February 6, 2024

Laurie Locascio
Director
National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20899

RE: Docket No. 230831-0207, Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights

Dear Director Locascio,

On behalf of the more than 30 million Americans living with one of the over 10,000 known rare diseases, the National Organization for Rare Disorders (NORD) is pleased to provide comments on 'The National Institute of Standards and Technology's (NIST) Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights.' We appreciate the opportunity to comment and would be delighted to further engage on this important issue.

NORD is a unique federation of non-profit and health organizations dedicated to improving the health and well-being of people with rare diseases by driving advances in care, research, and policy. NORD was founded 40 years ago, after the passage of the Orphan Drug Act (ODA), to formalize the coalition of patient advocacy groups that were instrumental in passing this landmark law. Since that time, NORD has been advancing rare disease research and funding to support the development of effective treatments and cures; raising awareness and addressing key knowledge gaps; and advocating for policies that support the availability of and access to safe and effective diagnostics and therapies.

We would like to thank NIST for soliciting public comments regarding the "Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights" and appreciate the opportunity to provide the rare disease perspective. We recognize the statutory authority granted by the Bayh-Dole Act of 1980 (P.L. 96-517) was intended to create appropriate incentives for the commercialization of innovations made with government funding (i.e., "conceived or first reduced to practice in the performance of work under a government-funding agreement"), while protecting the public's interests in the invention. In exchange for retaining title to the invention derived from government-funded work, the funding agency can require the contractor (or an assignee or exclusive licensee) to grant a license to the invention on reasonable terms – and under certain circumstances 'march in' to grant the license itself if the contractor refuses. We further recognize that, in the more than 40 years since the Act was passed, there have only been

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eight petitions to government agencies to exercise march-in rights – all directed to the National Institutes of Health (NIH) - and after careful consideration, the agency decided each time ***not*** to exercised march-in rights.[1] Finally, we recognize the contentious history and opposing views regarding whether pricing of commercial goods and services alone is sufficient justification to initiate march-in proceedings.[2]

We, like NIH, are concerned about the unintended impacts of any decision to exercise march-in rights on research and product development, particularly for rare diseases, which are notoriously hard to study and especially dependent on government funding.[3] We are concerned that the framework is too broad to appropriately account for the unique challenges of each industry sector and government agency, in particular, if pricing of consumer goods and services were to be considered as a determining factor to initiate march-in proceedings. Finally, as outlined, the framework lacks opportunities for meaningful stakeholder input including from patients and other end-users that are not directly part of the licensing negotiations, but directly benefit from the invention – and who could be irreparably harmed by a callous use of march-in rights. Below, we further discuss these three specific concerns and offer detailed recommendations to improve the framework's usefulness for rare disease patients and the broader community.

1. <u>The threat of irreparable damage to vital rare disease research funded by NIH and other government agencies</u>

The federal government is the largest source of funding for biomedical research in the U.S.[4] The role of the federal government is particularly vital for rare disease research. Given the economic realities of developing lifesaving therapies for very small patient populations, government funding plays an essential role in collecting natural history data, elucidating the diseases' underlying pathophysiology, identifying potential drug targets and deciphering their mechanisms of action, and ultimately bringing safe and effective therapies to the patients and

[1] Kersten, A & Athanasia, G. (2022, March 24) *March-In Rights and U.S. Global Competitiveness.* Center for Strategic and International Studies. https://www.csis.org/analysis/march-rights-and-us-global-competitiveness

[2] Sencer, S. et. Al. (2023, December 11) *Biden Administration's Proposal Under Bayh-Dole Act Signals Enhanced Focus on Use of March-In Rights and Lower Drug Pricing.* Ropes & Gray. https://www.ropesgray.com/en/insights/alerts/2023/12/biden-administrations-proposal-under-bayh-dole-act-signals-enhanced-focus-on-use-of-march-in-rights

[3] Tabak, L. (2023, March 21). *NIH*. Department of Health and Human Services. https://www.keionline.org/wp-content/uploads/NIH-rejection-Xtandi-marchin-12march2023.pdf

[4] U.S. Department of Health and Human Services. (n.d.). National Institutes of Health. https://www.nih.gov/#:~:text=NIH%20is%20the%20largest%20source,thousands%20of%20high%2Dquality%20jobs.

families impacted by any of the more than 95% of rare diseases that currently lack FDA-approved therapies.[5,6]

