



April 15, 2022

Federal Trade Commission
Office of the Secretary
600 Pennsylvania Ave NW
Washington, DC 20580

Re: Request for Information on Merger Enforcement

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 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 advancing the health and well-being of our families.

All of these companies depend on a highly specialized investment ecosystem, in which mergers and acquisitions from larger entities play a crucial and fundamental role. **Imposing additional restrictions on the opportunity for mergers and acquisitions will severely impede the ecosystem that has catapulted the U.S. life sciences and biomedical innovation sector into its current leadership position in the world**, which was not always the case. Policies that have fostered entrepreneurial risk taking and early-stage investment have allowed this ecosystem to flourish.

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 involving the purchase of a small biotechnology company by more experienced biopharmaceutical companies, which are often larger. The structurally low probabilities of success inherent in every clinical program makes decisions based on speculation about potential market share and competitive effects unfeasible.

The current scope of analysis at the product market level, involving modalities and therapeutic targets, has evolved with the industry and is considered the most sophisticated competition analysis known. **Arbitrarily expanding theories of harm, product market definitions, and/or competitive effects without a sound economic rationale for doing so will yield negative unintended consequences for the ecosystem**, which relies on merger and acquisitions by larger biopharmaceutical partners to maintain the momentum of innovation in the space.

In the following comment letter, BIO endeavors to illuminate the importance of mergers and acquisitions of small biotechnology companies by larger biotech partners, how the industry has transitioned to new models that already take into account many concerns voiced by the



Commission and Members of Congress, and we answer the questions posed by the Commission in order.

The Importance of Mergers and Acquisitions for Small Biotechnology Companies

According to economist Frank Knight, the role of the entrepreneur is to transform uncertainty into a calculable risk.¹

In biotechnology, these risks stem from all that is not known about the nature of disease and the infinite universe that is human physiology, both of which manifest in the extremely high failure rates of clinical programs. A recent study by MIT shows that oncology programs have a 3.4% chance of ultimate FDA approval² and yet tens billions of dollars are dedicated annually to finding, testing, and seeking approval for proposed treatments in an attempt to bend the arc of malady and extend quality life years.

These low probabilities of success and significant sums of money required to facilitate these scientific gambits requires a highly specialized ecosystem.

The American life sciences ecosystem has developed over decades to efficiently price, transfer, and absorb these entrepreneurial risks. It has developed into an arena of hyper-focused participants that specialize in research, development, and investment in the discovery as well as commercialization potential of life sciences endeavors.³

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 to further mature a technology or advise companies through a particular period.

Biopharmaceutical venture or business development teams seek acquisitions from the ranks of biotech entrepreneurs to complement (“bolt on”), redefine, and / or enter into new therapeutic areas. These acquisitions are almost universally pursued prior to product approval when competitive significance, pre-merger margin forecasts, expected pricing, and even the justification or validation of “disruptive” or “nascent competitor” claims remain uncertain since the future of an acquired pipeline remains uncertain until the FDA provides approval. Recall, that

¹ Braunerhjelm and Svensson, “The Inventor’s Role: Was Schumpeter Right,” *Journal of Evolutionary Economics* (August 2008)

² Lo et al, “Estimation of clinical trial success rates and related parameters,” *Biostatistics* (2018)

³ 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



according to Lo et al., the aggregate probability of successfully getting approval from the FDA is 20.9% for non-oncology programs but only 3.4% for oncology programs.⁴

These risks must be diversified among various participants with ever increasing investment horizons, capacity to sustain volatility, and deep experience to understand the risks and opportunities of a given technology at a certain point in the development lifecycle. In this regard, mergers and acquisitions of small biotechnology companies by large biopharmaceutical partners is absolutely critical in advancing therapeutics and maintaining the health of our ecosystem. This is because larger firms have the expertise and resources required for the next two stages in the process after initial concept development and early safety studies: later-stage development, including clearing regulatory hurdles before the FDA, followed by ramping up manufacturing and successful commercialization.

Due to the highly specialized nature of most biotechnical products, the number of firms that can realistically acquire a startup and speed up time to market is often small. For example, an incumbent firm with a portfolio of cardiac and vascular products is unlikely to have the experience, capabilities, and resources to efficiently and economically commercialize a product in a different space, e.g. diabetes. It is therefore unsurprising that acquirers are often already active in related product spaces, including markets upstream or downstream of the acquired firm.

In short it takes a village...a very specialized village to bring an innovative biotechnology product to market. Correspondingly, these participants need exit opportunities in order to recuperate and redeploy funds, talent, ideas, and lessons-learned back into the innovation ecosystem.

A Case Study

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.⁵ The exit opportunities required for these investments, via IPO or M&A, are necessary to sustain the pipeline of innovation coming out of universities with the hope being introduced into the market.

For the ecosystem to sustain itself, there must be a return on capital which bears the greatest risk given investment in nascent ideas, and a redeployment of those returns back into the system. Early-stage investors, who supply 53% of funding in this ecosystem, rely on acquisitions, IPOs, and/or other investors (other venture firms or public equity investors) to obtain that return. No bank, traditional financial institution, or government program can bear these sums of capital tied to high probabilities of failure. The innovation ecosystem has existed and evolved since the 1800s to allow for risk capital to finance risky endeavors.

⁴ Supra note 2

⁵ Id.



Large biopharmaceutical company acquisitions play a critical role in this ecosystem as they supply the remaining 47% of funding for small biotechs. They also provide greater clinical and regulatory speed, higher probability of success given institutional memory on decision making, and unequal reach to patients for the therapeutic candidates originating in small companies.

