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Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue, NW
Suite CC-5610 (Annex H)
Washington, D.C. 20580

RE: Comments on Revised HSR Premerger Notification and Report Form
*16 CFR Parts 801-803—Hart-Scott-Rodino Coverage, Exemption, and Transmittal
Rules, Project No. P239300*

Dear Commission,

Thank you for the opportunity to file these comments with the U.S. Federal Trade Commission (FTC, Commission, or Agency). The Biotechnology Innovation Organization (BIO) commends the Commission for taking a fresh look at the Hart-Scott-Rodino Antitrust Improvements Act Premerger Notification and Report Form (HSR Form).¹ Periodically re-assessing the effectiveness of the tools at the Commission's disposal is good management practice and reflective of good government. BIO supports the proposed streamlining of reporting of manufacturing revenue and revenues for specific NAICS codes, as well as elimination of the requirement to identify minority investors in certain targets entities. BIO further recognizes that new requirements relating to the reporting of foreign subsidies are needed, as that is a specific mandate from Congress in the 2022 Amendments.²

However, BIO strongly urges the Commission to reconsider many of the other proposed HSR Form revisions. The estimated additional burden imposed by the new requirements is extraordinary, particularly for smaller, research-focused companies with limited resources. According to the Commission's own assessment, using the revised rules and Form, the average HSR filing would require 144 hours to prepare – nearly 4x the average of 37 hours under the current rules. Such a dramatic increase in burden should be matched by an equally dramatic improvement in the HSR Form's screening function. BIO does not believe that many of the proposed revisions meet this high bar. Indeed, most of the proposed reforms could harm consumers, and the biotech industry, by potentially chilling investment, impeding innovation, and reducing patient access to life-saving medicines.

¹ Premerger Notification; Reporting and Waiting Period Requirements, 88 Fed. Reg. 42,178 (June 29, 2023) (HSR Form NPRM).

² Merger Filing Fee Modernization Act of 2022.



Interest of 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 abroad. BIO's members are involved in the research and development of innovative biotechnology products that will help to solve some of society's most pressing challenges, such as 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. In particular, BIO advocates for innovation in biotechnology in the healthcare space, to bring treatments and cures to patient populations in the U.S. and throughout the world.

Background

As a first step in assessing the value of the proposed HSR Form revisions, it is important to understand the goals of the exercise. This requires a brief examination of the objectives of both the HSR process and the HSR Form revision process.

Objectives of HSR Process

According to the Commission, the purpose of the HSR process is to “determine which acquisitions are likely to be anticompetitive and to challenge them at a time when remedial action is most effective” – that is, before deals are consummated.³ Because not all acquisitions are likely to be anticompetitive, a sorting function is needed. The HSR Form, which is completed by all parties that satisfy the filing threshold, provides enforcers with “the information needed for a *preliminary* antitrust evaluation.”⁴ Agency staff then use this information to determine “whether the proposed transaction is one that requires more in-depth investigation through issuance of Second Requests.”⁵

As this description makes clear, the HSR Form is intended to perform a preliminary screening function. If this preliminary screening suggests that there is potentially a competition concern – the vast majority of the time it will not – then Agency staff have another tool for obtaining more in-depth information. That tool is a Second Request.

³ FTC Premerger Notification Office, *Guide 1 – What Is the Premerger Notification Program: An Overview* at 1 (Mar. 2009), <https://www.ftc.gov/sites/default/files/attachments/premerger-introductory-guides/guide1.pdf>.

⁴ *Id.* (emphasis added),

⁵ HSR Form NPRM, *supra* note 1, at 42,179.



