

Comments on Senate Finance Committee Minority Staff Request for Information: Commonsense Policy Options to Lower Drug Prices for Patients

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 Senate Finance Committee Minority Staff's June 16th request for information (RFI) regarding *Commonsense Policy Options to Lower Drug Prices for Patients*.

PULSE's members consist of frontline researchers, employees and leaders of life science companies of all sizes, which together encompass a diverse, vibrant life science ecosystem across the U.S. Our focus is to promote the unique and vital role of pro-competitive mergers and acquisitions (M&A) and other collaborations, such as licensing agreements, joint ventures and incubators, in driving America life sciences global leadership.

The life sciences sector is one of the most dynamic and impactful segments of the U.S. economy, directly supporting nearly 2.3 million American jobs across every state, driving over \$3.2 trillion in economic impact and – most importantly – delivering new groundbreaking therapies that improve and save patients' lives.¹ The U.S. life sciences sector is successful because of decades of intentional and bipartisan policies that incentivized collaboration, innovation and investment. These include the *Bayh-Dole Act*, *Hatch-Waxman Act*, *Prescription Drug User Fee Act (PDUFA)*, *Orphan Drug Act*, *21st Century Cures Act*, the Small Business Innovation (SBIR) Program and many other economically grounded, fit-for-purpose policies.

While we recognize that competition policy falls outside of the Committee's immediate jurisdiction, the questions raised in Section III cannot be answered without addressing the critical role of M&A and other partnerships in fueling American life sciences innovation.

Our comments focus on highlighting the critical role of M&A across two areas included in the Committee Minority Staff's RFI:

- I. Bridging the “valley of death” between early-stage research and successful clinical development
- II. Supporting small biotechnology companies advancing high-risk science

We appreciate the Committee's recognition of biopharmaceutical innovation as an important priority in support of America's life sciences leadership, and the continued advancement of groundbreaking treatments and cures for patients.

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-andopportunities-in-states-and-regions>.

I. Bridging the “Valley of Death” Through Collaboration and M&A

A. Life Sciences Innovation is Collaborative, Sequential and Resource-Intensive

Developing a new medicine is an inherently long, costly and uncertain undertaking. Bringing a single new drug to market can take ten to fifteen years and cost more than \$2.6 billion.² Approximately 90% of drug candidates that enter clinical development ultimately fail to reach patients,³ while roughly 80% of biopharmaceutical companies operate without a profit.⁴ These harsh realities of the development process make sustained investment, collaboration and risk-sharing essential for life science companies.

Consequently, life sciences innovation is overwhelmingly collaborative and rarely the work of a single company or institution. Promising discoveries often advance through a sequence of pro-innovation collaborative partnerships – including M&A – between companies of all sizes. These partnerships allow companies to “pass the baton” and connect their discoveries with the resources and investment needed to bring them from the lab to the patient. Academic researchers, government agencies, investors, small and emerging life science companies, established companies and other partners each play a distinct and complementary role along this journey – from basic and translational research, to conducting clinical trials, securing regulatory approval and commercializing a new medicine.

This collaboration is the cornerstone of America’s highly dynamic life sciences ecosystem – which consists of more than 2,700 biopharmaceutical companies, collectively advancing over 11,600 drug candidates (more than half of the global pipeline).⁵ The scale and breadth of this ecosystem make it both a critical national asset and a powerful source of American innovation. In an increasingly competitive global life sciences industry, it is predictable, pro-collaboration policy that keeps investment, discovery and growth in the U.S., rather than overseas.

B. Bridging the “Valley of Death” Requires More than Early-Stage Funding

The Committee appropriately identifies the “valley of death” as a significant barrier between promising basic research and successful clinical development. This is not primarily a science gap, but rather a resource and capability gap. Small, pre-profit life sciences companies often lack the considerable infrastructure, experience and expertise needed to carry a candidate through late-stage clinical trials to manufacturing at scale and commercial launch.