For example, funding for NIH's National Center for Advancing Translational Sciences (NCATS) supported research that proved central to the development of life-altering therapies for patients suffering from Creatine Transporter Deficiency, GNE Myopathy, Niemann-Pick Disease Type C, AADC Deficiency, Pompe Disease, Duchenne Muscular Dystrophy, and many other devastating rare diseases.[7] From 2002 to 2020, NCATS' Rare Diseases Clinical Research Network (RDCRN), a network created specifically to foster collaboration between rare disease researchers, supported over 237 research protocols with more than 56,000 rare disease research participants across a wide range of rare diseases.[8,9] Government-funded research has provided a critical foundation for genome-editing for rare metabolic diseases; advanced gene therapies through the Bespoke Gene Therapy Consortium (BGTC); researched stem cell transplants for immune system disorders; and advanced critical research for many other rare diseases.[10,11] In fiscal year 2023 alone, the NIH awarded $6.8 billion in funding for rare disease research to ensure this lifesaving work can continue.[12] In fact, funding from NIH lead to several FDA drug approvals, including a life-altering treatment for progeria, a rare genetic condition that causes rapid aging in children and often leads to premature death before the 15th birthday; as well as to date 28 patents for rare disease therapies, and 14 investigational new drug (IND) applications between 2018 and 2021 alone.[13]

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[5] U.S. Department of Health and Human Services. (2019, October 3). *NIH funding Bolsters Rare Diseases Research Collaborations*. National Institutes of Health. https://www.nih.gov/news-events/news-releases/nih-funding-bolsters-rare-diseases-research-collaborations

[6] Damond, J. (n.d.). *Biden's "march-in" rights threaten long-term innovation in Pharmaceuticals and Biotech*. Edelman Global Advisory. https://www.edelmanglobaladvisory.com/insights/Biden-march-in-rights-threaten-long-term-innovation

[7] U.S. Department of Health and Human Services. (n.d.). *Therapeutics for rare and neglected diseases (TRND) projects*. National Center for Advancing Translational Sciences. https://ncats.nih.gov/research/research-activities/trnd/projects

[8] U.S. Department of Health and Human Services. (n.d.). *NIH funding Bolsters Rare Diseases Research Collaborations*. National Center for Advancing Translational Sciences. https://ncats.nih.gov/news-events/events/2019/rdcrn-funding

[9] U.S. Department of Health and Human Services. (n.d.). NIH funding Bolsters Rare Diseases Research Collaborations. National Center for Advancing Translational Sciences. https://ncats.nih.gov/news-events/events/2019/rdcrn-funding

[10] U.S. Department of Health and Human Services. (n.d.). NIH funding Bolsters Rare Diseases Research Collaborations. National Center for Advancing Translational Sciences. https://ncats.nih.gov/news-events/events/2019/rdcrn-funding

[11] *Ncats congressional justification FY 2023*. National Center for Advancing Translational Sciences . (2023). https://ncats.nih.gov/files/NCATS-FY-2023-CJ-508.pdf

[12] Mikulic, M. (2023, June 1). *Rare diseases funding by US National Institutes for Health 2013-2024*. Statista. https://www.statista.com/statistics/713320/rare-diseases-funding-by-the-national-institutes-for-health/

[13] *Ncats congressional justification FY 2023*. National Center for Advancing Translational Sciences . (2023). https://ncats.nih.gov/files/NCATS-FY-2023-CJ-508.pdf

NIH funding is by no means the only source of government funding for rare disease research. For instance, the Food and Drug Administration (FDA) has funded several natural history studies to support rare disease drug development.[14] Funding for rare disease natural history studies is vital to address knowledge gaps in disease manifestations, support clinical trials by leveraging data collected as real-world evidence (RWE), and developing clinical outcome assessments. In fiscal year 2022 alone, FDA awarded over $11.5 million in grants for eight natural history studies.[15] Similarly, federal funding through the Defense Health Research Consortium, the Advanced Research Projects Agency for Health (ARPA-H), the Department of Veterans Affairs, and other government agencies has meaningfully advanced research, drug development, and clinical care for many rare diseases.[16,17,18]

NORD, like other experts,[19] is concerned that the prospect of an indiscriminate exercise of march-in rights, including the use of price as the sole determining factor, would have a chilling effect on translating government-funded groundbreaking research into tangible cures.[20] This would ultimately risk wasting billions in taxpayer dollars already invested in rare disease research, and rob rare disease patients and families of the hope for a treatment they so desperately need.

