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Before the Senate Subcommittee on Competition Policy, Antitrust, and Consumer Rights
"The Impact of Consolidation and Monopoly Power on American Innovation"
December 15, 2021

Chairwoman Klobuchar, Ranking Member Lee, members of the Subcommittee on Competition Policy, Antitrust, and Consumer Rights: Thank you for this opportunity to present the views of the Biotechnology Innovation Organization (BIO) on the Impact of Consolidation and Monopoly Power on American Innovation. My name is John Murphy. I am BIO's Chief Policy Officer.

BIO is the world's largest life sciences trade association representing nearly 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations.

BIO's members are involved in the research and development of innovative biotechnology products that will help to solve some of society's most pressing challenges such as managing the environmental and health risks of climate change, sustainably growing nutritious food, improving animal health and welfare, enabling manufacturing processes that reduce waste and minimize water use, and developing the cures, therapeutics, and vaccines of the future.

We are proud to say that the United States leads the world in this innovation. We have an abiding interest in preserving the conditions that have made that leadership possible and commend the members of this Subcommittee for focusing on this critical question.

America's small biotechnology companies, both publicly traded and privately held, continue to lead efforts to address the most devastating health risks and diseases in the world. Small biotech companies are responsible for 80% of all scientific R&D.[1] In fact,

[1] https://www.iqvia.com/insights/the-iqvia-institute/reports/emerging-biopharmas-contribution-to-innovation

76% of all therapeutics and vaccines in development to treat to prevent COVID-19 originated from small biotech companies.[2]

All of these companies depend on a highly specialized investment ecosystem, in which mergers and acquisitions by larger entities play a critical role. Eliminating or restraining the opportunity for mergers and acquisitions will severely impede the ecosystem that has catapulted the U.S. life sciences and biomedical innovation ecosystem into its current leadership position in the world. Policies that have fostered entrepreneurial risk taking and early-stage investment have allowed this ecosystem to flourish and must be preserved.

BIO's small business entrepreneurs are translating basic research into innovations that challenge the existing structures of their target markets, whether that is a cancer treatment, microbial fertilizer that avoids the use of chemicals, biologically-created industrial chemicals, or biofuels.

This work carries with it a high risk for early investors. A recent study by MIT found that oncology programs have a 3.4% chance of resulting in an FDA approved product,[3] yet hundreds of millions of dollars in private capital are invested in finding treatments and attempting to bring them to patients.

No other investment carries with it such a low rate of success. These low probabilities of success and the significant sums of money required to develop new products has led to the development of a highly specialized ecosystem to efficiently price, transfer, and absorb these entrepreneurial risks. Investors typically specialize in investing in the discovery and commercialization potential of life sciences endeavors.[4]

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[2] https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/therapeutic-development/bio-covid-19-therapeutic-development-tracker

[3] Lo et al, "Estimation of clinical trial success rates and related parameters," Biostatistics (2018)

[4] Biotechnology is typically not an area where "generalist" investors participate full-time. "The moment there are better returns available elsewhere, the [non-traditional] investors will leave," says one biotech specialist. https://www.nature.com/articles/s41587-021-00876-w "If you can sort of stretch out your time frame, you can ride through this kind of volatility — but you have to be conditioned for it," he added. Not every investor can do that. For the last two years, people and funds have been more than willing to seize the opportunities that biotech companies have promised, including investors that don't typically consider life sciences companies. But in previous market cycles, so-called "generalists" left the sector as quickly as they arrived. https://www.statnews.com/2021/12/15/biotech-investor-eli-casdin-on-biotechs-bad-december/?utm_source=STAT+Newsletters&utm_campaign=f5a5d15f34-Daily_Recap&utm_medium=email&utm_term=0_8cab1d7961-f5a5d15f34-153571982

At the heart of this ecosystem are mergers and acquisitions (M&A) as a central vehicle for the pricing and transfer of risk to the appropriate party that can best bare those risks and guide companies through a particular period.

American Innovation in the Life Sciences

Innovation in the American biopharmaceutical industry is robust and growing. Combined the industry now spends $188 billion on research and development annually. [5]

Despite the increase in costs and regulatory hurdles, the biopharmaceutical industry is producing more novel medicines than ever before. From the gene-editing potential of CRISPR to the cancer targeting of CAR-Ts and novel KRAS inhibitors (a once thought "undruggable" cancer target) to non-opioid pain treatments and gene therapies that restore sight in the blind, biomedical innovation in the United States remains the envy of the world. Our ecosystem, in which M&A plays a crucial role, is the reason why we succeed. We must protect this national asset.