Objectives of HSR Form Revision Process

In the notice accompanying the proposed revisions, the Commission states that its objective is to “improve the efficiency and effectiveness” of the HSR Form.⁶ The goal is therefore to make the form even more useful as a screening mechanism. Ideally, this will “potentially narrow the scope of any investigation.”⁷

It is hard to disagree with these objectives. Unfortunately, the proposed revisions themselves lean almost uniformly in the direction of *expanding* investigations into every reportable transaction irrespective of competition concerns raised. BIO is concerned that the revisions ask the HSR Form to do too much and fail to give appropriate weight to other elements of the premerger process, particularly the Second Request. The screening function of the HSR Form – its primary purpose – seems to be lost as the proposed revisions would impose upon *all* filers Second Request-like obligations to produce voluminous information, documents, and data. This additional burden is especially concerning to the small innovators that make up the bulk of BIO’s membership. We respectfully request that the Commission consider a more narrowly tailored approach.

The Utility of the Additional Information Sought Does Not Justify the Additional Burden

BIO believes that both consumers and business are best served when firms prioritize competition law compliance, with the Agencies confirming that compliance through careful but vigorous enforcement. However, both recent Commission enforcement actions and policy statements suggest a move away from this approach. For example, both the Commission’s statement following resolution of the Amgen-Horizon case (“pharmaceutical mergers can stifle competition and harm patients even where the merging parties do not sell or develop overlapping drugs”)⁸ and the Pharmaceutical Mergers Workshop Summary (“[t]he Chair wants to learn more about what factors should specifically be considered in analyzing pharmaceutical mergers – beyond traditional concerns around horizontal overlaps”)⁹ suggest a sector-specific interest in expanding merger enforcement authority, perhaps even beyond what the law supports.

⁶ *Id.* at 42,178.

⁷ *Id.*

⁸ Commissioners Khan, Slaughter, and Bedoya, *Statement on In the Matter of Amgen, Inc. and Horizon Therapeutics plc.* at 2 (Sept. 1, 2023), at https://www.ftc.gov/system/files/ftc_gov/pdf/Statement-of-Chair-Lina-M-Khan-re-Amgen-Horizon.pdf.

⁹ FTC and DOJ, *The Future of Pharmaceuticals: Examining the Analysis of Pharmaceutical Mergers – FTC-DOJ Workshop Summary* at 1-2 (June 1, 2023) (FTC-DOJ Pharma Workshop), https://www.ftc.gov/system/files/ftc_gov/pdf/Future%20of%20Pharma%20Workshop%20--%20Summary.pdf.



BIO thinks this approach is misdirected and counter to the interests of consumers (in the biopharma context, patients). Robust biopharma M&A activity is an important component of the drug development ecosystem. Absent clear signs of antitrust concern, this activity should be welcomed and supported, not subjected to heightened suspicion.

BIO is concerned that this posture of deterring all mergers, rather than the subset identified through the HSR process as problematic, has been incorporated into many of the proposed revisions to the HSR Form. These revisions, which impose substantial new burdens on all filers, are not particularly well targeted to identifying merger-related antitrust concerns. Examples include new or expanded requests for:

- *Information on Past Transactions* – The lookback period for such transactions has been doubled from 5 years to 10 years. Also, the requirement has been extended from just the acquiring entity to both the acquiring and acquired entities. The motivation here appears to be identifying “serial acquisitions,” but there is nothing unlawful, or even inherently suspicious, about serial acquisitions. This mindset is particularly problematic for the biotech industry, where acquisition of small, research-based companies by larger, better-established firms is part of the process that drives innovation forward. For small innovators it is the heart and soul of the biotech innovation and R&D pipeline – the core of their business model.
- *Information on Unreportable Transactions* – The extended lookback to past transactions expressly includes transactions that were not HSR-reportable. This seems inconsistent with the goal of developing a more “efficient and effective” premerger screening process, as a significant category of transactions swept out as non-problematic (and hence unreportable) is now being swept back in.
- *Information on Future Competitive Overlaps* – For purposes of competition analysis, looking to the future tends to be more productive than looking to the past but presents its own set of challenges, with accuracy and reliability being two of the biggest. Nevertheless, the proposed revisions would require filers to identify current and *future* horizontal overlaps. For each overlap, the company is required to provide sales and customer information, describe licensing arrangements, and produce relevant non-compete and non-solicitation agreements. These requirements are especially challenging for biopharmaceutical firms, which often have multiple pipeline products and R&D initiatives whose future interaction with existing therapies is speculative at best.
- *Non-Deal Advice Provided to Company Leadership* – New Item 4(d) would require production of Confidential Information Memoranda prepared for a broad range of company leaders, regardless of whether they relate to the deal or to the standard



competition-related topics covered by Item 4(c). This goes well beyond any preliminary screening function. Indeed, such a request would seemingly need to be more limited even if included in a much broader Second Request.

