Comment on DOJ Anticompetitive Regulations Task Force – Docket No. ATR-2025-0001

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 submit these comments in response to the Department of Justice (DOJ)'s March 27, 2025, announcement of the Anticompetitive Regulations Task Force. We strongly support the Administration's efforts to support a more competitive, dynamic health care market and its focus on addressing regulations that undermine that core goal.

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. Pro-competitive M&A is the lifeblood of that process as it ensures a broad and efficient allocation of resources and investment across the life sciences ecosystem. 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 policies like the recently finalized changes to the Hart-Scott-Rodino (HSR) premerger notification requirements and the 2023 Merger Guidelines fail to account for the overwhelmingly pro-competitive role of M&A in the life sciences. Additionally, we urge the Department to remain vigilant as states consider new, state-specific standards of competition and premerger review processes, which could result in inconsistent requirements across state lines.

Our recommendations are designed to help the Task Force better recognize the unique market realities of the life sciences industry and ensure that antitrust policies continue to sustain 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.

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.[1] Flawed merger enforcement policies in the U.S. risk undermining the world-class life sciences ecosystem by chilling investment, pushing away talent and even leading U.S.-based startups to relocate to other jurisdictions.

Without clear and supportive competition standards, we risk losing both a vital economic engine and our global leadership in developing life-saving treatments. To maintain our edge, the U.S. must continue to support predictable, pro-innovation merger enforcement policies that have made the U.S. life sciences sector the most productive in the world.

We thank the Department for its leadership in launching this important initiative and stand ready to support the Task Force as it continues its work.

I. Promoting Competition and Investment Will Strengthen the U.S. Life Sciences Ecosystem

The United States stands as a global leader in the life sciences, driving medical breakthroughs and public health advancements for decades. America is home to more than 2,300 biopharmaceutical companies across every U.S. state, with hundreds more starting up every year.[2] Together, the industry is actively advancing over 8,000 potential new treatments and cures across a wide range of disease areas.[3] M&A fuels competition and innovation among companies of all sizes within this dynamic ecosystem, which is unique within the broader health care system.

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[1] National Security Commission on Emerging Biotechnology, *Final Report: Recommendations to Strengthen U.S. Leadership in Biotechnology*, Apr. 2025, https://www.biotech.senate.gov/final-report/chapters/recommendations/.

[2] Citeline. 2023. Pharma R&D Annual Review April 2023. https://www.citeline.com/-/media/citeline/resources/pdf/citeline-rd-review-white-paper.pdf. Booth, B. 2022. Life Sci VC. https://lifescivc.com/2022/04/biotechs-january-chill-big-drop-in-new-startups/; Armstrong, A. 2022. We have achieved peak biotech formation. It's time for 'musical chairs.' FierceBiotech. https://www.fiercebiotech.com/biotech/too-many-biotechs-musical-chairs-startup-funding-venture-capital.

[3] PhRMA. Research and Development Policy Framework. https://phrma.org/policy-issues/research-development.

Developing a new medicine is extraordinarily expensive and risky. On average, it can cost over $2.6 billion and take more than a decade to bring a single new therapy from the lab to the patient.[4] Even then, over 90% of drug candidates fail during clinical development.[5] Few other industries face such daunting R&D timelines and failure rates.

These inherent headwinds mean innovators must invest enormous resources with a low rate of success, creating a uniquely high-risk environment for innovation. Against these odds, more than 80% of U.S. life sciences companies operate without turning a profit.[6] Many are small, venture-backed startups that rely heavily on private investment. This investment is often driven and incentivized by the prospect of future M&A.

The scale of life sciences R&D activity and the economic contributions driven by this dynamic ecosystem are substantial, as highlighted by recent data:

- **R&D Investment:** The U.S. biopharmaceutical industry invested over $102 billion in R&D in 2021, and it reinvests in R&D at more than 3.5 times the rate of the average industry.[7] This makes the life sciences one of the most R&D-intensive sectors of the economy.[8]
- **High-Quality Jobs:** The life sciences ecosystem is a major contributor to high-paying American jobs. Pharmaceutical manufacturers directly employ roughly 291,000 U.S. workers and indirectly support an additional 1.5 million jobs across every U.S. state.[9] Per employee, the biopharmaceutical industry contributes more to America's economy than the average of all other industries.[10]
- **Economic Impact:** In 2021, pharmaceutical manufacturers contributed approximately $355 billion in value-added output to the U.S. economy.[11] This included about $192 billion in direct GDP contribution from the sector, a 24% increase over the previous two years, growth that underscores the sector's role as a key engine for U.S. economic growth.