According to the Information Technology and Innovation Foundation (ITIF), the U.S. biopharmaceutical industry is a key driver of U.S. competitiveness. We are one of the few countries in the world that possess all four components required to create a highly competitive biotechnology industry. These components include, (1) strong R&D infrastructure, (2) robust intellectual property protections, (3) integrated global standards, and (4) functioning markets offering sufficient reimbursement.[6]

ITIF found that European and Japanese firms have shifted some of their R&D operations to the United States to take advantage of these components. China has followed suit. As a result, the biopharmaceutical labor market has consistently outperformed the national average since the late 1990s.[7]

ITIF concludes:

> America's wresting of global life-sciences leadership [from Europe] has been no accident, but rather the result of a series of intentional policy decisions designed

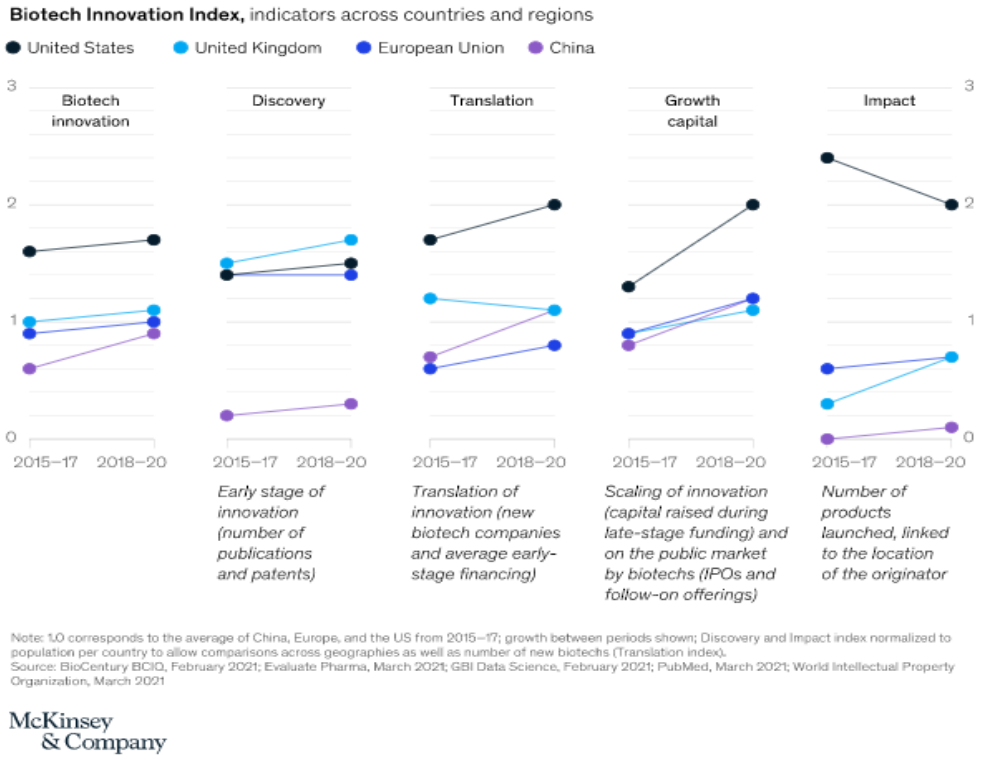
[5] https://www.evaluate.com/thought-leadership/pharma/evaluatepharma-world-preview-2020-outlook-2026
[6] Robert D. Atkinson, China's Biopharmaceutical Strategy: Challenge or Complement to U.S. Industry Competitiveness?, ITIF (Aug. 12, 2019) available at: https://itif.org/publications/2019/08/12/chinas-biopharmaceutical-strategy-challenge-or-complement-us-industry
[7] Id.