- *Draft Documents* – The concern motivating the new requirement for production of draft documents appears to be that final versions of these documents may be “sanitized” and misrepresentative. This again goes well beyond a preliminary screening function. The credibility and authenticity of documents is an issue much better suited to the litigation context, and even then only after evidence of “sanitizing” has emerged via other discovery.
- *Information on Non-Antitrust Issues* – Perhaps the most conspicuous example is the proposed “Worker and Workplace Safety Information” section, which would require reporting on penalties and findings issued by the U.S. Department of Labor’s Wage and Hour Division, the National Labor Relations Board, or the Occupational Safety and Health Administration. Some of this information (e.g., reporting on occupational safety and health issues) is arguably not relevant to a competition analysis at all. The competitive significance of other labor and employment-related information is a closer call, but even that information is not suitable for inclusion in a preliminary screening tool applicable to all filers.

Beyond these specific examples, the overbreadth of the revisions appears to be driven by a number of incorrect assumptions. The first is that the HSR Form is the Agencies’ only opportunity to obtain information about a proposed transaction. In fact, it is the first of at least three bites at the apple – HSR Form, Second Request, and litigation-related discovery – with even this summary assuming that the merging parties refuse to supplement or to pull-and-refile. There is no need to obtain *everything* at this stage.

The revisions also seem to assume that the merger review process will not only be the last opportunity to address competition concerns, but a host of non-competition concerns as well (e.g., labor, employment, trade, national security). In fact, the Agencies have a variety of tools at their disposal to address anticompetitive conduct that may arise post-merger, and a long history of doing just that. Private litigation plays a role as well. The Agencies should likewise acknowledge that sector-specific regulation takes some of the weight off their shoulders. Competition in the biotech sector, for example, is already subject to comprehensive legislation, ranging from Hatch-



Waxman¹⁰ and BPCIA,¹¹ addressing generic and biosimilar entry, to the Orphan Drug Act,¹² addressing rare disease innovation.

Lastly, the revisions seem to assume that the HSR Form is an appropriate vehicle for advancing novel legal theories. While it is certainly the Agencies' prerogative to push for good faith extensions of the law, this can be more efficiently accomplished through carefully selected test cases than through a preliminary merger screening tool applicable to all filers. Proposed revisions directed at gathering information in support of vertical and nascent competition theories, for example, should probably be postponed until those theories are better established in case law.¹³

The Proposed Revisions Will Be Particularly Harmful to the Biopharmaceutical Sector

This dramatic expansion of the scope of the HSR Form – which, again, applies to every filer – is not costless. Quadrupling the compliance time is just the beginning. Both the scope and the nature of the revisions send a clear message that *all* dealmaking will be subjected to greater scrutiny. Unfortunately, this includes the innovation-driving M&A activity on which the biotech sector depends.

The negative impact of the revisions is magnified by two biotech-specific factors. The first is that a prior expansion of HSR merger review authority already makes a broader swath of biotech dealmaking subject to scrutiny. Pursuant to the Commission's 2013 rule on pharmaceutical licensing agreements,¹⁴ a license or transfer of patent rights – provided that it encompasses all “commercially significant rights” to the patent and that the deal meets the filing threshold – is subject to the HSR Act's notice and reporting requirements. Such licensing arrangements are an important means of combining the complementary capabilities of two biotech firms without a merger. As reportable transactions, however, they too would be subject to the revised HSR Form's burdensome requirements, further delaying, and raising the cost of, procompetitive life sciences innovation.

