring new treatments to market and chill investment in the next generation of medicines.

Specifically, PULSE supports efforts to revisit the HSR requirements through new rulemaking that addresses the following issues:

1. Narrative Descriptions of Actual and Potential Competitive Overlaps:

We recommend that the HSR rule be revisited to ensure that it:

- Reflects input from the businesses and legal practitioners who use the HSR form;
- Provides clear, objective standards for the narrative, document and disclosure requirements it imposes;
- Corrects the overly broad scope of potential competitive overlaps, including overlapping North American Industry Classification System (NAICS) codes as indicative of a potential competitive overlap and thus requiring further disclosures; and

- Provides transparent guardrails for "potential competition" given the highly speculative and nonlinear process of life sciences R&D.

There is a new requirement in the HSR rule to provide narrative descriptions of actual and potential overlaps with a merging or acquired company. This would be particularly burdensome on the biopharmaceutical industry, where it can take over a decade to bring a new treatment or cure to market – during which the target indications for a potential therapy often evolve, and more than 90% of therapies ultimately stall.[8] This uniquely nonlinear journey from the lab to the patient means that products in preclinical or early clinical stages may or may not ultimately compete – making the requirement to assess potential overlap among these assets extremely challenging.

Under the final HSR rule, overlapping NAICS codes are an initial trigger that requires further disclosures. However, NAICS codes are very broad and often do not signify a competitive overlap in any relevant market, particularly given the increasingly differentiated therapies being developed in the life sciences, and even within specific therapeutic areas. FTC guidance is also vague on how early is too early for an asset to be "potentially overlapping," and does not define whether off-label prescribing constitutes a competitive overlap. These issues leave companies in a defensive posture, forced to over-disclose. For example, even if neither merging party has a commercial product, if both parties have the same NAICS code and/or pipeline assets that could compete, even if decades down the road, the parties would be required to submit extensive narrative disclosures on the so-called overlap.

2. Expanded Scope of Prior Acquisitions that Must Be Reported:

We recommend that the HSR rule be revisited to ensure that it:

- Revises the scope of prior acquisitions of competing or potential competing products that must be reported by both merging parties to exclude licensing agreements.

The HSR rule expands the scope of reportable prior acquisitions to include competing or potentially competing products. Previously, it just included acquisitions of entities classified with a NAICS code (e.g., a small biotech firm). For the biopharmaceutical industry, this means that previous licensing agreements are now considered reportable prior acquisitions, where they previously would not have been required to be reported on.

Since both acquiring and acquired parties must now report on prior acquisition and licensing agreements, smaller, pre-profit and early-stage companies (which are often less familiar or experienced with completing the HSR form) will face new burdens, potentially slowing or complicating their ability to engage in the pro-competitive M&A deals that are critical to advancing their pipeline.

3. Exclusive Licensing Agreements Are HSR-Reportable Transactions in the U.S., Unlike in Other Countries:

We recommend that the HSR rule be revisited to ensure that it:

- Reduces the reporting burden on exclusive licensing agreements in the life sciences – in line with requirements in most nations around the world.

The FTC requires HSR premerger reporting for exclusive license agreements (ELAs) – a requirement that pre-dates the recent HSR rule. ELAs are generally exempt from premerger reporting obligations outside the U.S., with the exception of Germany and Austria (which have narrower requirements for when an ELA triggers a reporting requirement).

Most ELAs involve preclinical and early-stage assets that will now be subject to the same increased burden from the new HSR rule. This burden risks deterring ELAs due to the significant added administrative burden, time and costs needed to fulfill reporting requirements, potentially stopping new, early-stage innovations in their tracks. One potential solution would be to allow ELAs to qualify for a short form version of the HSR form, or to exempt certain ELAs from reporting altogether, consistent with the standard in most other countries.

4. Final Rule Opens the Door to Political Influence and Enforcement Discretion:

We recommend that the HSR rule be revisited to ensure that it:

- Remains aligned with FTC Premerger Notification Office (PNO) guidance to ensure predictable and uniform administration of the law.

The enforcement of the HSR premerger notification requirements falls under the FTC's Premerger Notification Office (PNO), and its approach may vary from administration to administration. Under an FTC that prioritizes economic realities over ideologies, and aims to avoid unnecessary regulatory burdens for businesses, the rules might be enforced consistently and predictably. However, if an administration or agency leadership were driven by anti-M&A ideology, enforcement could become more aggressive and politicized. This could include demands for highly detailed competitive overlap narratives, or an overly expansive interpretation of "potential competitive overlaps" that does not align with the realities of biopharmaceutical innovation and development.

A Shared Commitment to Innovation, Competition and Patient Impact

PULSE commends the OMB for examining regulations that stifle American businesses and ingenuity. In the life sciences sector, removing regulatory barriers and promoting pro-competitive partnerships is not just pro-business, it is pro-patient. By reducing the unnecessary burden of the HSR requirements, we can ensure that America's life sciences ecosystem remains the most dynamic and innovative in the world, delivering cures to patients and bolstering our nation's economy.

Thank you for your leadership on this important issue and for considering our perspective. We look forward to continued engagement as the process moves forward and welcome you to reach out if we can provide further information.

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

PULSE
PARTNERSHIP FOR THE
US LIFE SCIENCE ECOSYSTEM

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