Robust investment and innovation in the life sciences not only lead to new biomedical advances but also stimulate domestic manufacturing and boost U.S. economic growth.[12]

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[4] 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 (2016), https://doi.org/10.1016/j.jhealeco.2016.01.012.
[5] Asher Mullard, *Parsing Clinical Success Rates*, 15 *Nat. Rev. Drug Discov.* 447 (2016), https://doi.org/10.1038/nrd.2016.136.
[6] Rottgen, R. Biotech Valuation Idiosyncrasies and Best Practices. https://www.toptal.com/finance/valuation/biotech-valuation.
[7] National Association of Manufacturers, *Creating Cures, Saving Lives: The Urgency of Strengthening U.S. Pharmaceutical Manufacturing* (2024), https://documents.nam.org/COMM/NAM-Creating%20Cures,%20Saving%20Lives_FINAL3.pdf.
[8] Ibid.
[9] Ibid.
[10] Pham, N. 2025. The Economic Performance of IP-Intensive Manufacturing and Service Industries in the United States, 2012-22. NDP Analytics. https://ndpanalytics.com/the-economic-performance-of-ip-intensive-manufacturing-and-service-industries-in-the-united-states-2012-22/.
[11] Ibid.
[12] Ibid.

Policies that incentivize, rather than deter, pro-competitive M&A activity will strengthen the U.S. life sciences ecosystem to the benefit of patients and the economy alike.

II. Life Sciences M&A Fuels Innovation and Competition

M&A plays a differentiated role in America's life sciences industry and is fundamentally about improving a company's chance of successfully bringing a new treatment or cure to patients. Life sciences M&A is also unique compared to M&A within the broader health care system.

For many early-stage firms, many of which operate without profit, it would be inefficient or prohibitively expensive to develop the in-house infrastructure needed to complete late-stage clinical trials, secure regulatory approval, and manufacture and distribute a new medicine at scale. Instead, drug development often functions like a relay race, with M&A allowing early-stage companies to "pass the baton" and connect promising discoveries with the infrastructure of larger, more established companies, accelerating their journey from lab to patient.[13]

Indeed, many of today's most important treatments and cures – including for rare genetic conditions, heart disease, cancers, and more – have reached patients through a merger or acquisition that helped connect early-stage innovation with the infrastructure and capabilities needed to complete later-stage R&D and manufacturing (see Appendix A).

Leading experts have long recognized this crucial market reality. The Congressional Budget Office, for example, has asserted, "In making [an] acquisition, a large company might bring a drug to market more quickly than a small company could have, or might distribute it more widely."[14] A 2024 review by Cornerstone Research also found that pharmaceutical M&A enhances innovation by creating economies of scale and scope, enabling the transfer of complementary assets, increasing access to capital for small firms, and optimizing R&D resource allocation.[15]

Pro-innovation M&A also helps ensure that promising breakthroughs are not left behind due to financial constraints. As noted above, the possibility of a future acquisition represents an important exit pathway for investors, driving investment in early-stage research.

Venture capital leaders have increasingly cautioned that an approach to M&A enforcement that creates uncertainty for investors risks "leaving startups with fewer exit

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[13] John Stanford, Executive Director, Incubate Coalition, *Life Science M&A: Supporting the Next Generation of Biopharma Breakthroughs* (PULSE webinar, Dec. 12, 2023), https://www.youtube.com/watch?v=2CzUDtx8akA.

[14] Congressional Budget Office, Research and Development in the Pharmaceutical Industry (Apr. 2021), https://www.cbo.gov/publication/57126.

[15] Lorenzo Cattivelli, Anca Cojoc, Penka Kovacheva & Maria Salgado, *The Impact of Pharmaceutical M&A on Innovation*, 3 *Concurrences: Law & Economics* (2024), https://www.cornerstone.com/insights/articles/the-impact-of-pharmaceutical-ma-on-innovation/.

options and making it harder for VCs to invest in innovative new ideas."[16] Indeed, recent data suggest that the climate for biotech financing is cooling as bioscience sector venture investments dropped by 49% since 2021, coinciding with investor concerns over regulatory intervention in M&A.[17] Such outcomes ultimately harm patients, as promising breakthroughs may languish for lack of funding or partner support. In fact, recent analyses suggest that up to $18 billion in annual venture funding and $152 billion in broader biopharma investment could be at risk if the M&A environment becomes too uncertain.[18] These are not theoretical losses, but represent real companies, real treatments, and real patients.

