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Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue, NW
Washington, D.C. 20580

RE: Request for Comment on Revised Merger Guidelines

Dear Commission,

Thank you for the opportunity to file these comments. The Biotechnology Innovation Organization (BIO) has a vested interest in federal competition policy that promotes and protects a vibrant biotech marketplace that generates innovative solutions in health, agriculture, and environmental science. Thoughtfully developed and carefully tailored Merger Guidelines are a core component of such a policy.

Introduction

BIO applauds the Commission's efforts to modernize competition policy, updating and adapting it to the contours of a new economic age. This is particularly imperative when addressing the market distortions that have been created by intermediaries in the prescription drug ecosystem.

The consolidation of supply chain intermediaries and the obtuse relationships within and between these entities have created asymmetries in the sector, exacerbated by vertical integrations that unfairly consolidated buyers, negotiators, and dispensers into conglomerates that are not incentivized to help patients receive necessary medicines that are in the best interest of their care.

However, BIO strongly cautions the Commission in their proposed revisions to the merger guidelines¹ as many of the guidelines and expanded definitions, though well-intended as they may be, threaten to destabilize the very foundations of the American innovation ecosystem and with it, America's leadership position in a sector that will shape the industrial, agricultural, and healthcare landscape of the 21st century.

Biotechnology innovations are replacing fossil fuels with those derived from waste, bolstering the resilience of crops and livestock against our changing climate and creating novel treatments for a spectrum of diseases from ultra-rare, inherited diseases and rare cancers to the surging

¹ U.S. Department of Justice and the Federal Trade Commission, "Draft Merger Guidelines" (2023)



tide of infectious diseases as well as metabolic diseases that have plagued society for decades. The ability of biotech innovation to deliver on the promise of a healthier planet, cures for a myriad of diseases, and extending the quality of life to people in every country is achievable if supported.

But, realizing this future is contingent on the ability of small companies to merge, be acquired, strike exclusive licensing deals, explore minority interest sales, and generally strike deals with larger companies with complementary resources that are more capable of absorbing the significant costs of late-stage clinical trials, domestic and global regulatory approvals, legal challenges and issues, global marketing and logistics, and continued investment to expand the utility of new drugs into other disease categories.

This future is at risk if mergers and acquisitions within our industry are limited or impeded.

About BIO

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.

Biotechnology stands as a beacon of human ingenuity. It is an industry where scientific research and the crucible of American capital forge the tools that will shape humanity's future. BIO members are among these trailblazers, architects of innovations that address society's most enduring and exigent challenges. From the quest to create a more sustainable future that bends the arc of climate change to advancing solutions for the tapestry of issues affecting human health and well-being, our laboratories and boardrooms are addressing the various riddles that have eluded us for generations. These pursuits are made possible not only by the indomitable brilliance of American scientific minds but also by the dynamism of American capital, which is the foundation upon which our innovations are built. Without it, the aspirations of innovators would languish unrealized.

Potential Impact of Proposed Guidelines to Small Biotechs

The proposed guidelines cast a large and perilous shadow upon the future of our ecosystem and threaten to shatter the unity of purpose built within the biopharmaceutical ecosystem. It is through these collaborations and alliances that the burdens of research, the challenges of clinical trials, and the increasing demands of health regulators are shared, and thus the weight of scientific progress made bearable.

Policies that bolster entrepreneurial risk-taking and foster early-stage investment have allowed our ecosystem to flourish and create more novel medicines than the rest of the world combined,



each year for the last 15+ years. For this to continue, deals within the biopharmaceutical ecosystem that advance experimental medicines through clinical trials and accelerate their global distribution must be able to continue as the Commission has done for decades to the benefit of patients globally.

BIO is concerned that several of the Commission's proposed Guidelines will stymie the very transactions that have allowed the ecosystem to thrive. Specifically, BIO is highly concerned with the implications of Guidelines 2, 3, 4, 9, and 12 as well as the proposed over-broadening of the definition of relevant market.

BIO contends that Guidelines 2 and 3 contradict each other in that what is considered evidence of competition in Guideline 2 becomes evidence of an environment conducive to the anticompetitive practice of implicit coordination in Guideline 3. Together, these Guidelines sow confusion and uncertainty, particularly as implicit in Guideline 3 is a desire for less transparent markets. Guideline 4, which seeks to block mergers that would eliminate a potential entrant, imbues in markets significant uncertainty for the future advancement of novel technologies. Guideline 9, which seeks to increase the scrutiny of smaller transactions that are part of a series of transactions from a large company, casts a long shadow over the biopharmaceutical industry as a central pillar of our ecosystem's success comes from these transactions. We are also concerned that Guideline 12, which seeks to increase scrutiny of minority stakes, may also erect an unnecessary roadblock to innovation capital and R&D productivity.

In the following pages, BIO outlines our thoughts about the potential consequences of the Commission's proposed merger guidelines and accompanying definitions. We will first address our main concerns with the Commission's general approach, and then dive into addressing select guidelines. We thank the Commission for the ability to opine on this important work and urge the Commission to sincerely consider our comments and concerns.

BIO's Concerns with the FTC's General Approach

As revised, the Guidelines will create regulatory uncertainty.

BIO's core concern with the proposed Guidelines lies in their expansive nature. They are overbroad and threaten to constrict a crucial element of capital formation for our Nation's biomedical innovation ecosystem. The evidence amassed just this year serves as a poignant reminder of real repercussions and is a harbinger of the erosion of human and working capital that the ecosystem faces should the current regulatory perspective persist as hypothesized in the revised Guidelines.