The stratification of outcomes, vis-à-vis development, regulatory approval, and manufacture in the COVID-19 vaccine product space is illustrative of the significant uncertainties associated with each step in the process and, ultimately, outcomes. Some companies, once considered frontrunners, have yet to produce a viable vaccine while other venerable institutions produced comparatively less-effective products. An acquisition of product pipelines and associated personnel throughout this product development journey would not have yielded clearly predictable postulates in the assessment of the proposed merger or acquisition.

The current hypothesis of shifting the theories of harm and evaluation to a state wherein a lack of evidence or understanding is a sufficient precondition for denying a merger or acquisition would have adversely affect lives in real-time. This case study holds true for the entire ecosystem of mergers and acquisitions by larger biopharmaceutical partners of small, innovative biotechnology companies.

Competition in Scientific Innovation

Contrary to recent statements made by academics and non-practitioners in the current debate on the structure and function of competition in the biopharmaceutical space, this ecosystem is not “a distortion of competition.” Rather it is the definition of competition in the world’s most dynamic and successful innovation ecosystem. The proof is in the success of the U.S. biotechnology sector, which leads the world in innovation. The U.S. model produces more new drugs each year than the rest of the world combined. Cutting edge gene therapies, mRNA vaccines, biologics, and other game changing innovations demonstrate the value and vitality of the U.S. model.

The American biotechnology ecosystem has evolved over decades to perform the very function that has allowed society to respond with novel technologies to a pandemic in record time despite inherently low success rates in our industry. For example, there are only two approved vaccines for COVID-19, one product with a U.S. emergency use authorization, 11 with ex-U.S. emergency use authorizations, and 18 that remain in Phase III clinical trials. Crucially to note, 26 vaccine candidates failed. For more context, a total of 54 proposed antiviral medications and 90 different treatments failed in the course of responding to the pandemic.⁶

This means only two in 58 vaccine attempts reached final approval, which is a 3.4% success rate.

⁶ <https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker>



BIO urges that new antitrust theories of harm should not disallow or dissuade these leaders from acquiring small, innovative biotechnology companies developing the next generation of mRNA products and new products based on mRNA technology. In fact, this should be encouraged to enhance the pipeline of new therapies to treat the myriad of diseases that would otherwise go untreated or prevent the creation of the next generation of therapeutics to treat chronic conditions that continue to plague western society, which are increasingly found in the Global South.

Acquisitions of small biotechnology companies by larger biopharmaceutical partners are demand-enhancing for biomedical innovation as these acquisitions intend to monetize product innovation for margin expansion.⁷ 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 as clinical trial requirements, and therefore costs and time, increase. Accordingly, R&D expense must 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. This strategy applies across an entire portfolio of disease categories and biotech products.

More than any other time in history, the biopharmaceutical ecosystem is tackling some of the rarest, most difficult to treat, and pernicious ailments known to society. The symbiotic relationship between small biotechs and larger partners, supported by the most robust innovation ecosystem in the world, has brought to market *more* therapies, not less as argued by many pundits and legislators that believe mergers in the space have led to a decline in innovation and new medicines.

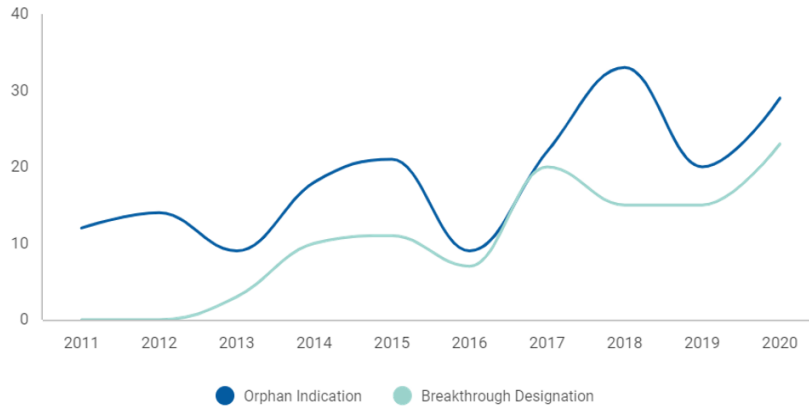
This ecosystem has designed more breakthrough technologies and targeted more orphan diseases than ever. And large pharmaceutical companies are spending more and more, not less. The ecosystem is what supports these rates of success.

⁷ 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*. This academic exercise in the competitive effects of the mergers of equals (“horizontal mergers”) has incorrectly been applied to vertical mergers. 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. Notably, said studies also specifically exclude the acquisition of small biotechs (defined in these studies as small companies with revenues less than €2,000,000. 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 biotech companies 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 antithetical to the industry as explained throughout this comment letter and in our comment letter to the Pharmaceutical Mergers Taskforce RFI.



