Comment on DOJ/FTC Joint Public Inquiry for Consideration of Guidance on Collaborations Among Competitors to Promote Certainty and Competition
Docket No. ATR-2026-0001

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 provide comments in response to the Department of Justice (DOJ) and Federal Trade Commission (FTC)'s February 23rd request for information (RFI) regarding updated guidance on collaborations among competitors. PULSE strongly supports the Administration's efforts to foster competition through predictable and fair enforcement that encourages a robust and collaborative life sciences market.

PULSE's members represent frontline researchers, employees and leaders of life sciences companies of all sizes, which together encompass a diverse, vibrant life sciences ecosystem across the U.S. We are focused on promoting 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 American biopharmaceutical 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 and groundbreaking therapies that improve and save patients' lives.[1] The success of the U.S. life sciences sector is the result of decades of intentional and bipartisan policy that has encouraged and incentivized collaboration, investment and innovation, including the Bayh-Dole Act, Hatch-Waxman Act, Prescription Drug User Fee Act (PDUFA), the Small Business Innovation (SBIR) Program, the 21st Century Cures Act and many more economically-grounded, fit-for-purpose policy achievements.

[1] Biotechnology Innovation Organization, *The U.S. Bioscience Economy: Driving Economic Growth and Opportunities in States and Regions* (2020), https://bio.widen.net/s/hflmb92hwx/the-us-bioscience-economy-driving-economic-growth-and-opportunities-in-states-and-regions

Any guidance on collaborations among competitors would interact with existing policy frameworks in the life sciences – such as the Merger Guidelines and Intellectual Property Guidelines. Together, these competition frameworks play a critical role in shaping how companies engage with one another to develop and deliver the cures of tomorrow. As such, it is essential that updated guidance be balanced and grounded in the economic realities of the industries it governs, particularly the unique and differentiated aspects of our life sciences industry.

At its core, life sciences innovation is overwhelmingly collaborative. The cutting-edge medicines and cures developed by America's life sciences industry are rarely the result of just one sole actor. Instead, they more often emerge from a calibrated sequence of partnerships – among startups, established companies, research institutions and others – that collectively usher a biomedical breakthrough from early-stage discovery to FDA approval and delivery to patients. This deliberate pathway is only possible when there is clear, predictable and economically-grounded competition policy, which includes the potential Guidelines for Collaborations Among Competitors. It is imperative that these renewed guidelines:

1. Preserve and incentivize the pro-competitive and collaborative innovation pathways that have led America to lead the world in life sciences innovation;
2. Avoid imposing unnecessary scrutiny on life sciences firms seeking to collaborate that could risk of chilling innovation and investment in new treatments for patients; and
3. Recognize the positive impact of innovation in life sciences collaborations and protect America's global leadership in biopharmaceutical and biomedical innovation.

Our recommendations are designed to ensure the renewed guidelines appropriately reflect the unique market realities of the life sciences industry and support America's leadership in the life sciences. We thank the DOJ and FTC for their leadership in supporting pro-competitive markets while encouraging innovation and appreciate the opportunity to share PULSE's unique perspective.

I. The U.S. Life Sciences Industry is Inherently Collaborative Against Enormous Risks and Costs

Innovation in the life sciences proceeds through a series of distinct but interconnected stages. Early-stage biotechnology and biopharmaceutical companies are uniquely specialized to focus on drug discovery and initial development, often working with limited resources. Larger firms, by contrast, are equipped to conduct large-scale clinical trials, navigate complex regulatory processes and manufacture and distribute therapies globally. The complementary roles of these entities give way to a pipeline of innovation where early innovators generate promising scientific assets to be advanced through collaborations with firms that have the significant resources and capabilities needed to bring treatments through rigorous regulatory requirements for approval and then commercialize and distribute approved treatment to patients.