So far this year, the Commission's assertive stance towards biopharmaceutical dealmaking has precipitated a downturn in deal activity for small companies as noted in several articles in



industry and financial press—an unexpected and ill-timed shift that bears adverse consequences to the ecosystem at a time when the cost of capital has become dramatically more expensive due to higher interest rates and the corresponding contraction in capital availability.² The latter of which is exacerbated by the Administration’s efforts to erode large biopharmaceutical company earnings power with consequences to the availability of low-cost financing in our ecosystem.³

As elaborated upon further below, retained earnings from large companies offer a low cost source of capital that extends to the entire ecosystem as these corporations pursue deals with smaller companies.⁴ Restraining the free flow of corporate retained earnings at a time when interest rates were raised from the zero lower-bound to 5.50 percent has critical consequences for capital-intensive innovators, such as biotechnology companies. For our industry in particular, these ramifications continue to ripple through therapeutic pipelines and biomedical labor markets, hurting “STEM” careers across the country as noted in Chart 1 below.

CHART 1: Biotechnology Industry Announced Layoffs

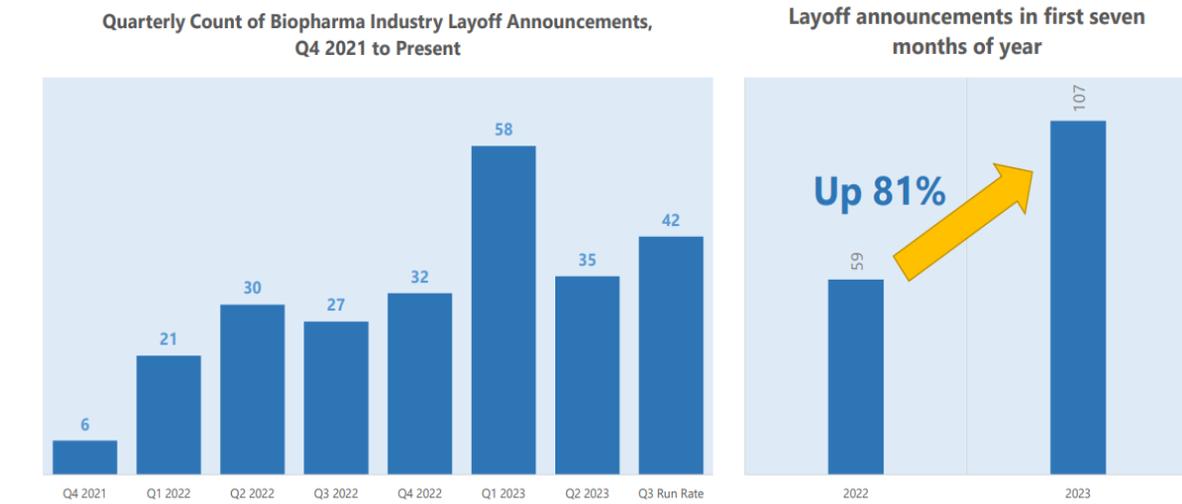


Chart: Torrey Stifel, Data: Fierce Biotech. Data show the number of layoff announcements, not the number of laid-off employees.

² <https://www.pharmaceutical-technology.com/features/money-moves-how-the-biotech-market-is-weathering-inflationary-storms/?cf-view>

³ <https://endpts.com/pharma-enters-age-of-uncertainty-amid-challenges-from-ira-ftc-and-patent-cliffs/>

⁴ “This lower cost of retained-earnings financing might be considered a real efficiency saving that large firms bring to their mergers and acquisitions of small and medium-sized firms.” Furthermore, “Larger firms’ acquisition of smaller firms also encourages early investment in small firms.” Danzon and Carrier, “The Neglected Concern of Firm Size in Pharmaceutical Mergers,” Antitrust Law Journal Vol. 84 (2022)

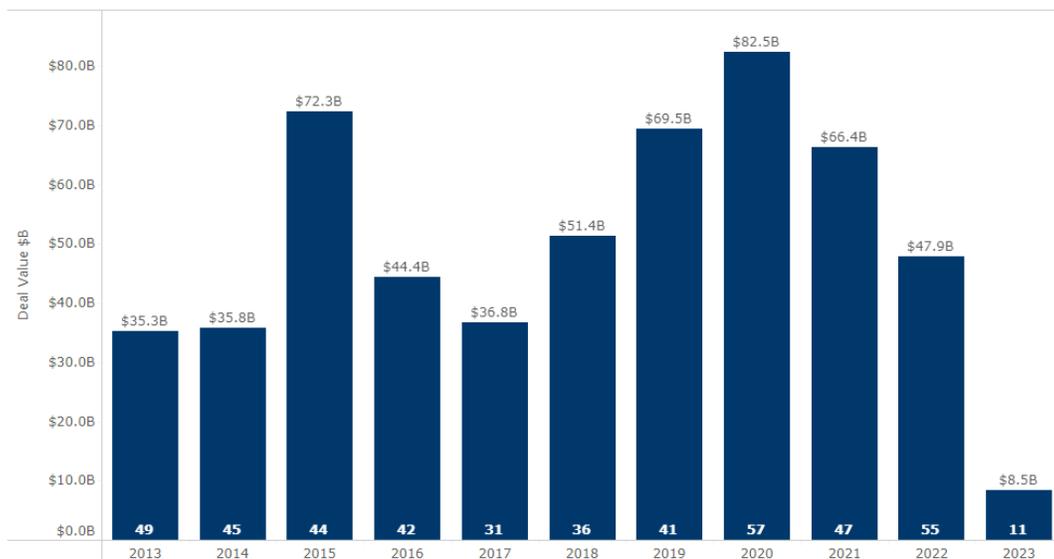


A charged regulatory environment sows seeds of uncertainty that spur a cascade of negative effects as corporate planners react to an erosion of capital access. Research plans are altered, development funding redirected, and ultimately biotech labor market slack (“layoffs”) becomes an unfortunate inevitability as companies focus on bolstering financial foundations.