¹⁰ Drug Price Competition and Patent Term Restoration Act of 1984.

¹¹ Biologics Price Competition and Innovation Act of 2009.

¹² Orphan Drug Act of 1983.

¹³ See, e.g., *FTC v. Microsoft Corp.*, No. 23-cv-2880-JSC, 2023 WL 4443412 (N.D. Cal. Jul. 10, 2023) (rejecting vertical merger theory); *FTC v. Meta Platforms*, No. 22-cv-04325-EJD, 2023 WL 2346238 (N.D. Cal. Feb. 3, 2023) (rejecting nascent competition theory); *United States v. AT&T, Inc.*, 916 F.3d 1029 (D.C. Cir. 2019) (rejecting vertical merger theory).

¹⁴ Premerger Notification; Reporting and Waiting Period Requirements, 78 Fed. Reg. 68,705 (Nov. 15, 2013).



The other factor is biotech firms' dependence on a small cadre of qualified directors and officers. There are only so many candidates with the appropriate business background and, say, expertise in gene therapy or pediatric oncology. Consequently, the HSR Form's expanded requirements regarding disclosure of these positions pose a heightened risk. Going forward, filers would be required to identify all directors and officers of all entities. Each identified individual would, in turn, be required to make additional disclosures, including disclosure of other director and officer roles held within the last two years. These burdensome requirements may discourage highly sought after experts and specialists from accepting biotech leadership roles or, worse, discourage companies intent on keeping these individuals from pursuing reportable transactions despite substantial potential patient benefit.

The Revisions Will Have a Negative Impact on Investment

Investors are savvy and understand that the antitrust agencies are gathering substantially more premerger information to deter deal-making. This is likely to produce, and arguably already has,¹⁵ an investment-chilling cloud of antitrust uncertainty. This will make the work of small biotech firms more difficult. Most often these firms do not yet have FDA-licensed, revenue-generating products and must depend on investment to fund their day-to-day operations.

According to one recent analysis, around two-thirds of FDA-approved new drugs originate with small biotech companies,¹⁶ whose business model is based on M&A deals. Individual scientific breakthroughs are difficult to plan and predict. What these companies have done instead is to cultivate an atmosphere in which innovation can flourish. Their small size gives them flexibility, the ability to pivot in response to new evidence, and a willingness to accept risk that is rare in larger firms. This "culture of creativity" is a powerful asset that facilitates recruitment of the best and most innovative scientific minds.¹⁷

The process of drug development is not easy, however, and success is exceptionally rare. One recent study found that the aggregate probability for obtaining FDA approval was 9.3% for non-

¹⁵ The pace of biotech investment in Q1 2023 was down nearly 40% from the prior year. See BIO, *Emerging Therapeutic Company Investment and Deal Trends (2023)*, <https://www.bio.org/emerging-therapeutic-company-investment-and-deal-trends> (BIO Investment Data), This slowdown is likely attributable to a number of factors, including the drug price negotiation provisions of the Inflation Reduction Act. Imposing additional obstacles to biopharma M&A will only worsen the situation.

¹⁶ Joanna Shepherd, *Consolidation, and Innovation in the Pharmaceutical Industry: The Role of Mergers and Acquisitions in the Current Innovation Ecosystem*, 21 J. HEALTH CARE L. & POL'Y 1, 16 (2018).

¹⁷ *Id.* at 22.



oncology programs and only 5.3% for oncology programs.¹⁸ As a general rule, banks, traditional financial institutions, and government entities will not fund an enterprise with a 90% failure rate (95% for oncology programs). A specialized segment of biotech investors, with scientific expertise and deep industry knowledge, will. In 2021 alone, venture capitalists invested in 3,100 biotech start-ups,¹⁹ with biotech companies raising \$45.3 billion globally.²⁰

Though certainly not the only factor, the prospect of an eventual acquisition was and is central to much of this investment. Acquisition of small innovators by larger, better established pharmaceutical companies is a core driver of the drug development ecosystem and critical to delivering new therapeutic options to patients in need. Investors look to such transactions as a primary source of return on capital to balance out the many promising products that never make it to FDA-approval or commercialization. By adopting burdensome premerger procedures that subject such transactions to unwarranted scrutiny, the antitrust agencies would put this consumer- and patient-benefitting investment at risk.