When regulatory policy discourages legitimate acquisition activity, innovation can stall or disappear entirely. PULSE is encouraged that the Task Force is seeking input and hopes the life sciences industry's strong track record of advancing innovation through M&A will help shape a thoughtful and balanced approach.

III. Reconsidering Regulatory Barriers Can Strengthen Competition and Innovation

As the DOJ works to identify existing regulations that unnecessarily hinder competition, we encourage the Anticompetitive Regulations Task Force to closely examine how recent federal and state developments in merger review policy have created uncertainty and unintended barriers for innovation in America's life sciences industry.

Reconsider the HSR Requirements to Promote Predictability

As the DOJ evaluates opportunities for reform, we urge reconsideration of the recent changes to the HSR premerger notification process. The final rule issued in October 2024 imposes a significant burden on the life sciences industry, 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 Federal Trade Commission (FTC)'s own data showing that 98% of mergers pose no risk to competition.[19] In the life sciences industry, this rule threatens to impede a critical

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[16] Bobby Franklin, President, National Venture Capital Association, quoted in Dan Primack, *VCs Still Struggle to Close Deals*, Axios (Oct. 11, 2024), https://www.axios.com/2024/10/11/venture-capital-deal-slow-liquidity.

[17] TEConomy, BIO. The U.S. Bioscience Economy (2024). https://bio.widen.net/s/hflmb92hwx/the-us-bioscience-economy-driving-economic-growth-and-opportunities-in-states-and-regions.

[18] Jeffrey A. Sonnenfeld & Steven Tian, *The FTC's Antitrust Overreach Is Hurting U.S. Competitiveness and Destroying Value*, Yale Insights (Dec. 13, 2023), https://insights.som.yale.edu/insights/the-ftcs-antitrust-overreach-is-hurting-us-competitiveness-and-destroying-value.

[19] Federal Trade Commission & U.S. Department of Justice, *Hart-Scott-Rodino Annual Report for Fiscal Year 2023* (Oct. 9, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/fy2023hsrreport.pdf.

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:

1. Is fit for purpose based on input from the businesses and legal practitioners who use the HSR form.
2. Provides clear, objective standards for the narrative, document, and disclosure requirements it imposes;
3. Corrects the overly broad scope of potential competitive overlaps, including overlapping NAICS codes, as indicative of a potential competitive overlap and thus requiring further disclosures;
4. Provides clearer guardrails for "potential competition" given the highly speculative and nonlinear process of life sciences R&D;
5. Revises the scope of prior acquisitions of competing or potential competing products that must be reported by both merging parties to exclude licensing agreements;
6. Reduces the reporting burden on exclusive licensing agreements in the life sciences, in line with requirements in most nations around the world; and
7. Remains aligned with FTC Premerger Notification Office (PNO) guidance to ensure predictable and uniform administration of the law.

Ensuring Merger Guidelines Reflect the Realities of Life Sciences Innovation

As the DOJ assess opportunities to improve merger policy, we urge reconsideration of the FTC and DOJ's 2023 Merger Guidelines, particularly as they apply to the life sciences industry.[20] Although they do not hold the force of law, these new guidelines introduce new, unclear standards of competition that may be used to challenge a merger, including without empirical evidence of consumer harm in some cases.

We applaud the Trump Administration's goal of ensuring predictability in merger enforcement for companies and believe that this begins with guidelines that reflect the unique market dynamics in the life sciences.

We urge the DOJ to tailor the application of the Merger Guidelines to account for the realities of biopharmaceutical development, including long R&D timelines, high failure rates, and the essential role of collaboration across firms of varying size. Specifically, we would encourage the Agencies to consider the following changes:

1. Restore the consumer welfare standard as the benchmark for evaluating a proposed merger.
2. Reconsider the focus on nascent competition in guidelines 4 and 6.

[20] Federal Trade Commission & U.S. Department of Justice, *2023 Merger Guidelines* (Dec. 18, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/2023_merger_guidelines_final_12.18.2023.pdf.