While this is a natural survival response, it has a significant impact on the future as short-term funding urgencies overshadow the once well-laid foundations of strategic, long-term planning. The above data are consequential because there are long-term effects on future industrial dynamism when small companies cull therapeutic programs and reduce the scientific labor force because products, experience, and knowledge are delayed.

Chart 2 below documents how dealmaking year-to-date has declined compared to historical standards, particularly in the prior decades, which ultimately yielded significant strides in therapeutic development.

CHART 2: Biotechnology Ecosystem M&A Activity



*2023 data through Q1

Chart shows M&A volume across lead stage of development across the biotech ecosystem. Chart and data found at <http://www.bio.org/emerging-therapeutic-company-investment-and-deal-trends>

Chart 3 dives further into the above data to illustrate how the decline in investment is manifesting across disease categories (“therapy areas”) and technologies for treating these diseases (“modalities”).



CHART 3: Licensing Deal Flows by Therapeutic Area and Modality

Top Therapy Areas and Modalities In-Licensed by Large-Cap Biopharma: Total Upfront Cash & Equity (\$B)

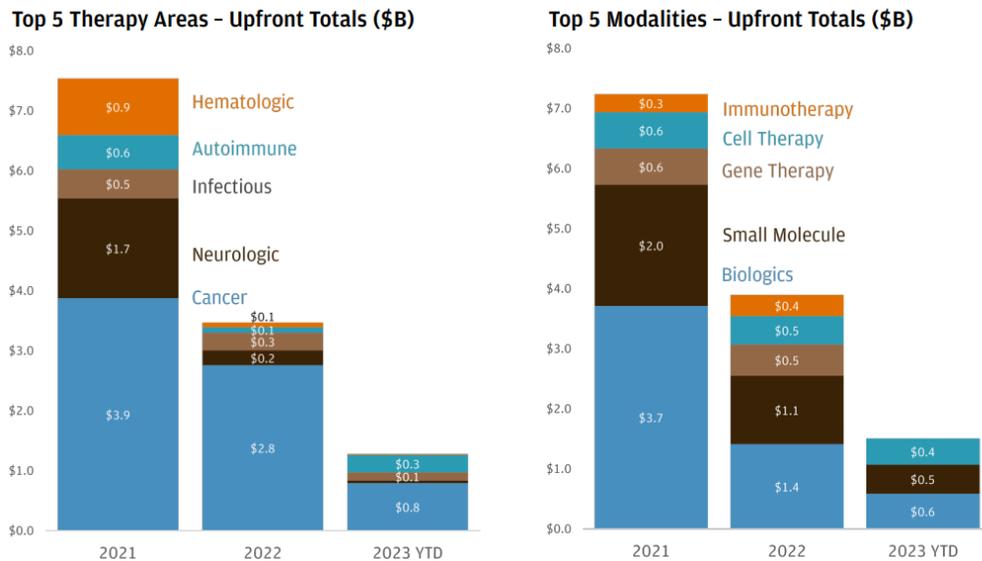


Chart from JPMorgan Q2 2023 Biopharma Licensing and Venture Report

Similar to other capital-intensive industries, investment flows are leading indicators of future output. A decline in investment today, as noted in the chart, is a harbinger of fewer medicines entering the domestic and global market in the future.

Put another way, biopharmaceutical deals yield two different outcomes that are critical to society. The first outcome is the accelerated development of experimental medicines into approved therapeutics. The second outcome is the global distribution of these medicines.

To put the above statements and data into context, mergers and acquisitions have assumed a pivotal role in facilitating the transmission mechanism that translates lab research, the “R” in R&D, into drug development, the “D” in R&D. Small biotechs have led the world in the research of new molecular entities (“NMEs”) while larger companies in the ecosystem dramatically accelerate the development stages and global distribution of approval products.

The latter stages are arguably the costliest of the entire product development pipeline as Phase III clinical trials cost up to \$500 million per trial to conduct across multiple hospital systems. And each large pharmaceutical company runs several Phase III trials concomitantly. Finally, global distribution requires an expert command of individual country regulatory systems and cultural



hurdles for physician education, which requires vast teams spread across the world. This infrastructure takes years to build and scale.

Danzon and Carrier, academics included in the FTC's Multilateral Pharmaceutical Merger Task Force and The Future of Pharmaceuticals virtual workshop, rightly point out the following in their research produced for and cited by the Commission,

“...[small companies] typically face higher costs in acquiring the financing and expertise needed to develop their drugs through large clinical trials and regulatory approval and then market and sell the drugs nationally and globally.”

Furthermore, and most importantly, Danzon and Carrier correctly agree with our contention that:

“This pattern of acquisition of innovation-focused small firms by larger firms with expertise in marketing and sales can create real resource savings. **And it generally poses no significant antitrust concerns.**”

and,

“These efficiency arguments based on R&D financing through retained earnings and avoiding duplication of marketing and sales capabilities, **argue in favor of allowing large and mid-sized firms to acquire smaller firms**, once any overlapping product issues have been addressed.⁵”

As noted by the authors, large companies' retained earnings provide a relatively low-cost source of financing for small companies, which brings down the cost of capital throughout the ecosystem. Thus, it can be concluded that the opposite also holds true; reducing retained earnings from large companies will increase the cost of capital for the biopharmaceutical industry writ large, reduce capital availability within the ecosystem, and therefore lead to a decline in innovation and new products.