The collaborative nature of the life sciences ecosystem is, in part, a result of the harsh realities of scientific uncertainty, high risks, long timelines and significant capital requirements:

- Bringing a single drug to market can take 10-15 years and cost more than $2.6 billion.[2]
- Approximately 80% of biopharmaceutical companies operate without a profit.[3]
- Drug development is an inherently speculative endeavor, with early-stage discoveries often possessing broad potential indications that shift throughout the development process.[4]

These conditions create the so-called "valley of death" between early discovery and commercial viability, where as many as 90% of drug candidates fail and never reach patients who could benefit from them.[5,6]

Collaboration between life sciences firms is what allows new innovations to cross that "valley." Without collaboration, fewer therapies would progress through development, fewer patients would benefit from scientific advances and fewer life sciences firms would be established in the U.S. Understanding the critical nature of interconnectivity and collaborations within the life sciences industry is essential to developing any new competition guidance.

II. The Pro-Competitive Role of Collaboration in Life Sciences

The life sciences sector provides clear, real-world evidence of how collaborations promote innovation, expand output and benefit patients.

Licensing Agreements

Licensing agreements are a critical mechanism through which life sciences companies collaborate to advance an innovative asset along the development pathway. Smaller, research-driven firms frequently license drug candidates, platforms or enabling technologies to larger partners that have the capabilities needed to conduct late-stage clinical trials, navigate regulatory approval and commercialize therapies at scale. These collaborations accelerate development timelines, reduce duplicative R&D efforts and ensure that promising scientific advances are matched with the resources required to bring them to patients. Licensing agreements are supported by longstanding federal policy, including the Bayh-Dole Act, which encourages the commercialization of federally-funded and academic research through licensing agreements.[7]

The following examples demonstrate the breadth and impact of licensing as a pro-competitive collaboration model:

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

[4] 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

[5] Ben Greenberg & David Greenberg, *The Biotech "Valley of Death" in Translational Medicine* (2023), https://swmedical.org/biotech-valley-of-death-translational-medicine-ben-and-david-greenberg/

[6] Biotechnology Innovation Organization, *Clinical Development Success Rates 2011–2020* (Feb. 2021), https://go.bio.org/rs/490-EHZ-999/images/ClinicalDevelopmentSuccessRates2011_2020.pdf

[7] Bayh-Dole Act, 35 U.S.C. §§ 200–212 (2011), https://www.govinfo.gov/content/pkg/USCODE-2011-title35/html/USCODE-2011-title35-partII-chap18.htm

- **Protein Design Labs (PDL BioPharma) / Roche** – Founded in 1986 in the U.S., PDL pioneered humanizing monoclonal antibodies. PDL licensed its technology to Roche – enabling the first humanized monoclonal antibody treatment to be approved for human use.[8] Moreover, further licensing of the technology platform to other biopharma companies enabled FDA approvals of new medications to that target HER2+ breast cancer, multiple solid tumors and even RSV.[9]
- **Vertex / CRISPR Therapeutics** – U.S.-based Vertex and CRISPR Therapeutics entered a strategic research and licensing collaboration in 2015 to develop gene-editing therapies. This partnership culminated in the development and approval of Casgevy, the first-ever CRISPR-based therapy to receive global regulatory approval for sickle cell disease and transfusion-dependent beta thalassemia. Under the licensing agreement, Vertex leads global commercialization and the therapy is now approved in the U.S. and multiple other countries.[10]
- **AstraZeneca / Daiichi Sankyo –** In 2019, AstraZeneca entered into a licensing and collaboration agreement with Daiichi Sankyo to co-develop and commercialize Enhertu, a transformative antibody-drug conjugate (ADC) for HER2+ cancers. This partnership has helped expand Enhertu in breast, gastric and lung cancers, including a historic "tumor-agnostic" approval for any HER2-expressing solid tumor. The collaboration continues to lead the ADC market with data showing significant survival benefits in early-stage breast cancer, further expanding the drug's reach.[11]

These examples and many others underscore how licensing agreements are a pro-competitive, fundamentally necessary collaboration tool in the life sciences. They enable multiple companies to build on shared scientific foundations, accelerate the development of new therapies and expand access to life-saving treatments around the globe.