Innovation Has Increased NOT Decreased

Trend in Disease Modifying Therapies

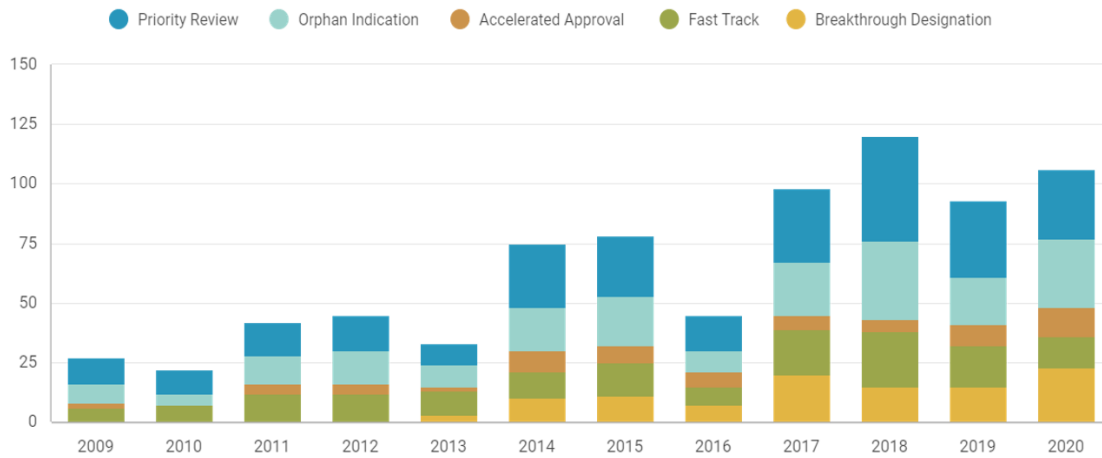


263%
Increase in **ORPHAN DRUG** Designations

160%
Increase in **Breakthrough** Designations

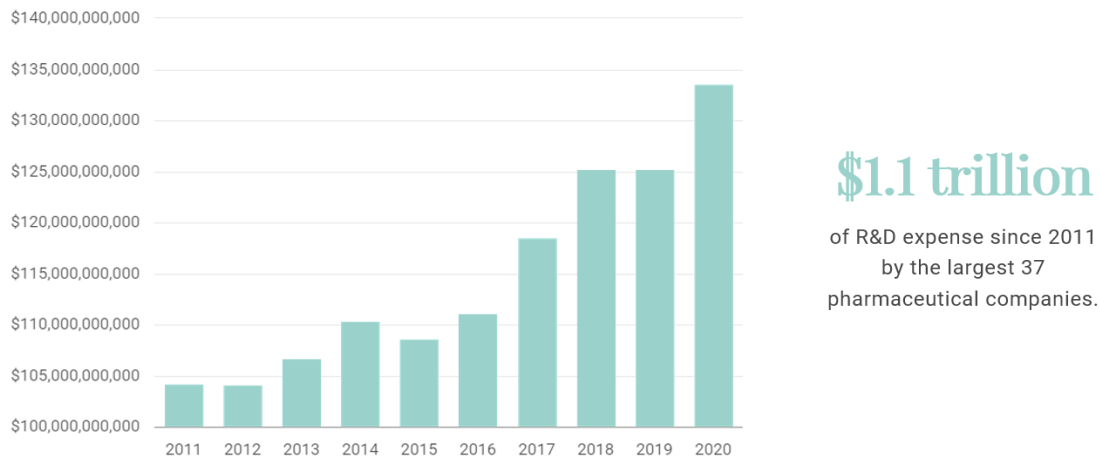
Trends in FDA's Designation

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





Top Pharmaceutical Company R&D Expense



Furthermore, the notion that companies will innovate differently if their intention is to be acquired versus how they would innovate if they intended to bring the product to market themselves does not apply in the biopharmaceutical industry as the ecosystem has required milestones to continue raising capital, and regulators have required standards of evidence to allow a company to progress through clinical trials and ultimately reach approval.

In order to attract investors, either venture capitalists or corporate partners, scientific entrepreneurs must present unique scientific ideas, replicable and enticing data, and transparent processes. And each new financing, be it private financing or follow-ons when public, requires incrementally more data to show investors progress in the development of the science and the therapeutic, known as milestones.

Accordingly, the innovation process is the same whether one anticipates merger or one anticipates self-launching a product; *in vitro* data, *in vivo* data across different animal models, toxicology data, pharmacokinetics, metabolite analysis, an understanding of the mechanism of action, safety in humans (Phase I), and effectiveness studies across different populations (Phase II and III). In short, the innovation process is not altered by exit opportunities. Rather innovation would not begin if exit opportunities were no longer available.

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 Atlantic⁸) and countries of comparative size (across the Pacific⁹) seeks to challenge in the coming decades.

Market Evolution

Not all mergers go as planned. Not all acquisitions yield positive results. The industry learns and adapts amid these shortcomings and has evolved into its current state of dynamic competition.

While the M&A of prior decades sometimes led to absorption and dilution of teams for the sake of “synergies,” most companies in the world, particularly in the biopharmaceutical industry, realize that a company’s greatest asset is its people. This has become particularly germane in the life sciences space over the last decade given the dearth of talent that has become especially problematic since COVID-19. Some acquisitions today are done with the goal of acquiring entire specialist teams in addition to acquiring research pipelines.

The industry has also learned that small biotechnology companies have a secret sauce that cannot be replicated within the structures of a large company, and that is culture. The phenomenon of company culture has evolved since the early 2000s and been taken to heart in the biopharmaceutical industry. The trend now is to maintain acquired small biotechnology companies as subsidiaries in order to preserve their culture, which is a critical attractor for talent and ideas.