> to make America the world's preeminent location for life-sciences research, product commercialization, and production. The lesson of the U.S. gain in global competitive advantage in the biopharmaceutical industry should be clear. It was not based on absolute advantage. Rather, it was and is based on competitive advantage.[8]

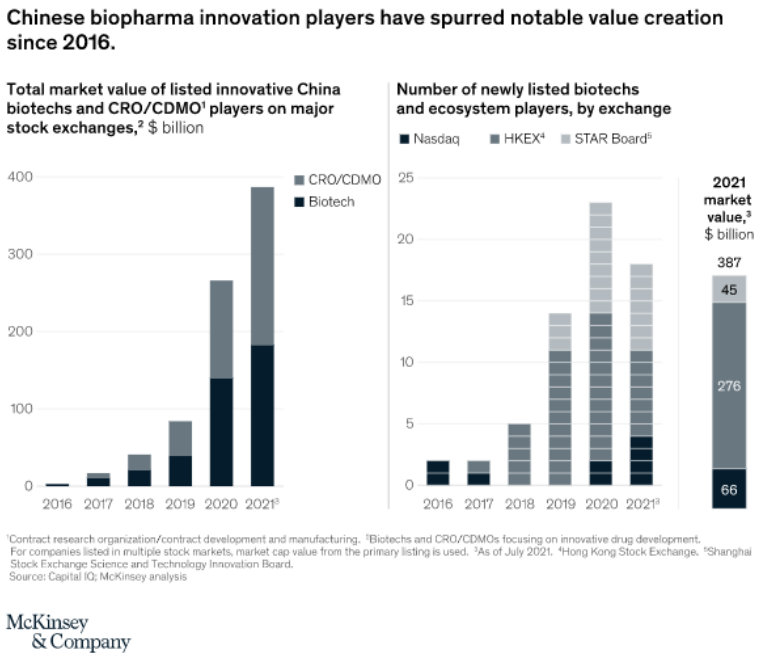
This global leadership has yielded significant gains in the field of public health. ITIF reports that throughout the 2000s, the United States produced more new chemical entities (new medicines) than the next five nations combined. A recent study by McKinsey and Co. confirms that the United Sates remains the most innovative biotech market in the world.[9]

The UK and the EU challenge us in scientific discovery. However, the United States still leads the world in innovation. We translate scientific discovery into life changing products better than anyone in the world. We have the most robust and dynamic capital ecosystem available and produce products that have the greatest impact.

[8] Id.
[9] https://www.mckinsey.com/industries/life-sciences/our-insights/the-dawn-of-china-biopharma-innovation



The UK and EU are actively positioning themselves to challenge our ecosystem. Both require growth capital to entice talent and recreate the dynamic ecosystem that we possess in the United States that efficiently absorbs failure and redeploys capital. China is aggressively challenging the UK and EU in innovation in the amount of capital they are deploying and their R&D infrastructure is rapidly evolving.



According to McKinsey, China has increased its share of the global innovation pipeline to 13.9% in 2020 from 4.1% in 2015.[10]

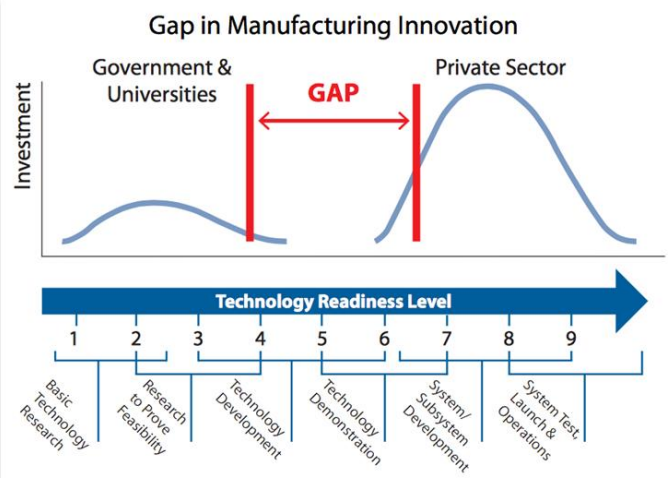
In the new age of innovation and dynamic competition globally, particularly for key technologies such as biotechnology, the United States should be focused on making our industries more resilient to exogenous challenges, bolstering our competitive advantages, and providing further capital access and protections to ensure that the United States continues to lead.

The Ecosystem

All investments carry risk. That risk dictates the price and the required return for a particular investment. The higher the risk, the higher the required return.

[10] https://www.mckinsey.com/industries/life-sciences/our-insights/the-dawn-of-china-biopharma-innovation

In biotechnology, the investment risk is among the highest in any market. At the earliest stages of company formation, the risk is near infinite, given the staggering 99% failure rate[11] widely known as the "Valley of Death" illustrated below as the "gap."