As a potential treatment advances, its development becomes substantially more complex and resource intensive. An early-stage Phase 1 clinical trial can cost as much as \$25.3 million, whereas a later-stage Phase III clinical trial can cost as much as \$255.4 million.⁶ This is a 10x increase in cost as the drug advances through clinical trials, and surmounting these costs is often only possible through the investment and resources unlocked by pro-competitive partnerships.

² 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/>.

³ Biotechnology Innovation Organization (BIO). New Clinical Development Success Rates 2011-2020 Report (February 2021), <https://www.bio.org/clinical-development-success-rates-and-contributing-factors-2011-2020>.

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

⁵ Citeline. Pharma R&D Annual Review 2026 (2026), <https://www.citeline.com/en/rd26>.

⁶ DiMasi et al, 2016.

M&A is a fundamental pro-competitive partnership in the U.S. life sciences industry. M&A represents a bridge that enables originating companies to partner and connect promising candidates with complementary capabilities and expertise that are best suited to advance them to patients. One analysis of first-in-class oncology medicines approved between 2010 and 2020 found that small biotechnology companies originated 46% of these medicines **and larger pharmaceutical companies launched or participated in launching 76%.**⁷

These findings illustrate the interdependent relationships that underpin life sciences innovation and U.S. leadership. M&A and other private-sector partnerships act as the lynchpin that enables U.S. life sciences companies of all sizes to compete, collaborate and innovate.

C. M&A Increases the Likelihood That Promising and Novel Medicines Reach Patients

Recent research demonstrates the importance of M&A as a crucial mechanism for advancing drug development. A 2025 empirical study from Cornerstone Research found that a large, positive, statistically significant association between M&A and measures of pharmaceutical innovation. In particular, the study found that:⁸

- Acquired drug projects are **nearly 2x more likely to launch** than non-acquired projects, and **more than 3x** more likely to launch as *novel* drugs

The association is especially significant when a small company (one that has not yet launched a drug) partners with a large company (one that has prior experience launching a drug). Compared with drug projects that undergo M&A between two small firms, projects that undergo M&A between a small and large firm are:

- Nearly **3x** more likely to launch
- **5x more likely** to launch as *novel* medicines
- Nearly **24 times** more likely to launch with a *new mechanism of action*, representing an entirely new way of treating a disease

These findings reflect the practical realities and intrinsic value of combining complementary capabilities through M&A. By connecting specialized innovators with experienced development partners, M&A can improve the odds that ambitious scientific ideas become viable treatments rather than stalling before they reach patients.

D. M&A Drives the Financing of Future Basic and Translational Research

For many early-stage life sciences companies and their investors, acquisition is the primary pathway for realizing a return on many years of high-risk investment; and therefore, M&A is often the primary incentive for private investment in early-stage research and development.⁹ The

⁷ Kate H Kennedy, Krisstel Gomez, Natalie J Thovamasian, et al. Small biotechs versus large pharma: Who drives first-in-class innovation in oncology, *Drug Discov Today* 28(2):103456 (February 2023), <https://doi.org/10.1016/j.drudis.2022.103456>.

⁸ 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>.

⁹ PitchBook. Biopharma VC Trends (February 13, 2026), <https://pitchbook.com/news/reports/q4-2025-biopharma-vc-trends>.

availability of that pathway helps attract private capital to emerging companies, novel technologies and scientific programs that may otherwise struggle to secure funding. In this way, M&A facilitates a broader flow of private investment in U.S. life sciences innovation.

Federal basic-research funding from entities such as the NIH, translational infrastructure such as the National Center for Advancing Translational Sciences (NCATS) and accelerators like SPARK, Blavatnik and JLABS are necessary but focused only on initial discovery. Robust federal support can help generate foundational discoveries and move promising concepts toward clinical development. Yet, basic research funding is not sufficient to fill the necessary and significant gap in funding required for later-stage clinical development and commercialization. At this point, it is often M&A-driven private capital that provides the crucial resources to turn discoveries into approved, commercially available therapies for patients.