For example, Roche acquired Spark Therapeutics and kept it as a subsidiary so as not to disturb the culture of innovation that made Spark a desirable target and allowed its team to develop the first gene therapy to treat a rare, inherited retinal disease that leads to blindness in childhood. Gilead’s acquired Kite Pharmaceuticals and maintained it as a subsidiary allowed to work independently to bring an immunotherapeutic to market. Similarly, Bayer recently acquired AskBio, which it is keeping as an independent subsidiary.¹⁰

Currently, post-acquisition integration strategy model is underpinned by this arm’s-length philosophy that shares three central principles: (1) protect ingenuity and culture, (2) empower founders and staff, and (3) change as little as possible.

In furtherance of this philosophy, many large pharmaceutical companies acquire small biotechs and create a governance structure familiar to all founders: a board. These boards include pharma executives, acquired company executives, and independent directors. These acquired biotechs are then provided with several years of R&D budgets to continue pursuing their work, which,

⁸ UK Life Sciences Vision: <https://www.gov.uk/government/publications/life-sciences-vision>

⁹ 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>

¹⁰ <https://www.askbio.com/bayer-acquires-askbio-to-broaden-innovation-base-in-cell-and-gene-therapy/>



when ready, would be integrated into the large pharma's development pipeline for clinical testing and regulatory approval.¹¹

The most recent evolution of the industry can be seen in the acquisition by Eli Lilly of Loxo Oncology. In this instance, Eli Lilly acquired Loxo Oncology to absorb and lead *all* of Eli Lilly's cancer research and product development in a new unit called, Loxo Oncology at Lilly. Put another way, Lilly acquired Loxo so that the Loxo team could lead Lilly's cancer programs.¹²

Finally, academic literature that has been cited to advocate against biopharmaceutical mergers and acquisitions also assumes that intellectual property is static and not dynamic.

Ideas continue to develop even after mergers. In many instances, intellectual property that is no longer part of core strategies is either spun-off (such as Cerevel Therapeutics spinning-off from Pfizer¹³) or sold to entrepreneurs who wish to advance the science with their own teams (such as Vincerx Pharma's exclusive license of Bayer's oncology portfolio¹⁴).

Purpose, Harms, and Scope

The current merger guidelines provide the antitrust agencies with effective tools to analyze transactions and their potential impact on competition. BIO cautions the antitrust agencies against implementing new, overly broad revisions to the merger guidelines that unduly restrict transactions that are not anticompetitive.

Our industry is very unconcentrated, with numerous small and large companies developing new therapies. In certain therapeutic areas, the number of competitors may be more limited, but this is simply an inherent feature of successful biopharmaceutical R&D. As noted above, out of the 58 total vaccines candidates only two have been approved and one has an emergency use authorization. This competitive landscape is universal in the industry.

Accordingly, the current framework from evaluating biopharmaceutical mergers, particularly vertical mergers between a biotech and a larger company, should continue to take into account this feature of the market and the R&D process and hence merger guidelines in this space should not be altered. Antitrust cases in the biopharmaceutical space have evolved over time to become specific and equitable in its determination of competitive concerns where there are reasonable assumptions of market entry and product concentration.

¹¹ There are manufacturing, clinical testing, and regulatory challenges that require scale, institutional memory, and significant capital to overcome.

¹² <https://www.biopharmadive.com/news/lilly-loxo-cancer-research-development-restructuring-josh-bilenker/568492/>

¹³ When the company decided that it could no longer compete and therefore no longer wanted to continue funding neuroscience programs, Cerevel was created and spun-off.

¹⁴ <https://investors.vincerx.com/news-releases/news-release-details/vincera-pharma-inc-announces-exclusive-license-agreement>



Furthermore, the low probabilities of success in the biotechnology space make estimating expectations of concentration unfeasible. There are instances where even the acquisition of Phase III assets from small biotechnology companies do not yield product approvals. In these cases, one may have incorrectly assumed that the acquisition would have “substantially lessened competition” even though the acquired product was never introduced into the market and therefore never materialized a competitive effect.

Thus, an adequate prospective definition for what constitutes a “substantial” lessening of competition remains elusive given the low probabilities of success of even Phase III clinical trials. The acquisition of even earlier stage companies, hence, becomes a substantial uncertainty whose effects on competition in designated product markets is incalculable to the point where analyzing estimations of “substantial” versus, say, “marginal” become merely guessing games.

Finally, current frameworks and case law has provided the requisite guardrails for the biotechnology industry while ensuring that patients have access to products that can and do improve quality of life as well as extend life years. BIO cautions the Commission on seeking to re-write and broaden what has taken decades to create.

Types of Sources of Evidence

The current guidelines and assessment frameworks, as they pertain the evaluation of biotech transactions, are adequate. As noted above, due to the evolving specificity of biological targets and changing modalities for achieving clinical results, evaluation frameworks should continue to narrow (become more specialized and specific) not broadened. It is dangerous to broaden the aperture of evaluation as many treatments will not materialize due to the lack of dynamism in the ecosystem as transactions will be stymied.

Finally, most economic analyses cited by the Commission and Members of Congress on biotech transactions focus on the competitive effects of mergers of companies of relatively equal size and/or revenue and inappropriately apply these analyses to the acquisition of smaller companies by larger ecosystem partners. Most commonly cited studies specifically exclude these acquisitions.

Accordingly, it is BIO’s position that the current framework for evaluating biotech transactions, particularly those involving smaller biotechnology companies and larger partner, are adequate and should not be broadened.

Competitive Effects

Frameworks currently used in the evaluation of mergers of the biotech industry, especially those transactions between smaller biotechnology companies and larger partners, remain adequate. BIO recommends no change as there has been no valid research to dictate otherwise.