Incubators and Accelerators

Large firms provide critical support for early-stage innovation through incubators and accelerators. These platforms provide startups with access to capital, laboratory space, equipment, data, scientific and regulatory expertise, and more.[12] Often, startup life sciences companies hold significant debt and have just a few employees, yet are pursuing high-risk, high-reward research to discover new medicines, technologies or mechanisms of action.[13] Importantly,

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[8] Lawrence K. Altman, *Genetically Engineered Drug Approved for Kidney Transplants*, N.Y. Times (Dec. 12, 1997), https://www.nytimes.com/1997/12/12/us/genetically-engineered-drug-approved-for-kidney-transplants.html
[9] Nature Biotechnology, *Humanized Monoclonal Antibodies* (Oct. 2005), https://www.nature.com/articles/nbt1005-1221
[10] Vertex Pharmaceuticals, *Vertex and CRISPR Therapeutics Announce Licensing Agreement to Accelerate Development of Vertex's Hypoimmune Cell Therapies for the Treatment of Type 1 Diabetes* (2023), https://investors.vrtx.com/news-releases/news-release-details/vertex-and-crispr-therapeutics-announce-licensing-agreement
[11] AstraZeneca, *AstraZeneca and Daiichi Sankyo enter collaboration for novel HER2-targeting antibody-drug conjugate* (2019), https://www.astrazeneca.com/media-centre/press-releases/2019/astrazeneca-and-daiichi-sankyo-enter-collaboration-for-novel-her-2-targeting-antibody-drug-conjugate.html#
[12] Life Science Leader, *Evolving Business Models: Pharmaceutical Incubators* (2014), https://www.lifescienceleader.com/doc/evolving-business-models-pharmaceutical-incubators-0001
[13] BioSpace, *More Than One-Third of Biotechs Have Under a Year of Cash Left, EY Finds* (2023), https://www.biospace.com/business/more-than-one-third-of-biotechs-have-under-a-year-of-cash-left-ey-finds

start-ups are critical to the broader life sciences ecosystem – expanding the innovation pipeline and advancing new ideas, assets and cutting-edge science.

Programs such as Johnson & Johnson Innovations' JLABS, Lilly Gateway Labs and Co.Lab facilitate and support startups in this risky research. By lowering barriers to entry and supporting early experimentation, these collaborations expand the pipeline of potential therapies – particularly novel and first-in-class therapies:

- **JLABS by Johnson and Johnson** is a global network of life sciences incubators that provides early-stage companies with access to lab space, equipment, scientific expertise and connections to capital, allowing start-ups to retain independence while accelerating development of novel therapies across oncology, immunology and other critical disease areas.[14]
- **Lilly Gateway Labs** offers emerging biotech companies fully equipped laboratory space and access to Eli Lilly's scientific and operational expertise, enabling early-stage firms to advance high-potential research programs while benefiting from proximity to a large pharmaceutical partner's development resources and capabilities.[15]
- **Co.Lab** by Bayer is a global network of life sciences incubators focused on disruptive innovation and scientific breakthroughs. Co.Lab strives to connect early-stage entrepreneurs with world-class expertise, resources and global networks.[16]

These platforms operate at the earliest and highest-risk stages of the innovation lifecycle. Success at this stage is not typically measured by FDA approval, but by companies' ability to progress into clinical development, attract follow-on investment and enter into partnerships or engage in M&A with larger firms that can help advance therapies through later stages. For example, JLABS has supported hundreds of early-stage companies, many of which have advanced into clinical trials or explored new areas of research.[17]

Joint Ventures & Strategic Alliances

Joint ventures and strategic alliances allow firms to combine complementary capabilities to advance potentially complex innovations. These arrangements enable risk-sharing and accelerate the scaling of new technologies through the combination of resources. For example:

- **Seagan (Pfizer), Astellas and Merck** collaborated to explore the combination of Keytruda and Padcev to treat bladder cancer.[18] In 2007 and 2009, Seagan and Astellas entered into and subsequently expanded a joint agreement to co-develop Padcev. In 2021, Seagan and Merck announced a clinical trial evaluating Padcev and Keytruda to treat