A healthy market for collaboration and M&A helps provide the downstream capital, infrastructure and expertise needed to translate those discoveries into approved medicines. Weakening this ecosystem would reduce the number of promising programs able to cross the valley of death.

E. Principles for Supporting High-Risk Research and Development

As the Committee considers policies to strengthen basic research, translational science and clinical development, PULSE encourages it to recognize the full pathway through which innovation reaches patients. Specifically, we encourage the Committee and your colleagues to:

- **Recognize M&A as a fundamental part of the life sciences innovation infrastructure.** Policies intended to bridge the valley of death or incentivize innovation should account for the critical role that pro-competitive M&A plays in connecting early-stage science with late-stage development capabilities to bring new medicines to market.
- **Use tax and innovation levers to promote early stage and high-risk research that is essential to sustaining the cycle of innovation.** For example, strengthen R&D expensing/credits oriented to early and translational research; support Small Business Innovation Research (SBIR)/translational bridges; preserve existing policy incentives (*Orphan Drug Act, Hatch-Waxman Act, Prescription Drug User Fee Act*) that make high-risk programs financeable.
- **Assess drug-pricing proposals for their upstream innovation effects,** particularly on the early- and mid-stage investment and M&A incentives that often bridge promising drug candidates across the valley of death.
- **Preserve U.S. competitiveness** by keeping the collaborative M&A environment predictable and robust so that investment and translational activity stay onshore.

America's life sciences ecosystem has succeeded because it enables organizations with different strengths to specialize, collaborate and share risk. Sustaining that model is critical to converting publicly and privately funded research into new treatments, supporting high-risk science and preserving American leadership in life sciences innovation.

II. Supporting Small Biotech Companies Advancing High-Risk Research

A. Supporting Small Biotech Companies is Critical to Fuel Innovation

PULSE appreciates the Committee Minority Staff’s acknowledgement of the important role that small and early-stage life sciences companies play in advancing high-risk science, and its focus on identifying ways to better support these innovative companies.

The lean, agile structure of early-stage companies makes them particularly well-suited for the discovery and development of novel treatments. Early-stage companies are often able to pivot quickly to follow the science and pursue the newest therapeutic opportunities. That process is inherently iterative and high-risk. Although many discoveries originating from early-stage firms will never reach patients, they are nonetheless critical in revealing new scientific knowledge about treating a disease.

These small and early-stage companies face significant financial and operational challenges. It has been estimated that about **80-percent of life sciences companies operate without a profit**¹⁰ – relying on outside capital to support initial discovery and development. As a result, many of these companies lack the resources needed to finance large-scale clinical trials, or to build the regulatory and commercial capabilities required to bring a new medicine to patients.

This is a critical reason why many small companies look to partner with larger, more established companies to bring promising new discoveries to patients. These pro-competitive partnerships allow companies at different stages of drug development – from those with no experience launching a drug, to those with experience launching 100+ drugs – to partner and combine complementary resources, expertise and investment. This is an important, fundamental and often expected pathway for small life sciences to be able to bring a therapy through late-stage clinical trials, regulatory approval and, ultimately, to market.

B. M&A Provides a Crucial Pathway for Small Companies to Advance Promising Innovations

M&A is often a necessary and anticipated step in a company’s journey to bring a new therapy to market. As the primary exit pathway for investors, an acquisition allows them to recoup their initial investment and creates a critical incentive to support the next generation of scientific breakthroughs.¹¹ For many pre-profit life sciences companies, M&A is not an alternative to continued innovation – it is the primary exit point that helps fund it.