We ground this concern in learnings from relevant past experience. In the early 1990s, the NIH instituted a "reasonable pricing clause" which attempted to curb high drug prices set by companies using NIH funding. Five years after the program's enactment, NIH vacated the "reasonable pricing clause" because companies started avoiding collaboration with NIH over concerns about the pricing clause, impeding the agency's mission and stalling progress on vital research.[21] Once the "reasonable pricing clause" was removed, the NIH saw a four-fold increase in companies entering research agreements with the agency.[22] NIH itself has voiced concerns

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[14] Office of the Commissioner. (n.d.). *Clinical trial and natural history study grants*. U.S. Food and Drug Administration. https://www.fda.gov/industry/clinical-trial-and-natural-history-study-grants

[15] Office of the Commissioner. (n.d.). *Clinical trial and natural history study grants*. U.S. Food and Drug Administration. https://www.fda.gov/industry/clinical-trial-and-natural-history-study-grants

[16] Defense Health Research Consortium. (n.d.). https://defensehealthresearch.com/

[17] *Research & Funding*. ARPA. (n.d.). https://arpa-h.gov/research-and-funding

[18] *Office of Research & Development*. US Department of Veteran's Affairs. (2023, March 8). https://www.research.va.gov/topics/default.cfm

[19] Shivakumar, S., & Howell, T. (2023, December 20). *Proposed federal use of March-in rights would weaken American Innovation: Perspectives on Innovation*. CSIS. https://www.csis.org/blogs/perspectives-innovation/proposed-federal-use-march-rights-would-weaken-american-innovation

[20] Shivakumar, S., & Howell, T. (2023, December 20). *Proposed federal use of March-in rights would weaken American Innovation: Perspectives on Innovation*. CSIS. https://www.csis.org/blogs/perspectives-innovation/proposed-federal-use-march-rights-would-weaken-american-innovation

[21] Retrieved from: https://www.techtransfer.nih.gov/sites/default/files/CRADA%20Q%26A%20Nov%202021%20FINAL.pdf

[22] Retrieved from: https://www.techtransfer.nih.gov/sites/default/files/CRADA%20Q%26A%20Nov%202021%20FINAL.pdf

that the potential use of march-in rights may drive potential partners away from collaborations with the agency, ultimately stunting research and drug development for years to come.[23] Given this history, NORD urges the utmost caution when considering the initiation of march-in proceedings, particularly in situations where price would be the only, or primary determining factor, for the initiation of the proceedings. It is imperative to carefully weigh the long-term impacts on research, innovation, and the return on investment for the billions of dollars invested in biomedical research, as well as the dire consequences for many patients and families with unmet medical needs.

2. March-in proceedings may not actually lead to increased access to safe and effective therapies

Many innovative new therapies, including many rare disease treatments, are exceedingly complex to manufacture, often making it very difficult or impossible to simply transfer manufacturing capacity to a new entity.[24] In fact, even for relatively 'simple' products like sterile water for injection, quickly transferring manufacturing capacity from one facility or sponsor to another to alleviate supply shortages is typically not an option - for a host of reasons, including the schedule of FDA inspections of production lines, the complexity of retooling manufacturing lines for new products, access and availability of raw materials, amongst others.[25]

The prospect of transferring manufacturing capacity is even more daunting for many innovative new therapies. To illustrate this point, even though the approval of an abbreviated new drug application (ANDA) for a generic product (i.e., a medication create to be the same as an already marketed brand-name drug) is somewhat more involved than the transfer of manufacturing capacity for an approved product to a licensee, in 2017, the average time for the FDA to review a generic drug application was over 37 months, and only 15 percent of applications to manufacture generic versions of branded drugs reviewed by the FDA were approved.[26] Product manufacturing, also referred to as Chemistry, Manufacturing, and Controls (CMC), is a frequent challenge to the development of innovative brand-name and generic drugs alike. In fact, CMC development has become such a potential barrier to timely approval, FDA announced a pilot program last year specifically to ensure the manufacturing procedures for those therapies designed to address urgent unmet medical needs can keep pace with other parts of expedited

[23] Owermohle, S. (2024, January 17). *The new NIH director is walking a tightrope on Biden's drug pricing vision*. STAT. https://www.statnews.com/2024/01/16/nih-director-biden-drug-prices/

[24] GAO. (2023, March). *FDA Should Fully Assess Its Efforts to Encourage Innovation.* https://www.gao.gov/assets/820/818048.pdf

[25] Ventola, L. (2011, November). *The Drug Shortage Crisis in the United States.* Pharmacy and Therapeutics. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278171/

[26] (2019, February). *FDA Approves More Generic Drugs, but Competition Still Lags.* Pew Charitable Trusts. https://www.pewtrusts.org/-/media/assets/2019/02/fda_approves_more_generic_drugs_but_competition_still_lags.pdf

clinical development programs.[27] Similarly, the agency has promulgated extensive guidance on post-approval plans that are needed for any manufacturing changes – by the same manufacturer and in the same FDA-inspected facility - after initial FDA approval.