Global Federation of Competitiveness Councils[12]

This term reflects the "vast number of companies that are unable to raise the needed capital to progress into the clinic. Ultimately, the Valley of Death reflects the perceived imbalance of risk and reward for an investment at this stage as well as the resulting difficulty for a biotech company in raising capital during this time. For companies focused on a rare or neglected disease, this risk/reward profile is even more skewed, with significantly greater market risks and fewer exit opportunities for an investor."[13]

Companies that make it past the Valley of Death, having spent years developing the basic technology and feasibility studies to begin clinical trials, face additional challenges. They must obtain regulatory approval to conduct clinical trials which, if successful, could lead to approval to market a product. These entrepreneurs will need to raise $1.04 to $2.5 billion over a decade[14] to successfully bring an approved product to market. Once a candidate begins clinical trials, there is only a 10% chance of

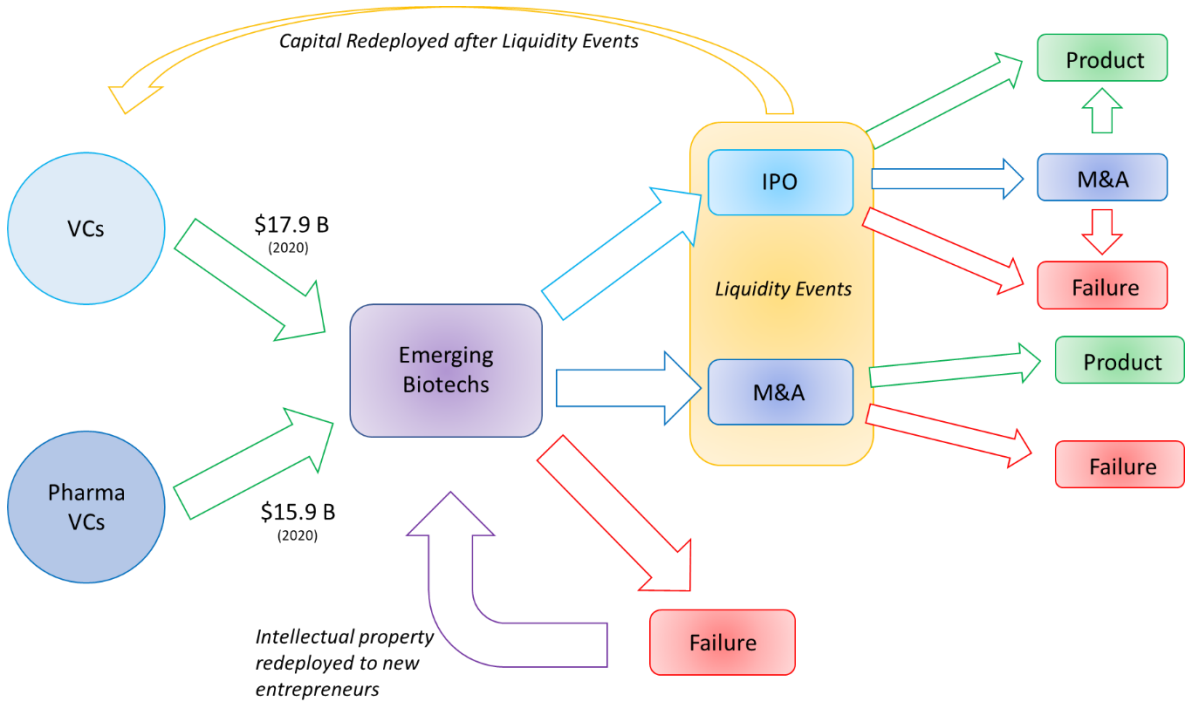
[11] BIO Comment Letter to the Federal Trade Commission Pharmaceutical Task Force Project No. P212900
[12] https://blog.thegfcc.org/universities-are-wellsprings-of-innovation-drivers-of-regional-economies-8a3c097e6cc
[13] Miller, Brian, "Financing the "Valley of Death": An evaluation of incentive schemes for global health businesses," MIT Press (2009)
[14] Id

success for most biopharmaceuticals and only a 3% chance of success for cancer treatments.

The ecosystem we have developed in the United States successfully allocates these tremendous costs and risks among multiple parties. No single entity can bear the total risk and total cost associated with a single program that inherently has low probabilities of success. The risk has to be diversified among various participants with long-term views, capacity to sustain volatility, and have experience to understand the risks and opportunities of a given technology.

In order to attract these high risk-high dollar investments, participants need exit opportunities in order to recuperate and redeploy funds back into the innovation pipeline.