Furthermore, the current guidelines have proven robust and already provide the agencies with the necessary tools to analyze potential competitive effects, including coordinated and unilateral effects, in the biotechnology industry.

The modern economy has become more specialized not more generalized. This is especially true in the biotech space where even organ-specific cancers are stratified by genomic definitions. Broadening the aperture of evaluation in the biotech space will be detrimental the proper functioning of our ecosystem, which remains an exemplar market with dynamic competition where patients across a variety of increasingly specific disease categories continue to benefit from innovative new treatments and diagnostics.

Today, more rare- and orphan-diseases now have treatments than at any other time in history. Transactions between smaller biotechnology companies and larger partners are instrumental in driving this innovation ecosystem forward as we endeavor to treat complex, unique diseases as well as those that continue to plague society, such as cardiovascular disease.

As noted above, some product markets, such as COVID-19 vaccines, only have two approved products, one product with emergency use authorization, and 18 in Phase III evaluation. While this may be considered oligopolistic when compared to gas stations, for example, the cracking of petroleum and processing into various grades of fuel can be done by anyone with the capital to pursue such an endeavor since the chemistry and process engineering are assured through decades of study and improvement.

However, in the biotech domain, positive outcomes are not guaranteed. In fact, given the single-digit probabilities of success associated with taking an idea from lab to market, one can say that failure is more guaranteed than is success. But society still needs newer and better medicine, so the ecosystem is willing to absorb those losses and continue to develop new therapeutics. M&A between large biopharmaceutical companies and smaller biotechnology companies is critical to maintaining this ecosystem.

There is little economic research or real-world evidence to suggest the presence of unilateral effects resulting from mergers and acquisitions between smaller biotechnology companies and larger partners. The current guidelines and assessment frameworks, as they pertain the evaluation of biotech transactions, are adequate.

Presumptions

Agencies and courts should only create presumptions when there is strong evidence that some easily identifiable set of conditions consistently creates undesirable outcomes. That is not the case for biotech mergers. The current guidelines and assessment frameworks, as they pertain the evaluation of biopharmaceutical transactions especially those transactions between smaller biotechnology companies and larger pharmaceutical partners, are adequate and should not be



broadened. In particular, there is no evidence suggesting that vertical mergers are inherently anticompetitive.¹⁵ In the absence of any evidence that vertical mergers are inherently anticompetitive, they should not be subject to an antitrust regime of strong presumptions that create *de facto per se* rules of illegality.

Further, given the low probabilities of success associated with even Phase III clinical trials, there currently is no appropriate methodology to conclude with a significant degree of certainty that any smaller biotechnology company could ever be labeled as a “maverick firm,” “closest competitor, or “nascent competitor.”

BIO has no position on labor concentration and its effects on competition. We will note, however, that the current state of labor shortages in the life sciences and the ensuing competition for talent is hard to improve absent a broader national commitment to improve and broaden access to STEM education and associated career choices, especially for underrepresented demographic groups. BIO continues to work towards building this awareness and partnering at the state level to increase K-12 awareness of STEM opportunities. Unless we are able to direct our best and brightest young people from all backgrounds into STEM education and professions, the U.S. will inevitably lag behind our global competitors in these innovation intensive fields.

Market Definition

Precise definitions are required when evaluating transactions in the biotech space. Evidence of substantial competition between merging parties, when those parties are a smaller biotechnology companies and larger partner, is lacking in the literature and in real-world evidence of how the biotech market functions. The current guidelines and assessment frameworks, as they pertain the evaluation of biotech transactions especially those transactions between smaller biotechnology companies and larger partners, are adequate and should not be broadened.

Potential and Nascent Competitors

The ability to enter into a new product market via acquisition in the biotech space is not a precursor to competition or guarantee of successful competition in a given product market, and, therefore, cannot be considered as a predicate for determining competitive effects or establishing whether a smaller biotechnology company can be considered a potential or nascent competitor or a maverick firm. The biotechnology industry is a graveyard of great ideas that never worked due to all that is not known about the nature of disease and human physiology. As noted above, the aggregate probability of successfully taking a molecule or program from lab to FDA approval is 20.9% for non-oncology programs and only 3.4% for oncology programs. These probabilities

¹⁵ See e.g., Francine Lafontaine & Margaret E. Slade, *Presumptions in Vertical Mergers: The Role of Evidence*, REV. INDUS. ORG. (2021) at 1, available at <https://doi.org/10.1007/s11151-021-09831-0>: (“We conclude that while some vertical mergers may raise concerns, the evidence at this point does not provide sufficient guidance to develop presumptions that are related to strictly vertical issues.”); Marissa Beck & Fiona Scott Morton, *Evaluating the Evidence of Vertical Mergers*, REV. INDUS. ORG. (2021) available at <https://doi.org/10.1007/s11151-021-09832-z>.



prove that acquisitions cannot predict the future of a given product market and, therefore, cannot be used to forecast the potential lessening of competition in the biotech space.

The current guidelines as they are applied in the evaluation of biotech transactions are adequate, particularly as they pertain to transactions between smaller biotechnology companies and larger partners.