As we will explain in the next section, large company transactions, and the corresponding relationships, not only lower the cost of capital but they also improve innovation output, increase scientific knowledge, and strengthen regional economies.

⁵ ibid



As revised, the Guidelines will chill innovation-driving M&A activity.

Deals within the biopharmaceutical industry are a sign of dynamic innovation, not a sign of declining innovation. The network of relationships within the ecosystem has been developed over decades to drive demand for new technologies and the incentives to produce them. The mergers within the sector improve innovative output and quality as the relationships between small, mid-sized, and large companies in the industry are, with rare exception, complementary.

America's small biotechs lead the world in innovation and R&D spending. Consequently, we are also responsible for an increasing number of new medicines, producing more than the rest of the world combined. This unparalleled feat has been accomplished because of our nation's innovation ecosystem and the supportive policies that support them.

As BIO has noted, U.S. small, research-intensive biopharmaceutical companies lead the world across innovation productivity and intensity metrics. According to a recent study on the competitiveness of the U.S. biopharmaceutical industry, 81 percent of the world's top small research-intensive companies are domiciled in the United States with biopharmaceutical companies representing 91 percent of total R&D spending.⁶ Furthermore, U.S. biopharmaceutical companies spend almost twice as much on R&D per employee than the rest of the world, as noted in the Chart 4 below.

CHART 4: R&D Spend per Employee at Small Biotechs: U.S. versus Rest of World

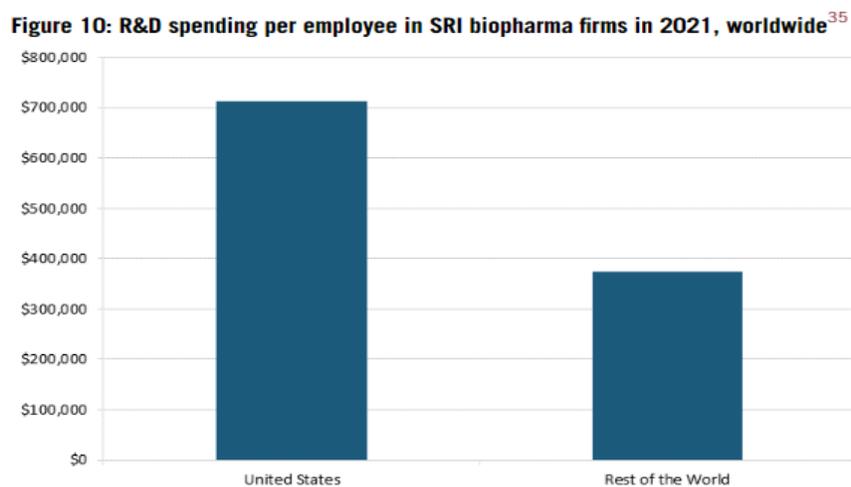


Chart from ITIF at reference 6

⁶ <https://itif.org/publications/2023/08/21/preserving-us-biopharma-leadership-why-small-research-intensive-firms-matter/>



The result of this capital intensity is that small biotechs have an outsized contribution to the biomedical innovation landscape, bringing new drugs to market both on their own as well as by transactions with larger companies. On both paths, larger companies play a critical role in providing financial as well as complementary knowledge resources through deals that can range from licensing experimental products to acquiring an entire entity.

As noted in Chart 5 below, Schuhmacher et al found that, between 2015 and 2021, the top 20 biopharmaceutical companies were responsible for 43 percent all new drugs approved by the FDA (138 of the 323 cited in the study). This comports with existing evidence showing that the majority of new medicines come from small companies,⁷ whether it is on their own or through a larger company.

From the 138 new drugs advanced by the top 20 biopharmas Schuhmacher and colleagues reviewed, 41 percent were gained through mergers and acquisitions.⁸ This illustrates, once again, that small innovative entities work on their own and with mid-sized and large companies to advance medicines to the bedside.

CHART 5: R&D Origin of Select Medicines Taken to Approval by Select Large Companies

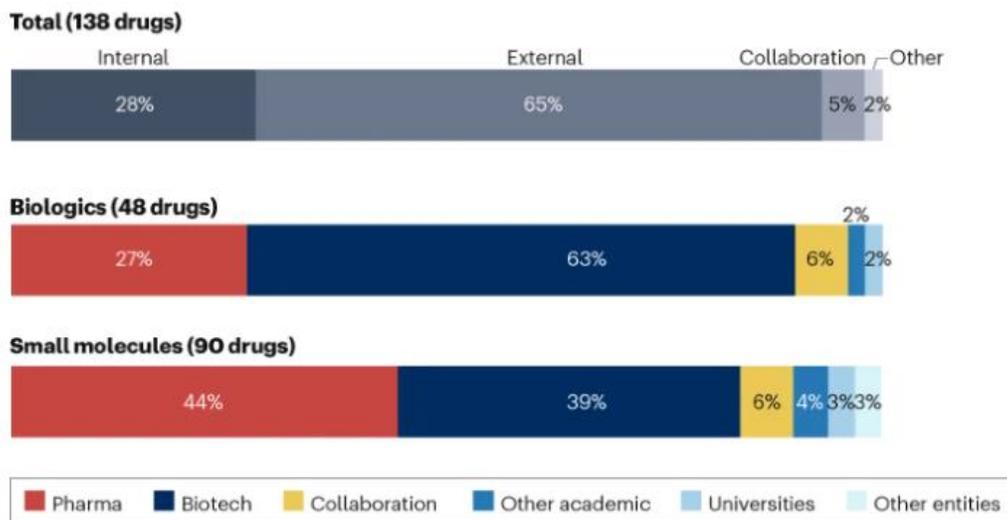


Chart from Schuhmacher et al at reference 6

This distribution of innovation production is an example of an ecosystem designed with a unity of purpose to push forward biomedical R&D and medicine development. But it happens as an