[14] Johnson & Johnson Innovation, *JLABS* (2024), https://jnjinnovation.com/jlabs
[15] Eli Lilly and Company, *Lilly Gateway Labs* (2026), https://gatewaylabs.lilly.com
[16] Bayer AG, *Bayer Co.Lab* (2024), https://colab.bayer.com/en/
[17] Johnson & Johnson Innovation, *JLABS* (2024), https://jnjinnovation.com/jlabs
[18] Merck & Co., *Seattle Genetics and Merck Announce Two Strategic Oncology Collaborations* (2014), https://www.merck.com/news/seattle-genetics-and-merck-announce-two-strategic-oncology-collaborations/

cancer.[19] Seagan was then acquired by Pfizer in 2023, and the combination of Padcev and Keytruda is now an FDA-approved, first-line treatment for advanced, metastatic bladder cancer.[20]

- **BMS and Ono Pharmaceutical** entered into a strategic agreement in 2011 to expand BMS's territorial rights to develop Opdivo as well as Ono's rights to co-develop and commercialize Orencia.[21] Opdivo was first approved in 2014 as a treatment for metastatic melanoma and has since gained over two dozen FDA approvals across different types of cancer.[22]
- **Sanofi and Alnylam** conducted a strategic restructuring of their RNAi therapeutic alliance in 2018, with Sanofi gaining global development and commercialization rights to Qfitlia, and with Alnylam receiving royalties upon commercialization.[23] In 2025, Qfitlia was approved as the very first RNAi therapeutic for the treatment of hemophilia A or B.[24]

These joint ventures and strategic alliances illustrate how diverse types of partnerships can bring together scientific, clinical and commercial expertise to develop and deliver therapies more efficiently and effectively to patients.

Collaborations Provide Bridge to Pro-Competitive M&A

These types of collaboration in the life sciences rarely operate in isolation. Licensing agreements, joint ventures, strategic alliances and incubators often serve as critical steps in a broader continuum of partnership. These collaborations enable risk-sharing and early validation of technologies and therapeutic approaches, providing a structured pathway for increasing investment and accelerating innovation. As a result, many collaborations naturally evolve into a merger or an acquisition as a company or asset matures. This progression reflects a deepening of pro-competitive collaboration, whereby innovation, capital resources and development expertise are brought together within a single organization. Mergers and acquisitions often serve as the final "pass of the baton" that brings new therapies to patients.

While not included in the purview of these guidelines, it's extremely important to underscore that M&A is a critical component of the life sciences innovation ecosystem. M&A enables the scaling and acceleration of innovation, facilitates the efficient allocation of capital and provides a pathway for early-stage discoveries to reach patients and overcome the "valley of death."[25]

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[19] Astellas Pharma, *Seattle Genetics and Astellas Announce Clinical Trial Collaboration with Merck* (Dec. 3, 2019), https://newsroom.astellas.com/2019-12-03-Seattle-Genetics-and-Astellas-Announce-Clinical-Trial-Collaboration-with-Merck-to-Evaluate-Enfortumab-Vedotin-in-Combination-with-KEYTRUDA-R-pembrolizumab-in-Patients-with-Metastatic-Urothelial-Cancer

[20] Pfizer Inc., *U.S. FDA Approves PADCEV Plus KEYTRUDA* (2023), https://www.pfizer.com/news/press-release/press-release-detail/us-fda-approves-padcevr-plus-keytrudar-certain-patients

[21] Bristol Myers Squibb, *Bristol-Myers Squibb and Ono Enter into Strategic Agreement* (2011), https://news.bms.com/news/details/2011/Bristol-Myers-Squibb-and-Ono-Enter-into-Strategic-Agreement-for-Anti-PD-1-Antibody-BMS-936558ONO-4538-and-ORENCIA-abatacept/default.aspx

[22] Drugs.com, *Opdivo (Nivolumab) History* (2024), https://www.drugs.com/history/opdivo.html