There are only three options for an early-stage company: bankruptcy, an IPO, or M&A, as illustrated by the figure below.



In 2020, private venture capital invested $17.9 billion into emerging biotechs and large pharmaceutical venture capital arms invested $15.9 billion in upfront payments to emerging biotechs.[15]

Early-stage investors, who supply 53% of funding in this ecosystem, rely on acquisitions or other investors (other venture firms or public equity investors) to obtain that return. Large biopharmaceutical company acquisitions play a critical role as they provide liquidity, resources, and expertise especially with respect to completing large scale clinical trials and navigating the rigorous regulatory landscape.

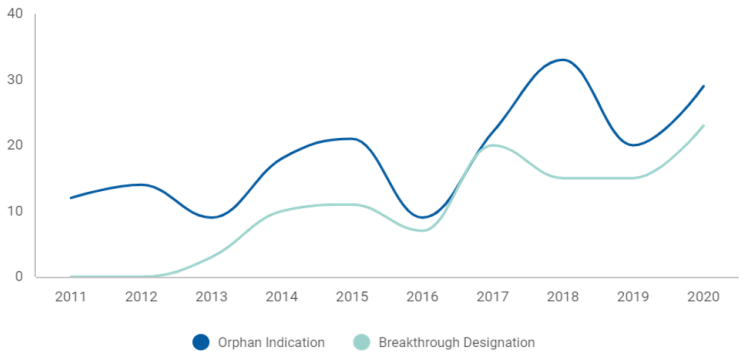
Further, these mergers are demand-enhancing for biomedical innovation as acquisitions in the biopharmaceutical space monetize product innovation for margin expansion.[16] After acquisition, R&D expenses related to acquired innovation must still occur to bring therapeutics through clinical trials and into the market. These costs increase over time. The business strategy is that the return on investment of a successful therapeutic is enough to offset the sunk costs of failures and the rising costs of drug development and approval.

[15] Id.

[16] Bourreau et al, "Merges and demand-enhancing innovation," CEPR (2021). We note that we do not agree that this study is appropriate for assessing the nature of mergers in the biopharmaceutical industry as the central assumption for the study is the merger of *duopolists* and then extends the research to *oligopolies*. Unfortunately, as noted in our comment letter to the FTC's Pharmaceutical Mergers Taskforce, many of the economic studies cited in support of the need to change theories of harm in the pharmaceutical industry assume *mergers of equals* and applies these academic studies to the hypothesized effect of mergers throughout the entire industry. BIO has no position in the theories of harm governing the merger of the largest pharmaceutical companies. BIO's main concern is the limitation of mergers and acquisitions by large pharmaceutical of smaller biotechs as these are required in order to sustain biomedical innovation in the United States. Further, many of these economic studies also assume that post-merger R&D outcomes have no profits at risk and have no spillovers. Both assumptions are flawed.

Innovation Has Increased NOT Decreased

Trend in Disease Modifying Therapies



263%

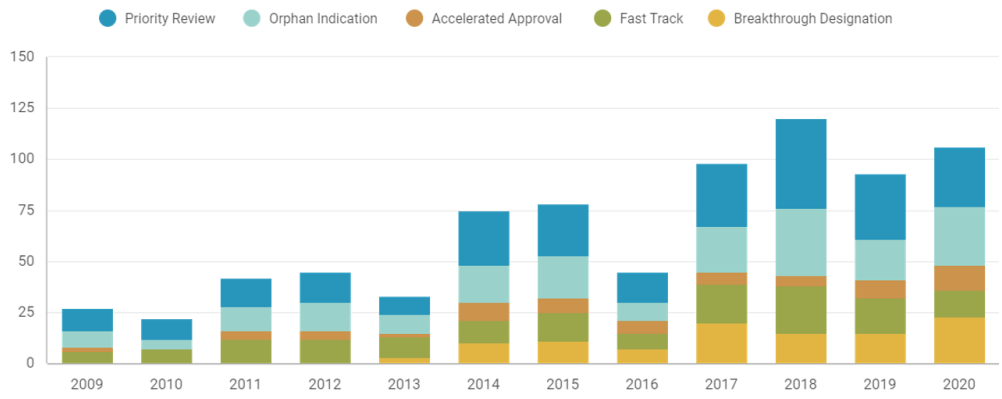
Increase in **ORPHAN DRUG** Designations