⁷ <https://www.bio.org/fda-approvals-clinical-development-pipeline>

⁸ Schuhmacher et al, "Investigating the origins of recent pharmaceutical innovation," Nature Reviews Drug Discovery, 05 July 2023



ecosystem—a network of stakeholders that includes academia, small innovators, investors, and large companies—connected through and supported by transactions and deals that advance R&D and translate it into medicine and other biomedical products.

An MIT study analyzing the differences between the biotechnology ecosystems in the United States and Japan found that Japan had several challenges versus the U.S. including “the weakness of the network among stakeholders and of the support system for startups; the low level of entrepreneurship and of opportunities to foster it; and the limitation in the capital available. These challenges exist even though there is strong support from the government.”⁹

In other words, what makes the U.S. biopharmaceutical industry work is the ecosystem and capital availability. Effectively, the Commission’s proposed actions are challenging our industry’s competitive advantage vis-à-vis the rest of the world.

A perfect example of the utility of these deals is Pfizer’s financing deal with BioNTech in 2018 that laid the foundations upon which their rapid response to the SARS-CoV-2 pandemic were built.¹⁰ Not only did Pfizer possess the supply chain networks to procure all novel and critical inputs at scale and internal experts necessary to design and run global clinical trials, they also possessed the industrial know-how to quickly solve manufacturing challenges and scale production capacity from 200 million doses per year to 2.5 billion doses in less than a year. This compares to the decade it took to first achieve the 200 million dose capacity.¹¹

The Commission’s current path represented in both the revised merger guidelines as well as the proposed changes to the Hart-Scott-Rodino form threaten these types of deals that are a fundamental feature of the innovation ecosystem.

The Pfizer-BioNTech story is a quintessential example of the dynamism of the American ecosystem and the symbiotic and critically important relationships between small innovators and larger companies. The same can be said about the acquisition of Immunex by Amgen.

Few people recall what the world was like for patients with rheumatoid arthritis (“RA”) before the advent of biological medicine. While the disease had always been a feature of the human condition, it was not until median life expectancy improved that the “pains of aging” became

⁹ <https://dspace.mit.edu/handle/1721.1/122248>

¹⁰ <https://investors.biontech.de/static-files/e5cda6ca-5527-45d7-a840-98376bb3d2d3>

¹¹ Lewis et al, “The Race to Develop the Pfizer-BioNTech COVID-19 Vaccine: From the Pharmaceutical Scientists’ Perspective,” *Journal of Pharmaceutical Sciences*, 18 September 2022



commonplace,¹² as did the progressive damage to joints wrought by the disease, resulting in deformities and loss of function.

To that end, Immunex produced one of the most important medicines ever created, Enbrel, that would go on to treat a number of autoimmune diseases. Immunex, immediately prior to the Amgen acquisition, had already been acquired twice before—first, by American Cyanamid and then by American Home Products—as the small company faced revenue headwinds and mounting R&D costs. These transactions ensured their survival. Immunex stayed focused and advanced their pipeline of experimental medicines with Wyeth-Ayerst Pharmaceuticals, at the time a subsidiary of American Home Products, helping to finance development and marketing of Enbrel.¹³

However, in its early launch stages, the company miscalculated demand and experienced several manufacturing challenges.¹⁴ It took the acquisition by a skilled manufacturer, Amgen, to scale-up production¹⁵ and invest in more clinical trials that expanded Enbrel’s use into other autoimmune disease indications, such as axial spondyloarthritis. Enbrel was also the first medicine for the treatment of axial spondyloarthritis, a chronic inflammatory disease of the spine and axial skeleton (from the skull to the tail bone and everything in between).

These stories of successful innovations that address some of society’s most pressing health challenges is possible because of the U.S. innovation ecosystem. We are home to 43 percent of the world’s top ecosystems (13 of the top 30), according to Startup Genome, who also estimates that Silicon Valley alone generates \$2.4 trillion in economic value versus \$757 billion for Beijing and \$364 billion for London.¹⁶

¹² Entezami et al., “Historical Perspectives on the Etiology of Rheumatoid Arthritis,” *Hand Clinics* (2011)

¹³ <https://www.encyclopedia.com/social-sciences-and-law/economics-business-and-labor/businesses-and-occupations/immunex-corp>

¹⁴ “The patient waiting list already had soared to tens of thousands for the rheumatoid arthritis drug Enbrel when Amgen Inc. sent its biotech SWAT team of 100 experts to Rhode Island last spring on a critical mission: to clean up a drug factory and get it ready for production by year-end...When Amgen inherited the Enbrel factory, more than 40,000 people suffering from arthritis were on a waiting list for the drug...The Rhode Island plant “would never have passed FDA inspection” without a major overhaul.” <https://www.latimes.com/archives/la-xpm-2002-dec-24-fi-amgen24-story.html>