[23] Alnylam Pharmaceuticals, *Alnylam and Sanofi Announce Restructuring of RNAi Therapeutics Alliance* (Jan. 2018), https://investors.alnylam.com/press-release?id=22251

[24] Alnylam Pharmaceuticals, *Alnylam Announces FDA Approval of Qfitlia* (2025), https://investors.alnylam.com/press-release?id=28901

[25] Cornerstone Research, *The Impact of Pharmaceutical M&A on Innovation* (2024), https://www.cornerstone.com/insights/articles/the-impact-of-pharmaceutical-ma-on-innovation/

As such, it is critical that these guidelines preserve the myriad upstream collaborations that so often serve as a bridge to pro-competitive M&A and, ultimately, to bring new treatments and cures to patients.

Empirical evidence demonstrates the pro-competitive impact of these transactions:[26]

- Drug development projects that undergo M&A are **nearly twice as likely** to be launched as those that do not;
- Novel drugs in development that undergo M&A are **over three times more likely** to launch than non-acquired ones;
- Relative to drugs originating from a small firm that are then acquired by a small firm during development, drugs originating from a small firm that are then acquired by a large firm during development are:
    - Nearly **three times more likely** to launch;
    - **Five times more likely** to launch as novel drugs;
    - Roughly **24 times more likely** to launch with a new mechanism of action – representing an entirely new way of treating disease.

Beyond individual therapies, M&A plays a central role in the innovation financing cycle. For many life sciences startups and their investors, M&A rather than IPOs are the primary exit point for investment, and a primary incentive for early-stage research funding. The capital generated through these transactions is then reinvested into new ventures, supporting continued entry, experimentation and innovation across the life sciences ecosystem.

In the life sciences, M&A often emerges directly from the earlier-stage collaborations described above – licensing, joint ventures, incubators and strategic alliances – bringing together expertise, capital and infrastructure needed to move therapies through late-stage development and into the hands of patients.

Guidance that deters early-stage collaboration will not only affect those initial partnerships, but will also reduce the number of programs that advance to later stages where M&A becomes viable. This, in turn, weakens capital formation, limits investment in high-risk research areas, and ultimately reduces the number of therapies that reach patients. Preserving clear and workable pathways for collaboration is therefore essential to sustain the broader ecosystem that delivers innovation and sustains America's status as the world leader in life sciences innovation.

Artificial Intelligence (AI) & Data-Based Partnerships

Emerging collaborations in AI and data are beginning to shape the next phase of life sciences innovation. Partnerships between life sciences companies and AI-focused firms are increasingly

[26] 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

prevalent, focused on accelerating and refining the drug discovery and development process and clinical trial optimization.[27]

These emerging collaborations bring together biomedical expertise, proprietary datasets and groundbreaking AI technology. For example, Formation Bio is an AI-focused drug development company, acquiring promising clinical-stage drug candidates, developing them in-house leveraging its proprietary technology, then licensing them to larger companies.[28] Utilizing this model, Formation Bio has executed multiple licensing deals with companies such as Sanofi and Eli Lilly.[29,30]

These collaborations highlight the growing importance of integrating technology and life sciences capabilities, and evolving capabilities of AI underscore that flexible and forward-looking competition policy is essential to continue to recognize and support pro-competitive activity.

III. Recommendations & Principles for Updated Guidance

As the DOJ and FTC assess opportunities to improve and clarify competition policy, updated collaboration guidance should begin from a clear and reaffirmed understanding that, particularly in sectors such as the life sciences, collaboration is a central driver of innovation and competition – not an exception to it. The agencies' 2000 Antitrust Guidelines for Collaboration Among Competitors recognized that competitor collaborations frequently generate pro-competitive benefits, including enabling products to be developed more efficiently, brought to market faster and improved in quality.[31] This principle remains directly applicable today and should be explicitly reaffirmed in updated guidance.