3. Revise the emphasis on "serial acquisitions" and partial ownership/minority interests in guidelines 8 and 11, respectively.
4. More fully account for the pro-competitive effects of mergers and acquisitions, including driving increased efficiency and innovation.
5. Eliminate the structural presumption against deals that increase market concentration reflected in guidelines 1 and 7.
6. Clarify the definition of "coordination" in guideline 3 to exclude pro-competitive observation and response to rivals.
7. Revise the broadened definition of "relevant market" to reflect the increasingly differentiated products being developed in the life sciences.
8. Eliminate the highly speculative focus on potential future conduct by merging firms in guideline 6, and return to enforcement based on clear evidence of consumer harm.

Doing so would provide clarity and predictability for companies advancing life sciences innovation, while allowing enforcement efforts to focus on transactions that pose real and demonstrable harm to competition.

Avoiding a Patchwork of Divergent State-Level Antitrust Frameworks

Finally, we encourage continued engagement with state Attorneys General to avoid a fragmented approach to merger review. While state enforcement plays an important role in protecting local competition, emerging efforts to adopt state-level premerger notification regimes (or apply novel competition standards) risk creating a confusing and duplicative regulatory environment. This is especially true for companies engaged in transactions that span multiple jurisdictions.

Specifically, we are concerned that recent state-level proposals could result in a patchwork of reporting burdens, conflicting disclosure thresholds, and varied legal standards for assessing mergers, increasing transaction costs and regulatory uncertainty for merging parties. This complexity would be particularly disruptive for life sciences companies whose transactions often span multiple states and involve time-sensitive collaborations that are essential to advancing innovation and getting treatments to patients.

PULSE encourages federal and state authorities to collaborate on a coherent, harmonized enforcement approach that promotes competition while avoiding undue complexity for merging parties. A nationally consistent standard, applied with appropriate flexibility for industry-specific contexts, will better support innovation and ensure that enforcement efforts remain focused on protecting consumers and promoting market dynamism.

IV. Conclusion: A Shared Commitment to Innovation, Competition, and Patient Impact

PULSE commends the DOJ for launching the Anticompetitive Regulations Task Force and for examining how antitrust enforcement can better support free markets. In the life

sciences sector, removing regulatory barriers and promoting pro-competitive partnerships is not just pro-business, it is pro-patient.

PULSE shares your dedication to supporting competitive markets and fueling innovation and would be happy to serve as a resource as the Task Force develops its recommendations. By refining antitrust policy in the ways discussed above, 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

Appendix A – Life Sciences Innovations Advanced by M&A

The examples below are just a small sample of the many critical and life-saving therapies that have reached patients through pro-competitive life sciences M&A. As these examples illustrate, life sciences M&A is fundamentally about bringing together the investment, infrastructure, and operational capacity needed to transform a breakthrough scientific discovery into an approved medicine for patients.

- **The first gene therapy approved for inherited blindness** came after Roche's acquisition of Spark Therapeutics in 2019. Spark developed the therapy to treat biallelic RPE65 mutation-associated retinal dystrophy, but required greater global manufacturing and distribution capabilities to bring it to patients. Roche provided the necessary infrastructure and has continued to invest in Philadelphia-area infrastructure focused on developing new gene therapies, including for conditions like Hemophilia A and Pompe disease.[21]
- **The first FDA-approved therapy for chronic graft-versus-host disease (cGVHD)** was brought to patients worldwide through Kadmon's acquisition by Sanofi in 2021. Following the initial approval of Rezurock to treat cGVHD – a serious and often life-threatening complication of stem cell transplants – Kadmon's acquisition by Sanofi helped connect the new therapy with the infrastructure and expertise needed to expand its global reach, while continuing to drive investment in additional clinical research.[22]
- **The first treatment targeting the genetic cause of hypertrophic cardiomyopathy (HCM)** was made possible through the acquisition of MyoKardia by Bristol Myers Squibb (BMS). Mavacamten, the first FDA-approved therapy that directly targets the underlying cause of obstructive HCM, was discovered by MyoKardia, a company founded by the scientists who discovered the genetic basis of the disease. MyoKardia's subsequent acquisition by BMS helped connect this therapy with the resources and regulatory expertise needed to secure FDA approval in 2022 and continue to conduct research into additional cardiovascular indications.[23]
- **Two breakthrough therapies for rare, aggressive cancers** were brought to market through Eli Lilly's acquisition of Loxo Oncology in 2019. Loxo Oncology had pioneered Retevmo and Jaypirica, targeted treatments for cancers caused by rare genetic mutations, including non-small cell lung cancer and mantle cell lymphoma. Eli Lilly's acquisition provided the infrastructure, regulatory capabilities, and global reach needed to accelerate FDA approvals and expand patient access to these