The Revisions Will Have a Negative Impact on Innovation

The proposed revisions to the HSR Form also fail to recognize the vastly different roles that small and large firms play in the biotech innovation and R&D pipeline for drug development. By moving forward many of the “deep dive” reporting requirements from the Second Request phase to the HSR Form, the revisions seem to preclude the possibility of transaction rationales other than the elimination of competition. For many of BIO’s members, however, acquisitions can be a necessary link between early stage R&D and late stage approval and commercialization. Burdensome premerger reporting requirements that impede such transactions will stymie, if not overtly thwart, innovation, as will the Commission’s express concern regarding “serial acquisitions.”

The drug development ecosystem is working efficiently and should not be subjected to heightened antitrust scrutiny. The U.S. produces more new drugs each year than the rest of the world combined, including new gene therapies, vaccines, and biologics.²¹ Over time the ecosystem has

¹⁸ BIO, QLS Advisors, Informa UK Ltd., *Clinical Development Success Rates and Contributing Factors 2011-2020* at 27 (Feb, 2021), https://go.bio.org/rs/490-EHZ-999/images/ClinicalDevelopmentSuccessRates2011_2020.pdf.

¹⁹ McKinsey & Co., *What are the biotech investment themes that will shape the industry?* (June 10, 2022), <https://www.mckinsey.com/industries/life-sciences/our-insights/what-are-the-biotech-investment-themes-that-will-shape-the-industry#>.

²⁰ BIO Investment Data, *supra* note 15, at 1.

²¹ McKinsey & Co., *The UK biotech sector: The path to global leadership* (Dec. 3, 2021) (noting that the UK continues to lag behind the U.S. on many metrics),



not only evolved but optimized, with small and large companies essentially playing complementary, rather than competitive, roles. Small innovators excel at discovery and early development, but beyond that typically need the assistance of a larger partner or acquirer to efficiently, effectively, and expediently bring their discovery to market. Superior capabilities in communicating with healthcare providers and institutions are one advantage that these large firms bring to the table,²² along with a host of other exceedingly high cost functions, ranging from clinical development and product manufacturing to commercialization.

Biotech M&A activity is an important way that firms bring these capabilities together. As the Congressional Budget Office has acknowledged, “[t]he acquisition of a small company by a larger one can create efficiencies” by bringing together two entities that “specialize in activities in which they have a comparative advantage.” This view was reiterated by multiple speakers at the Agencies’ “Future of Pharmaceuticals” Workshop.²³ Nor is it unusual to see this dynamic manifest itself as “serial acquisitions,” as the larger, more established acquiring firm may have developed expertise in a particular field of care that accelerates delivery of therapies to patients.²⁴ A carefully calibrated premerger reporting regime would seek to identify such deals for early clearance, not to burden them with mandatory Second Request-like requirements.

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

²² Barak Richman et al., *Pharmaceutical M&A Activity: Effects on Prices, Innovation, and Competition*, 48 LOYOLA U. CHI. L.J. 787, 802 (2017) (“Small firms developing drugs typically do not have the marketing capabilities required to bring those new drugs to global and segmented markets on their own.”).

²³ FTC-DOJ Pharma Workshop, *supra* note 9, at 2-3 (Prof. Patricia Danzon found that “small firms originate seventy percent of new active substances” and that “firm size enabled by merger and acquisition activity may provide advantages in contracting, marketing, financing, and regulatory activities”) and 5 (Prof. Robin Feldman described “the bulk of current consolidation since 2010 as consisting of large firms acquiring smaller firms to bolster their innovation portfolios, with larger firms being responsible for later stage clinical trials and regulatory approval”).