R&D Market Definition and Scientific Uncertainty

In evaluating collaborations in R&D markets, guidance should reflect the unique characteristics of life sciences innovation. A key risk in the development of future guidance on collaborations among competitors is the potential for guidelines to emphasize speculative impacts on future competition. Treating early-stage pipeline assets as if they represent current competitive constraints fails to account for the high degree of scientific uncertainty inherent in drug development. Overly rigid approaches risk mischaracterizing pro-competitive collaboration as harmful conduct. Updated guidance should:

1. Acknowledge the high degree of scientific uncertainty and risk in drug development;

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[27] Nature, *AI Partnerships in Drug Discovery* (2025), https://www.nature.com/articles/d43747-025-00027-z
[28] Formation Bio, *Our Model* (2024), https://www.formation.bio/our-model
[29] Fierce Biotech, *Sanofi Signs €545M Deal to Explore Formation's JAK Inhibitor* (2024), https://www.fiercebiotech.com/biotech/sanofi-signs-545m-eur-deal-explore-formations-jaksyk-inhibitor-new-indication
[30] Ibid.
[31] U.S. Dep't of Justice & Fed. Trade Comm'n, *Antitrust Guidelines for Collaborations Among Competitors* (Apr. 2000), https://www.ftc.gov/sites/default/files/documents/public_events/joint-venture-hearings-antitrust-guidelines-collaboration-among-competitors/ftcdojguidelines-2.pdf

2. Recognize the dynamic and complementary innovation pathways in the life sciences ecosystem, where firms specialize across different stages; and
3. Avoid treating pipeline overlaps as direct competition.

Consistent with the 2000 Guidelines' recognition of efficiencies from combining complementary assets and sharing risk, a flexible approach is necessary to avoid mischaracterizing pro-competitive collaboration.[32]

Enforcement Safety Zones

As the 2000 Guidelines recognize, identifying circumstances where collaborations are unlikely to harm competition reduces uncertainty and facilitates pro-competitive activity.[33] Any reinstated guidelines should preserve and clarify the enforcement safety zones established in the 2000 Guidelines, which provided predictability for routine, beneficial collaborations. Updated guidelines should:

1. Maintain clear safety zones for early-stage research collaborations, licensing agreements and joint ventures; and
2. Avoid establishing arbitrary and burdensome thresholds for safety zones, based on loosely defined "close substitutes" in early-stage pipelines.

The Value of Clear, Workable and Predictable Guidelines

Finally, guidance should provide clear, workable standards that firms can reliably apply in practice. Unclear guidance, which leaves room for ambiguity and alternative interpretations, invites unpredictability and even more risk into the life sciences innovation ecosystem. Updated guidance should:

1. Avoid overly subjective or ambiguous standards that deter beneficial collaboration;
2. Ensure practical usability for firms structuring partnerships across long development timelines; and
3. Continue to recognize cognizable efficiencies, including faster innovation, improved quality and the introduction of new products, as emphasized in the 2000 Guidelines.

Grounded in these principles, updated guidance can preserve effective enforcement while supporting the collaborative ecosystem that drives life sciences innovation and patient benefit. Firms may delay or forgo licensing agreements, joint ventures or other collaborations due to uncertainty regarding potential antitrust risk. These effects would have significant consequences. Reduced collaboration can limit access to capital, slow development timelines and decrease the number of therapies reaching patients. In addition, policies that deter collaboration risk shifting investment and innovation activity to jurisdictions with more predictable frameworks, undermining U.S. leadership in life sciences.

[32] Ibid.
[33] Ibid.

IV. Conclusion

PULSE applauds the DOJ and FTC for their commitment to providing businesses with clear and actionable guidelines for collaborations among competitors. In the life sciences, the development of new therapies – from early discovery through clinical development and commercialization – depends on a collaborative, partnership-driven ecosystem.

PULSE shares your dedication to supporting competitive markets and fueling innovation that benefits Americans. By establishing competition guidance as outlined above, we can work to ensure that America's life sciences ecosystem remains the most innovative in the world, delivering new cures to patients and bolstering our nation's great economy.

PULSE appreciates the opportunity to provide these comments and thanks both the DOJ and FTC for their thoughtful consideration.

Sincerely,

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