¹⁵ <https://rapport.bio/all-stories/innovation-and-acquisitions-feature-not-bug>

¹⁶ Startup Genome, *Global Startup Ecosystem Ranking (GSER)*, 2023



CHART 5: Economic Value of Global Startup Ecosystems

North America Is Home to 45% Of the World's Top Ecosystems

Share of the Global Startup Ecosystem Ranking 2023 (Top 30 + Runners-up)

Source: Startup Genome, 2023

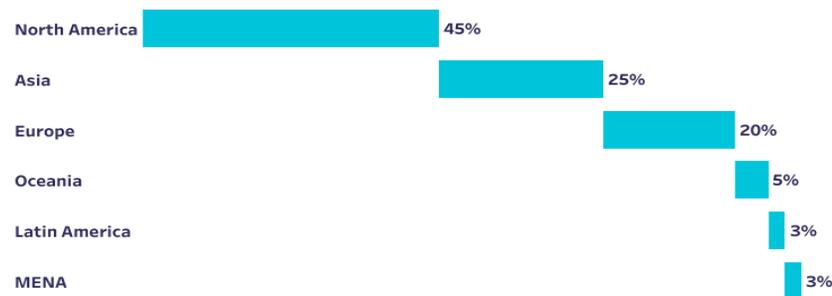


Chart from Startup Genome

The dynamism of American capital, and the various deal structures that define it, is the necessary element that makes our innovation economy work. Dr. Charles Wessner, of the National Academies, noted in his chapter in the publication *Local Heroes in the Global Village* that a strong innovation ecosystem incentivizes “complex inter-linkages among a variety of participants in an innovation economy...and the importance of the incentives the various actors encounter.”¹⁷

These incentives are made possible by our current laws and regulations governing the flow of capital and the deals that define them as they are part of the set of exit opportunities for early investors. These exit opportunities attract investment to drive both the funding of discovery research and the translation of these inventions into medicines. Research shows that ecosystems flourish where there are ample exit opportunities for investment capital.¹⁸

Critically, the presence of and participation by large companies underpins the dynamics of this ecosystem. There is a body of literature discussing the optimal structures for nurturing innovation and the role of investors in innovation outcomes. This body of empirical research

¹⁷ Wessner, C.W., “Entrepreneurship and the Innovation Ecosystem Policy Lessons from the United States,” in *Local Heroes in the Global Village*, International Studies in Entrepreneurship, Volume 7 (2005)

¹⁸ Eisa Aleisa, “Startup Ecosystems: Study of the ecosystems around the world,” University of Hamburg (2013)



highlights the critical role of large corporations in the biomedical innovation ecosystem and the acceleration of output that results from these relationships.

Shuwaikh and Dubocage¹⁹ as well as HD Park and Steensma²⁰ have found that the participation of large corporations is essential to an ecosystem as large companies raise both the chance of survival and probability of successfully developing a novel product. Shkolnykova and Kudic²¹ found that direct cooperation between large companies and small- and mid-sized “radical innovators” yield higher innovation performance across all entities. This latter point is confirmed by Shuwaikh and Dubocage, who show that small biotechs with corporate parents yield almost 2.5-times the number of patents per year versus companies backed by private venture capitalists.

While BIO takes issue with the use of patents as a measure of R&D productivity, because not all science is patentable and given the long gap between patent application and product introduction, the authors also found that small biotechs with corporate partners had more citations. This implies that they made significant contributions to the global body of knowledge.

The positive impulse into an ecosystem from large companies is attributed to the specialized information and complementary resources needed for success, in addition to the financial resources that they provide. This especially holds true in innovative sectors, such as biotechnology.

The biomedical ecosystem, especially the relationship between small and large companies, is defined by their complementary nature, which has been shown to lead to enhanced innovation output and quality. BIO supports policies that allow for deals furthering innovation in mergers and acquisitions between complementary partners. We are concerned that Guidelines 9 and 12, as well as the broadened definition of product market, are decidedly negative for biotech deals.

According to Cassiman et al, “M&A between partners with ex-ante complementary technologies result in more active R&D performers after the M&A. Moreover, R&D efficiency increases more prominently when merged entities are technologically complementary than when they are substitutive.” The authors go on to find that economies of scope in product markets lead to efficiencies in the R&D process but also stimulate R&D and have a positive effect on R&D performance.²²

¹⁹ Fatima Shuwaikh and Emmanuelle Dubocage, “Access to the Corporate Investors’ Complementary Resources: A Leverage for Innovation in Biotech Venture Capital-backed Companies,” *Technology Forecasting & Social Change* (2022)

²⁰ H.D. Park and H.K. Steensma, “The Selection and Nurturing Effects of Corporate Investors on New Venture Innovativeness,” *Strategic Entrepreneurship Journal* (2013)

²¹ *ibid*

²² Cassiman et al, “The impact of M&A on the R&D process: An empirical analysis of the role of technology- and market-relatedness,” *Research Policy* (2005)



However, the dynamism of capital and the interconnected network within the U.S. biotech ecosystem yet again provides evidence of its unity of purpose in driving forward biomedical R&D in the face of disposals. Even in these circumstances, small biotech innovators spring into action as they too make acquisitions from small, mid-sized, and large companies. Hammoudeh *et al* show that small biotechs improve innovation efficiency and the probability of innovative product development when they acquire technology from large companies.²³ Most times these acquisitions are still financed with capital from the selling party and from private investors.

The current ecosystem of entrepreneurial risk taking compels large companies to collaborate with small companies to develop ideas. Large companies cannot advance all ideas by virtue of investor demands for streamlined operations across therapeutic categories, so they need external innovators to take non-core ideas forward.