²⁴ BIO, *Response to FTC Merger Enforcement Request for Information* at 3 (Apr. 15, 2022), <https://www.regulations.gov/comment/FTC-2022-0003-1784> (“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.”).



The Revisions Will Have a Negative Impact on Patient Access to Life-Saving Medicines

As a final note, one of the major advantages of the U.S. regulatory framework for drug development is speed. Compared to peer nations, new drugs move from the R&D phase to a retail or hospital pharmacy, where they can be used to treat actual patients, much faster in the U.S. Here too unnecessarily burdensome premerger reporting requirements can be a step in the wrong direction, both by taking away the advantages gained by regulatory efficiency in other areas and by impeding access to rapid, well-established distribution networks.

As a recent Wall Street Journal op-ed observed, “Waiting 15 months longer to get access to a new drug may not sound like a big deal. But if you have a debilitating disease, even a few months can make a difference in your prognosis.”²⁵ The same op-ed notes that, compared to Canadian drug approvals, U.S. approvals come 468 days earlier. U.S. patients also benefit from more rapid access to clinical trials.

In contrast, the proposed revisions to the HSR Form pull in the opposite direction, not because of the premerger waiting period (which remains unchanged), but because the scope and complexity of the additional information requests are likely to result in delays. Just as in the Second Request context, the prospect of disputes over filers’ compliance and requests to pull-and-refile looms. Protracted disputes over the attorney-client privilege status of particular documents also loom, especially in light of the HSR Form’s new and expanded requests for draft documents and confidential advice provided to company leadership. These delays seem even more inevitable when one considers that, though the burden of compliance has increased by a factor of four, there has not been a corresponding request to quadruple Agency premerger staff or a projection of greater efficiencies.

More importantly, the proposed revisions to the premerger process potentially impede access to the efficient, global distribution networks that put new therapies in the hands of patients. Large biotech firms have such networks and small innovators do not. Unsurprisingly, the Congressional Budget Office found that a major advantage of biotech M&A is that “[the] large company might bring a drug to market more quickly than the small company could have or might distribute it more widely.”

As a real world example of this phenomenon, one need look no further than Pfizer’s recent acquisition of Global Blood Therapeutics (GBT). GBT developed Oxbryta, the first drug to treat sickle cell disease – an inherited blood condition that leads to pain, organ failures, and early death – by addressing its root cause. Rather than attempting to manage later stage clinical trials, FDA approval, and commercialization on its own, GBT entered into a deal with Pfizer. A principal

²⁵ Editorial Board, *Debunking Drug Price Myths*, WALL ST. J. (Sept. 17, 2023).



consideration was “aiming to take advantage of the global company’s reach so that Oxbritya could benefit more patients – particularly in Africa, India, and South America.”²⁶

As the process of finalizing the HSR Form moves forward, BIO urges the Commission to carefully weigh these important considerations of patient access against the scope of information that is truly needed to conduct an effective premerger screening. As GBT’s CEO, Dr. Ted Love, has noted “We could not have reached patients in lower-income countries, where child mortality from sickle cell disease is much greater, without being acquired by Pfizer.”²⁷

Conclusion

BIO thanks the Commission for its work in this important area of competition policy. We welcome the opportunity to engage with the Commission to better align its antitrust and merger review objectives with the needs and incentives of biopharmaceutical innovation. We trust that the Commission shares our collective goal of ensuring that the U.S. continues to have the world’s leading drug development ecosystem far into the future.

Sincerely,

A handwritten signature in black ink that reads "John T. Delacourt". The signature is fluid and cursive, with a prominent "J" and "D".

John T. Delacourt
Deputy General Counsel,
VP – Health, Regulatory & Commercial Ops.

²⁶ Ted Love, *New attacks on the drug industry would have made my breakthrough sickle cell treatment impossible*, STAT (July 21, 2023).

²⁷ *Id.*