[21] Partnership for the U.S. Life Science Ecosystem (PULSE), *Innovations Advanced by M&A: A Cure for Inherited Blindness* (Apr. 18, 2024), https://pulseforinnovation.org/innovations-advanced-by-ma-a-cure-for-inherited-blindness/.
[22] Partnership for the U.S. Life Science Ecosystem (PULSE), *Innovations Advanced by M&A: A First-in-Class Therapy for Chronic Graft-Versus-Host Disease* (Jan. 29, 2025), https://pulseforinnovation.org/innovations-advanced-by-ma-a-first-in-class-therapy-for-chronic-graft-versus-host-disease/.
[23] Partnership for the U.S. Life Science Ecosystem (PULSE), *Innovations Advanced by M&A: A First-In-Class Treatment for Hypertrophic Cardiomyopathy* (Oct. 2, 2024), https://pulseforinnovation.org/innovations-advanced-by-ma-a-first-in-class-treatment-for-hypertrophic-cardiomyopathy/.

therapies. Loxo now serves as Lilly's dedicated oncology division, continuing to develop new medicines to treat a variety of cancers.[24]

- **A novel CAR-T therapy for patients with blood cancer** was delivered to patients through Juno Therapeutics' 2018 acquisition by Celgene. Juno spun out from leading cancer research institutions and had pioneered Breyanzi to treat aggressive blood cancers like diffuse large B-cell lymphoma (DLBCL) but faced costly clinical setbacks. Celgene's established infrastructure helped secure initial FDA approval for Breyanzi in 2021, as well as subsequent approvals that expanded its use to other blood cancers. The merger also spurred regional biotech investment, helping make Seattle a hub for cell and gene therapy innovation.[25]
- **Two groundbreaking immuno-oncology treatments** were brought to patients through Medarex's acquisition by BMS in 2009. Medarex had developed two early-stage therapies – Yervoy and Opdivo – targeting CTLA-4 and PD-1 proteins, but the company needed a partner to complete late-stage trials and scale distribution. Following Medarex's acquisition by BMS, the combined company was able to secure FDA approval for these two therapies to treat melanoma, lung cancer, and other cancers, helping bring transformative frontline treatment options to patients around the world.[26]
- **The first treatment for Pompe disease** was advanced through the acquisition of Novazyme by Genzyme. Novazyme was a small Oklahoma-based startup founded by John Crowley, whose own children were living with Pompe disease. Novazyme discovered a promising enzyme replacement therapy, but it took an acquisition by Genzyme to unlock the infrastructure needed to bring this treatment to patients. The Crowley family's children became among the first to receive the life-saving drug.[27]

[24] Partnership for the U.S. Life Science Ecosystem (PULSE), *Innovations Advanced by M&A: Breakthrough Treatments for Rare, Aggressive Cancers* (July 17, 2024), https://pulseforinnovation.org/innovations-advanced-by-ma-breakthrough-treatments-for-rare-aggressive-cancers/.

[25] Partnership for the U.S. Life Science Ecosystem (PULSE), *Innovations Advanced by M&A: An Innovative CAR-T Therapy for Blood Cancer* (June 5, 2024), https://pulseforinnovation.org/innovations-advanced-by-ma-an-innovative-car-t-therapy-for-blood-cancer/.

[26] Partnership for the U.S. Life Science Ecosystem (PULSE), *Innovations Advanced by M&A: Opdivo and Yervoy's Substantial Impact on Cancer Treatment* (May 15, 2024), https://pulseforinnovation.org/innovations-advanced-by-ma-opdivo-and-yervoys-substantial-impact-on-cancer-treatment/.

[27] Partnership for the U.S. Life Science Ecosystem (PULSE), *Innovations Advanced by M&A: The First Therapy for Pompe Disease* (May 1, 2024), https://pulseforinnovation.org/innovations-advanced-by-ma-the-first-therapy-for-pompe-disease/.