Remedies

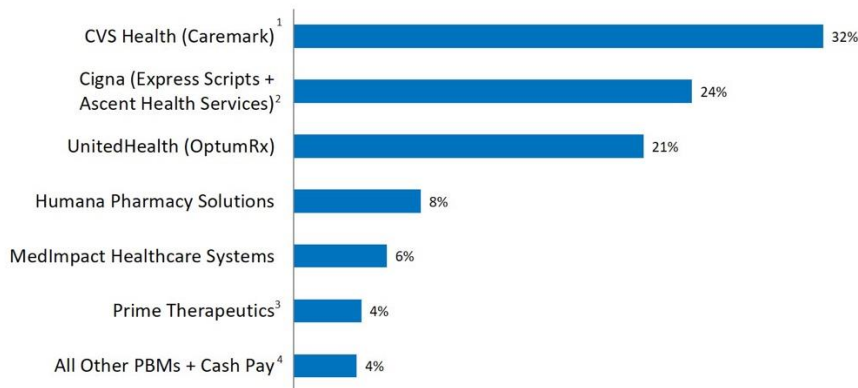
No position.

Monopsony Power and Labor Markets

BIO strongly recommends that the Commission study the impact of pharmacy benefit managers (PBM) healthcare market. Consolidation of the pharmacy benefit manager industry and ownership by insurers represents significant market concentration in the “powerful buyer” category that can represent oligopsonistic power in the direct customer base for most biopharmaceutical companies. Furthermore, the current guidelines provide the agencies with the necessary tools to undertake this PBM initiative.

Vertical consolidation in the PBM space has distorted the market for prescription medicines and is harming consumers. In 2020, the three largest PBMs managed more than three-quarters (77%) of all prescription drug claims in the United States. The top six handled more than 95% of all claims (see below).

PBM Market Share, by Total Equivalent Prescription Claims Managed, 2020



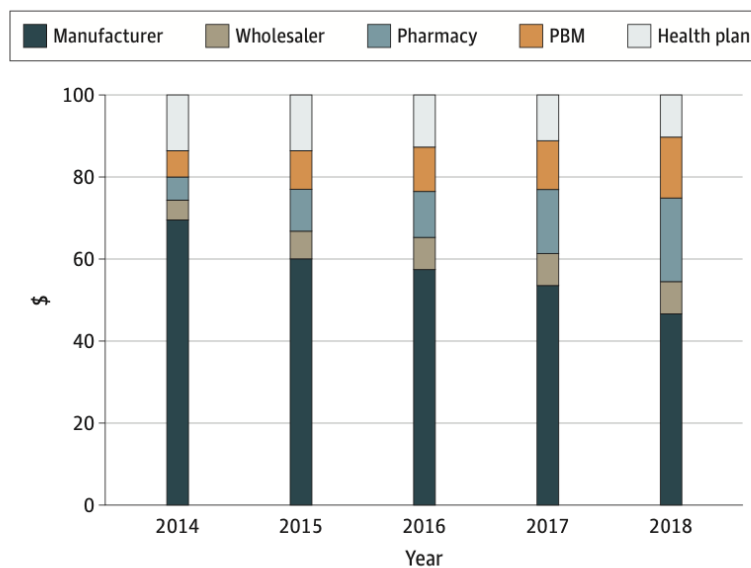
1. Excludes Drug Channels Institute estimates of double-counted network claims for mail choice claims filled at CVS retail pharmacies.
 2. Includes Cigna claims, which fully transitioned to Express Scripts by the end of 2020. Includes Ascent Health Services, which includes Kroger Prescription Plans and a partial year of Prime Therapeutics.
 3. Excludes Drug Channels Institute estimates of 2020 claims for which Ascent Health Services handled rebate negotiations and pharmacy network contracting.
 4. Figure includes some cash pay prescriptions that use a discount card processed by one of the 6 PBMs shown on the chart.
 Source: *The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute, Exhibit 92. Total equivalent prescription claims includes claims at a PBM’s network pharmacies plus prescriptions filled by a PBM’s mail and specialty pharmacies. Includes discount card claims. Note that figures may not be comparable with those of previous reports due to changes in publicly reported figures of equivalent prescription claims. Total may not sum due to rounding.



The vertical consolidation of pharmacy services paired with relatively few competitors in the space has led to some markets which exhibit monopsonist characteristics – the PBMs can represent the sole purchaser of prescription drugs for a majority of covered lives, employer plans or fully insured commercial products may have few (or no) alternatives to the dominate PBM(s) in their market if they wanted to seek out another entity to manage their pharmacy benefit, and the complexity of the pharmaceutical supply chain and scale that existing PBMs can leverage represent significant barriers for new entrants.

This market power enables PBMs to capture an outsized amount of value than would be observed in a competitive market. Consider the market for insulin – one category of prescription medicines that has garnered a great deal of attention in the debate of prescription drug pricing. A recent study analyzed the hypothetical distribution of \$100 of spending on 32 insulin products across manufacturers, insurers, and other supply chain entities from 2014-2018. The authors found that while expenditures per 100 units of insulin changed little over this time, the distribution of spending changed significantly (see below).¹⁶

Figure 3. Average Distribution of \$100 in Insulin Expenditures for 32 Insulin Products Across Distribution System Participants, 2014-2018



Over this period, the share of spending retained by insulin manufacturers and health plans fell (by 33% and 24.7%, respectively), while the amounts retained by supply chain intermediaries increased substantially: wholesalers (74.7%), pharmacies (228.8%), and PBMs (154.6%).

¹⁶ Van Nuys, Ribero, Ryan, and Sood, “Estimation of the Share of Net Expenditures on Insulin Captured by US Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans from 2014 to 2018. JAMA Health Forum. November 5, 2021. Available at: <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2785932>



While analysis of monopsony power has traditionally focused on labor markets, we believe these dynamics in the market for pharmacy benefit management warrant additional consideration and analysis by the Commission.