Research also shows that M&A between small and larger companies significantly increases the likelihood that a drug will reach patients, particularly for the high-risk science that helps advance new classes of treatment. As shared above, empirical research demonstrates that **drugs that undergo M&A involving an experienced pharmaceutical company are significantly more**

¹⁰ Raphael Rottgen. Biotech Valuation Idiosyncrasies and Best Practices, *Toptal* (last updated June 5, 2026), <https://www.toptal.com/management-consultants/valuation/biotech-valuation>

¹¹ PitchBook. Biopharma VC Trends (February 13, 2026), <https://pitchbook.com/news/reports/q4-2025-biopharma-vc-trends>.

likely to launch – nearly **3x** more likely to launch in general, and nearly **24x** more likely to launch with a new mechanism of action.¹²

Accordingly, the Committee’s efforts to support high-risk science conducted by small biotechnology companies should complement the pro-competitive partnerships that support early-stage discoveries by small biotech companies, from discovery to launch. Policies that preserve predictable conditions for collaboration will help ensure that promising scientific discoveries continue to attract investment and ultimately reach the patients who need them.

C. Defining “Small” Biotechnology Companies

In identifying which companies should be considered in scope of any efforts to support “small” biotechnology companies, the Committee should adopt a framework that reflects the unique risks associated with advancing innovative science with limited resources and expertise. Rather than relying solely on traditional measures like revenue or company size, the Committee should consider both a company’s stage of development and the nature of the science it is pursuing.

Suggested parameters for defining “small” biotech companies include:

- **Development-stage companies that have not yet successfully brought a product to market.** These pre-launch companies face some of the greatest barriers to securing the investment, expertise and infrastructure needed to advance promising therapies through development and commercialization.
- **Companies pursuing the high-risk and innovative science.** This includes therapies addressing significant unmet medical needs, advancing novel mechanisms of action, introducing new methods of treatment administration or seeking to become first-in-class treatments. These programs often carry the greatest scientific and financial uncertainty, but also the greatest potential to meaningfully improve patient outcomes.

Companies within these categories face unique headwinds to bringing their discoveries to market and, as illustrated in the Cornerstone Research report, also stand to benefit the most from pro-competitive collaboration. Any framework designed to encourage high-risk scientific research should recognize the critical role that M&A and other partnerships play in helping these early-stage innovators bring new therapies to patients.

D. Principles for Supporting Small Companies Advancing High-Risk Science

Taken together, PULSE believes that several principles should guide the Committee’s important efforts to supporting high-risk science conducted by small biotechnology companies:

- **Define which companies are “in scope” based on development stage and scientific risk.** The Committee should ensure their definition of “in scope” includes pre-launch

¹² 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>.

companies and those advancing high-risk science, rather than relying solely on revenue or company size.

- **Recognize the essential role of M&A and other partnerships.** The Committee should recognize that M&A provides a critical pathway for small and early-stage companies to secure the investment, resources and capabilities needed to bring new treatments and cures from the lab to the patient.
- **Ensure federal research support complements, rather than displaces pro-competitive partnerships.** Research funding and other forms of federal support should aim to complement the mergers, acquisitions and other partnerships that allow small biotechnology companies to access the funding and expertise they often lack internally.

Together, these principles will help ensure that small biotechnology companies can continue to access the capital, expertise and infrastructure needed to translate high-risk scientific discoveries into life-changing medicines for patients.

Conclusion

PULSE appreciates the opportunity to engage with the Committee's Minority Staff to share input on opportunities to strengthen innovation in America's life sciences ecosystem. PULSE believes that maintaining a predictable environment for M&A and other pro-competitive partnerships must be a core tenet of the Committee's approach to fueling American life sciences innovation.

As the Committee considers policies to drive basic research and translational science, and policies to support and small and early-stage biotechnology companies, it is critical to recognize that scientific discovery alone is not enough. Bringing a medicine from the laboratory to the patient requires a dynamic ecosystem that often relies on a pro-competitive merger or acquisition to secure investment and connect a promising discovery with the resources and expertise needed to bring a treatment to patients.

PULSE appreciates the opportunity to provide these comments and looks forward to working with the Committee to advance policies that strengthen American innovation, improve patient outcomes and reinforce the U.S.'s global leadership in the life sciences.