The existing frameworks and analyses used to evaluate mergers and acquisitions in the biopharmaceutical domain are adequate and supported by a body of consistent and coherent economic evidence, particularly for those transactions in the biopharmaceutical domain. BIO contends that certain elements of the proposed Merger Guidelines may be harmful to the biomedical innovation ecosystem.

Imposing additional restrictions or creating a hostile regulatory landscape that punishes the existing mechanisms of innovation development will severely impede domestic output of biomedical innovation across the biotechnology sector—from the farm gate to the lab bench. The threat of longer lead times and additional costs, vis-à-vis longer administrative form submissions, and the additional scrutiny of life sciences deals can chill investment to the point that the additional uncertainty commands too high of a premium that deals will no longer be pursued or be skewed away from those that the need the support the most.

BIO's Concerns with Specific Guidelines

Guidelines 2 and 3 Are Contradictory

BIO is concerned that Guideline 2 and Guideline 3²⁴ disagree with each other and may create a general sense among market participants that the Commission is creating a framework whereby any proposed merger can be considered anticompetitive for any reason.

²³ Hammoudeh et al, "Dusting off the old ones: drug licensing to startups, innovation success and efficiency," (2023)

²⁴ For context, Guideline 2 is titled "Mergers Should Not Eliminate Substantial Competition Between Firms," and Guideline 3 is titled "Mergers Should Not Increase the Risk of Coordination."



In Guideline 2, the Commission writes that “the more the merging parties have shaped one another’s behavior, or have affected one another’s sales, profits, valuation, or other drivers of behavior, the more significant the competition between them.” The Commission goes on to provide examples, suggesting that firms monitoring each other and “taking steps to preserve or enhance the competitiveness or profitability of their own products or services” is considered “evidence of competition between merging firms.” Yet, in Guideline 3 the Commission suggests that this type of behavior, which the Commission calls “observation and response to rivals,” represents tacit coordination and is deemed as anticompetitive behavior.

This is confusing.

In the span of three pages, the Commission explains a general thesis that mergers should not eliminate “substantial competition” between firms while at the same time providing as evidence of anticompetitive practices the very behaviors previously extolled as evidence of substantial competition. In other words, what is considered positive evidence of competition between firms under Guideline 2 is also considered negative evidence of market concentration and the increased risk of coordination (anticompetitive practices) under Guideline 3.

BIO is concerned that this confusion needlessly increases the risk of lengthy and expensive litigation in the future. What is considered evidence of competition should remain flexible, but principles-driven and should not also be considered evidence of anticompetitive practices. A green light cannot simultaneously mean both stop and go and should not be open to interpretation. Guidelines help to guide market participant behaviors. BIO encourages the Commission to clarify this further. We seek to ensure that any possible future accidents are mitigated by some clarity upfront.

Finally, within the context of this confusion created by Guidelines 2 and 3, it is not immediately clear whether the Commission desires a transparent or an opaque marketplace.

The Commission categorizes market transparency as a secondary factor in determining if a “merger may meaningfully increase the risk of coordination, even absent primary risk factors.”²⁵ The Commission also writes, “A market is more susceptible to coordination if a firm’s behavior can be promptly and easily observed by its rivals.”

BIO is confused and concerned with this language as it implies that market transparency can be anticompetitive.

BIO believes that market transparency is critical to a dynamic and highly competitive marketplace. It should be encouraged and not viewed as a possible anticompetitive practice.

²⁵ *ibid*



BIO recommends that the Commission provide clarity on this point. As written, Guideline 3 risks unintended consequences for market transparency.

Guidelines 4, 9, and 12 Cast a Shadow Over the Biopharmaceutical Industry

As explained throughout this comment letter, Guidelines 4, 9, and 12 strike at the heart of the biopharmaceutical ecosystem. Small research-intensive biotechs count on funding, partnerships, alliances, and a myriad of deals with large companies to advance R&D and rapidly expand the reach of approved medicines.

As we noted in detail above, M&A within the biopharmaceutical ecosystem are necessary conduits of capital as they offer the lowest cost of capital available (stemming from large company retained earnings), and lead to R&D and innovation productivity gains, output gains, and improves the quality of innovation, provided that the deal is between complementary firms.

BIO contends that Guidelines 4, 9, and 12 needlessly put a roadblock in the way of the very transactions that are responsible for ensuring the competitiveness of our industry. BIO has cited numerous academic studies in the previous section that point to these benefits and counter the contentions upon which the Commission based their decision. Our citations include authors, such as Dr. Patricia Danzon, who was part of the Commission's Multilateral Biopharmaceutical Mergers Taskforce and agrees that these mergers do not pose a threat to industry competition. Other authors we cite show that these mergers have significant, positive amplifying effects on R&D and innovation.

BIO's main concern with Guidelines 4 and 9 is the potential for a de facto adversarial position to develop with respect to large biopharmaceutical companies. Almost all of these companies acquire programs, pipelines, and entire companies, as explained above, and undergo licensing deals, in part or in whole.

Guideline 4 threatens to block deals whereby a larger firm *could have* internally developed its own product rather than by entering into an agreement with smaller companies. The proposed revisions suggest that the Commission will look for evidence that a "firm has sufficient size and resources to enter [into a market]²⁶" without indication as to what criteria may be used for such evaluations nor indications as to how the Commission will treat such internal analysis composed by companies. This proposed stance suggests that the Commission will become the final arbiter of capital allocation decisions for private enterprises who must justify allocations to independent Boards and shareholders. Effectively, the Commission seeks to uproot decades of decision science for investments, such as cost-benefit analyses.