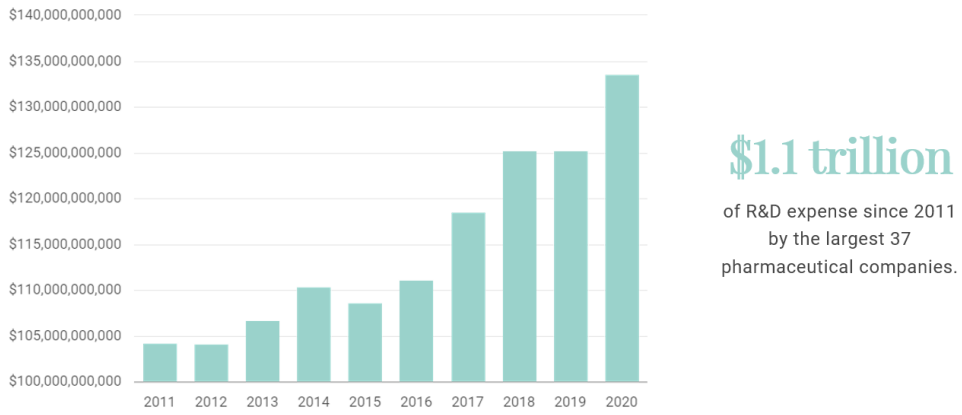
160%

Increase in **Breakthrough Designations**

Trends in FDA's Designation

The below are the various ways the FDA designates treatments for rare, neglected, and paradigm changing treatments





Disrupting the freedom for mergers and acquisitions in this delicate ecosystem will yield significant alterations to incentives needed to maintain the U.S. competitive advantage in biotechnology, which every major economic block (across the Atlantic[17]) and country of comparative size (across the Pacific[18]) seeks to challenge in the coming decades.

Market Evolution

While the M&A of prior decades sometimes led to absorption and dilution of teams for the sake of "synergies," most companies now recognize that talent is an important benefit of an acquisition. Some acquisitions today are done with the goal of acquiring entire teams in addition to acquiring product pipelines. Assembling expertise can create a more robust and efficient team and advance science.

It is a mistake to assume that post-merger R&D should continue its prior form or should be distributed equally in the merged enterprise. Post-merger R&D is asymmetric and can best be characterized as innovation-weighted, which avoids duplicative efforts and unproductive expenditures while maximizing the potential for success. In the case of

[17] UK Life Sciences Vision: https://www.gov.uk/government/publications/life-sciences-vision
[18] The next biotech superpower: https://www.nature.com/articles/s41587-019-0316-7, https://itif.org/publications/2019/08/12/chinas-biopharmaceutical-strategy-challenge-or-complement-us-industry, https://www.nationaldefensemagazine.org/articles/2020/7/9/china-pursuing-aggressive-biotechnology-strategy

innovation-weighted redistribution of efforts, these mergers increase the level of innovation in merged entities.[19]

Similarly, intellectual property acquired by a company is dynamic rather than static, and continues to develop. In many instances, intellectual property that is no longer part of core strategies is either spun-off or sold to entrepreneurs who wish to advance the science with their own teams.

Conclusion

More than any other time in history, the biopharmaceutical ecosystem is tackling some of the rarest, most difficult to treat ailments known to society. The symbiotic relationship between small biotechs and large pharmaceutical companies, supported by the most robust innovation ecosystem in the world, has brought to market more therapies, not fewer. This ecosystem has designed more breakthrough technologies and targeted more orphan diseases than ever. Large pharmaceutical companies are spending more, not less, on cutting-edge innovation.

Disrupting the existing M&A market in the biopharmaceutical industry would impede the ecosystem that currently supports our dynamism would reduce investment in startups responsible for most of the innovation and impede the development of early-stage work into the therapies, vaccines, and cures of the future. The dispersion of risk among various specialists, the freedom to acquire and reallocate talent and assets, and our capital markets sustain the capital cycle required to propel innovation forward and maintain competition throughout our market and globally. The acquisition of small biotechnology companies by larger players with significant resources is a feature of this system that should be allowed to evolve on its own and should not be restrained.

Thank you for the opportunity to present the views of the Biotechnology Innovation Organization. We look forward to working with the members of the Subcommittee to ensure that our antitrust laws preserve competition, innovation, and our country's global leadership in this strategically important field.

[19] Denicolo and Polo, "Duplicative research, mergers and innovation," CEPR (2018)