Innovation and IP

- a) **Should the guidelines use a different approach to market definition when considering innovation as compared to price effects? Should market definition play a secondary role to analysis of how the merger directly affects the incentive to innovate?**

The current guidelines as they are applied in the evaluation of biotech transactions are adequate, particularly as they pertain to transactions between smaller biotechnology companies and larger partners. BIO also advises against relaxing the need to clearly identify a relevant market in antitrust analysis in the biotech industry. Proper market definition is an important guardrail in analyzing the lawfulness of proposed mergers, and absent a clearly defined market, the analysis risks losing focus and getting obfuscated in the debate about innovation incentives generally. This is especially a concern when proposed mergers involve early-stage technology that is still untested and that may have multiple applications in different disease markets.

Further, as noted in the *Competition in Scientific Innovation* section above, current hypotheses on post-merger and post-acquisition declines in innovation are false as disproven in the data presented above.

R&D expense from the largest pharmaceutical companies has increased over time (not decreased as decried by regulators and legislators), and the number of new molecular entities that target previously untreated rare and orphan diseases has also increased over time. Together, this means that more money is being spent by the industry to produce more new medicines that treat previously untreated diseases. The U.S. domestic biopharmaceutical industry continues to lead the world in developing new, impactful medicines.¹⁷

- b) **To what extent does a focus on product market overlaps fail to identify broader concerns about incentives to innovate, particularly given that innovation may involve the creation of new product or service categories?**

The current guidelines as they are applied in the evaluation of biotech transactions are adequate, particularly as they pertain to transactions between smaller biotechnology companies and larger partners. It is dangerous to arbitrarily broaden the aperture through which transactions in the biotechnology ecosystem are evaluated.

¹⁷ <https://www.mckinsey.com/industries/life-sciences/our-insights/the-uk-biotech-sector-the-path-to-global-leadership>



BIO cautions the Commission against crafting an analysis that would tend to produce a presumption of anticompetitive or anti-innovative effects, or any analysis that would overweight said presumptions at the consequence of adequately capturing procompetitive or pro-innovation effects as these are much harder to forecast for products that are untested and in the development stage, where there is a high risk of development failure and where the commercial form and use of any resulting product is still uncertain.

In such situations, merging firms may find it very difficult to prove likely procompetitive effects. This does not imply and should not be used to infer anticompetitive or anti-innovative effects of a possible merger or acquisition. Further, anticompetitive or anti-innovative effects should not be the basic presumption of mergers and acquisitions in the biopharmaceutical space.

Due consideration should be given in situations where firms merge in order to combine complementary assets, including those at different levels of product development, to advance a product towards regulatory approval and market-readiness. A single firm able to coordinate how such assets are used in integrated research and product development programs may be able to streamline regulatory strategies, manage inventory of investigational products, clinical site selection and trial design, and so on, and thereby accelerate the creation of innovative products in ways that would not likely be achieved via alternative transactions or absent any transactions.

- c) **What approaches can the guidelines use to determine whether technologies subject to a license or acquisition either compete with or complement the licensee's or acquirer's own technologies? How do those approaches perform in circumstances where parties own or license many patents related to the same categories of products?**

In the biopharmaceutical space, such analysis must be nuanced and include an analysis of the product at the genetic level as well as holistically as some acquisitions may be needed to complete a product from (1) a mechanism of action perspective, (2) a method of treatment perspective, (3) a delivery optimization perspective, (4) a therapeutic window perspective, (5) a safety and/or pharmacokinetic, metabolism, absorption, excretion, distribution, and toxicity perspective, and (6) efficacy and effectiveness of the ultimate product. This may require acquisitions of bolt-on technologies or entirely new programs that tackle the same disease from a different mechanism of action or method of treatment that may or may not be an improvement from current program or licenses. The stage of the product should also be considered. Broad categories of technologies in the biopharmaceutical space would freeze transactions in the industry and extend timelines that are already on the order of years and decades. Finally, the existing guidelines already afford this flexibility.



d) Where technology-by-technology analysis is impractical, what alternative methods of analysis could be used to identify anticompetitive concerns in merger cases involving intellectual property?

The current guidelines as they are applied in the evaluation of biotech transactions are adequate, particularly as they pertain to transactions between smaller biotechnology companies and larger partners. BIO further contends that it is dangerous to arbitrarily broaden the aperture through which transactions in the biotechnology ecosystem are evaluated, particularly with respect to licenses and other intellectual property-related transactions since patent law already provides avenues to facilitate the dissemination of technology amongst collaborators, potential competitors, other market participants, and all should be allowed to cooperate.

BIO cautions the Commission against expanding the aperture of analysis to include merger cases involving intellectual property as antitrust law, in such circumstances, may be a poor vehicle with which to evaluate perceived competition concerns. For example, in the biotech space competitors can undertake a very wide range of research and development activities free from liability for patent infringement, thereby creating space for pre-market competition and innovation without the need for antitrust intervention.

Patent law also is designed to create other dynamics; for example, it stimulates the development of non-infringing substitutes thereby generating more alternative products and choices for consumers. Clear and enforceable intellectual property rights are also necessary to facilitate our robust private investment in cutting-edge research and development. Weakening those legal rights will inevitably threaten future investment in this high-risk field. Strong patent rights also facilitate publication of new discoveries which fuels further research. BIO encourages the Commission to not interfere in the role of patent and copyright law in stimulating and disseminating technological innovation.