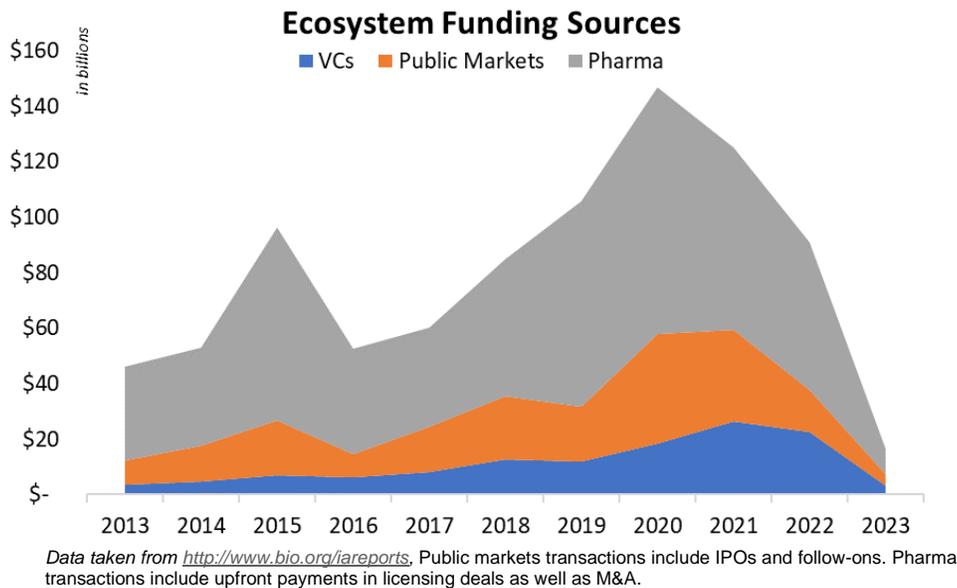
²⁶ *ibid*



The implication of Guideline 4 and 9 is that future deals may be automatically blocked, with Guideline 9 implying a more pernicious outcome in that previous acquisitions may be challenged or unwound. This potential would, in no uncertain terms, be catastrophic to the industry as the consequences for small biotechnology companies would be a severe downturn. Without these deals to provide capital and complementary resources, the virtuous cycle for which the industry is known will grind to a halt and the industry will face significant headwinds. The consequences will echo for generations to come and the promising future which is within our grasps will be forfeited.

As mentioned, large companies provide significant amounts of funding for small biotechs. As noted in the charts below, corporate deals constitute more than 50 percent of capital flowing into the ecosystem every year. This is important to note relative to Chart 5 above, which shows where innovation is most productive (small companies). In short, small companies produce the most medicine and most of their funding comes from the source with the lowest cost of capital and most complementary resources: large biopharmaceutical companies.

CHART 5: U.S. Biopharmaceutical Ecosystem Funding Sources



With respect to Guideline 12, BIO shares similar concerns as with Guideline 9. Chiefly, these are commonplace transactions in our ecosystem as these transactions can occur at any point in the lifecycle of a biotech. BIO can support post-acquisition observation in lieu of the



dangerously prospective nature of the majority of the proposed guidelines as this gives all parties incentives to show by example the benefits of the deals to the ecosystem. As we previously mentioned, transparency is a critical component to markets and competition.

BIO does, however, disagree with the contention that partial acquisitions can lessen competition by reducing the incentive of the acquirer to compete, and the contention that coordination between the partial acquirer and the smaller entity can lessen competition.

BIO cannot speak to evidence in other industries and BIO fully appreciates the possibility for anticompetitive behaviors that could result from improper coordination amongst rivals. However, in the life sciences, as noted above, the complementary resources available for R&D and other business aspects of the biotechnology industry accelerate innovation, improve R&D quality, and increase innovative output. The symbiotic relationship between complementary small, mid-sized, and large companies advances medical research and has been broadly viewed as pro-competitive. The academic literature cited above provides ample evidence counter to the propositions outlined in Guidelines 9 and 12.

BIO respectfully requests that the Commission reconsider the inclusion of Guideline 9 and Guideline 12 as they both run counter to recent academic studies, including those studies highlighted by the Commission. These data suggest that the Commission's views may not accurately reflect the incentives and behaviors of the biopharmaceutical ecosystem, and BIO is concerned with potential unintended consequences that may result.

The Guidance on Product Market Definition Is Imprecise and Overly Flexible

As noted in our previous letter,²⁷ BIO is very concerned with the arbitrary expansion of the definition of relevant market beyond appropriate product markets because a broader definition fails to appreciate the increasingly specific and differentiated products that are being developed in the biopharmaceutical industry. New modalities with new targets and novel methods of treating diseases are being developed at an accelerated rate. And a broader net will needlessly slow down necessary financing transactions.

As we noted in our previous letter to the Commission, BIO maintains our level of concern with the unintended consequences and direct, predictable deleterious effects of applying a broad approach to biomedical markets as it would entail substantial uncertainties that require a significant number of assumptions about the manifestation of competition in future markets.

²⁷ BIO Comments to FTC Merger Guidelines Request for Information



Conclusion

BIO thanks the Commission for their work in these important areas of competition policy. We welcome the opportunity to engage with the Commission to better align regulatory objectives with biomedical ecosystem needs and incentives. We seek to ensure that what makes our ecosystem the best in the world continues that way far into the future.