Finally, BIO welcomes the opportunity to discuss with Commissioners and Commission staff the limitations of technology-by-technology analysis to better understand definitions and instances where technology-by-technology analysis is considered impractical and what the Commission believes is a fair alternative method of analysis in these instances.

e) How should the guidelines analyze innovation in markets with high failure rates?

BIO prefers a more appropriate definition of “high failure rate” markets as those “fields with high rates of innovation, precommercial products, and high risk of development failure.” BIO is highly concerned in the unintended consequences and direct, predictable deleterious effects of applying a broad approach to antitrust enforcement in these markets as it would entail substantial uncertainties that require a significant number of assumptions about the manifestation of competition in future markets. BIO’s concerns is that these assumptions would translate into a de facto position that any merger in the



biotech space, particularly a transaction is between a small biotechnology company and a larger partner, is anticompetitive or anti-innovative.

The current guidelines as they are applied currently in the evaluation of biotech transactions are adequate, particularly as they pertain to transactions between smaller biotechnology companies and larger partners. BIO further contends that it is dangerous to arbitrarily broadened the aperture through which transactions in the biotechnology ecosystem are evaluated.

Digital Markets

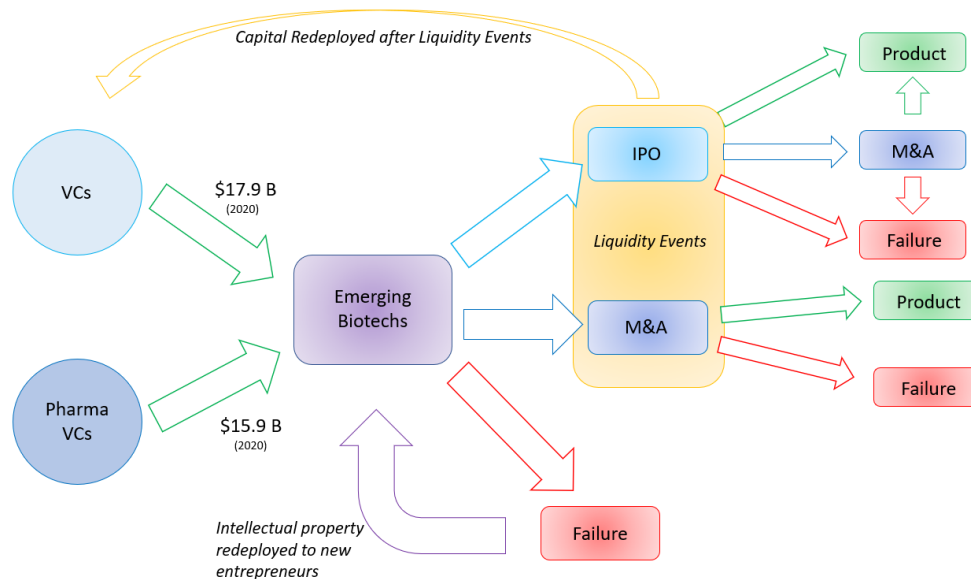
BIO has no position in digital markets antitrust.

Special Characteristics Markets

The current guidelines as they are applied in the evaluation of biotech transactions are adequate, particularly as they pertain to transactions between smaller biotechnology companies and larger partners. BIO further contends that it is dangerous to arbitrarily broadened the aperture through which transactions in the biotechnology ecosystem are evaluated.

Barriers to Firm Entry and Growth

In the case of modern learning in the biotech industry, the publication of scientific research in peer-reviewed journals and public knowledge of company R&D pipelines make the dissemination of knowledge unparalleled when comparing the biotechnology's knowledge ecosystem to those of other markets. Notably, the high failure rates in biotechnology and the associated ecosystem that has evolved to support scientific discovery has developed to recycle all forms of capital be it human capital, intellectual capital (IP), or investment capital as crudely illustrated in the chart below.



The ability to enter into a new product market via acquisition in the biotech space is not a precursor to competition or guarantee of successfully competition in a given product market, and, therefore, cannot be considered as a predicate for determining competitive effects. As with any market, expertise and capital serve as the main barriers to entry in the biotechnology industry.

Efficiencies

However, as noted above, the biotech post-merger / post-acquisition integration strategy has evolved and matured over recent years. Currently, post-acquisition integration strategy model is underpinned by this arm's-length philosophy that shares three central principles: (1) protect the small biotech's ingenuity and culture, (2) empower founders and staff, and (3) change as little as possible.

The current guidelines as they are applied in the evaluation of biotech transactions are adequate, particularly as they pertain to transactions between smaller biotechnology companies and larger partners. BIO further contends that it is dangerous to arbitrarily broadened the aperture through which transactions in the biotechnology ecosystem are evaluated.

Failing and Flailing Firms

The current guidelines as they are applied in the evaluation of biotech transactions are adequate, particularly as they pertain to transactions between smaller biotechnology companies and larger partners. It is dangerous to arbitrarily broadened the aperture through which transactions in the biotechnology ecosystem are evaluated.



BIO thanks the Federal Trade Commission and the Department of Justice for the opportunity to comment on the importance of mergers and acquisitions in maintaining a healthy and robust ecosystem for biomedical innovation. We look forward to working with the Commission and the Department to ensure that our antitrust laws preserve competition, innovation, and our country's global leadership in this strategically important field.

Carlo Passeri
Senior Director
Biotechnology Innovation Organization