The manufacturing challenge is even more pronounced for complex biologics including many regenerative therapies.[28] The National Academies of Sciences, Engineering, and Medicine recently held a workshop dedicated to the challenges surrounding manufacturing of regenerative medicines, following a similar workshop in 2017, that identified manufacturing challenges as one of the key barriers to the field of regenerative medicine.[29,30] Similarly, FDA has promulgated extensive guidance for how to demonstrate that cell and gene therapies remain comparable to the initially-approved product after minor changes to the manufacturing procedures, demonstrating the difficulty of transferring manufacturing across facilities and sponsors.[31]

As these data show, granting a license to the innovation is only the first step in allowing a new sponsor to manufacture an FDA-approved therapy. The reality of turning that license into safe and effective therapies that are manufactured with consistent quality is considerably more complex than the march-in procedures may imply. Ultimately, indiscriminate use of march-in rights risks harming rare disease drug development without meaningfully improving access to safe and effective therapies for the patients and families that depend on these therapies.

3. Patients, families, and other end-users of the inventions must be an integral part of the process

As written, the guidance lacks clear processes for how the perspectives of patients, families, and other consumers or end-users of the innovations at issue will be considered. Such feedback is

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[27] (2023, September 11). *Chemistry, Manufacturing, and Controls Development and Readiness Pilot Program; Program Announcement.* 88 FR 62381. https://www.federalregister.gov/documents/2023/09/11/2023-19502/chemistry-manufacturing-and-controls-development-and-readiness-pilot-program-program-announcement

[28] CDER, CBER. (2022, October). *Comparability Protocols for Postapproval Changes to the Chemistry, Manufacturing, and Controls Information in an NDA, ANDA, or BLA.* U.S. Food and Drug Administration. https://www.fda.gov/media/162263/download

[29] Beachy, Sarah. (2023, October 17). *Emerging Technologies and Innovation in Manufacturing Regenerative Medicine Therapies: A Workshop.* National Academies for Science, Engineering and Medicine. https://www.nationalacademies.org/our-work/emerging-technologies-and-innovation-in-manufacturing-regenerative-medicine-therapies-a-workshop

[30] Beachy, Sarah. (2017, June 26). *Navigating the Manufacturing Process and Assuring the Quality of Regenerative Medicine Therapies: A Workshop.* National Academies for Science, Engineering and Medicine. https://www.nationalacademies.org/our-work/navigating-the-manufacturing-process-and-assuring-the-quality-of-regenerative-medicine-therapies-a-workshop

[31] Center for Biologics Evaluation and Research. (2023, July). *Manufacturing Changes and Comparability for Human Cellular and Gene Therapy Products.* U.S. Food and Drug Administration. https://www.fda.gov/media/170198/download

vital as the agency ponders the key questions outlined in the draft framework, including whether a reduction in price would meaningfully increase access to the subject invention and whether the externalities caused by the march-in procedures are tolerable and justified. NORD strongly suggests including formalized mechanisms for soliciting feedback from patients, consumers, and other end-users of the product about whether to initiate march-in proceedings. These stakeholders can offer firsthand experience with the selected product and provide specific, nuanced perspectives on access and cost challenges.

Solicitation of such feedback may take shape in several ways. Federal agencies, such as FDA[32] and CMS[33] have successfully used listening sessions to understand vital patient perspectives including which aspects of a treatment are most important to patients, and how patients navigate affordability challenges and clinical alternatives in the drug price negotiation process. Other options to consider include standing or ad-hoc patient advisory committees, as well as opportunities for feedback through requests for information and public comment requests. We would be delighted to work with NIST and all relevant stakeholders to help develop a patient engagement process that meets the needs of the agencies and gives patients, families, and the general public a seat at the table – the potential risks are too great to exclude those that would be most impacted from the decision.

4. **Specific recommendations to strengthen the proposed framework**

Below, we outline several specific recommendations for revising the framework. These recommendations are rooted in our deep concern about the potential unintended consequences associated with any callous use of march-in rights, and serious concerns about using cost alone as a criterion to initiate march-in proceedings.

Do not use cost alone as a criterion for the initiation of march in rights; should you decide to proceed with using cost as a criterion, clarify parameters around when pricing becomes prohibitive and ensure actual savings are passed onto consumers.

Proposed questions to add to the framework:

- *Who cannot afford the product due to price?*
- *How do most consumers access this product? How do most end-users access this product?*
- *How would the use of march-in impact consumer or end-user access to the selected product?*

[32] (2024, January 23). *FDA Patient Listening* Sessions. U.S. Food and Drug Administration. https://www.fda.gov/patients/learn-about-fda-patient-engagement/fda-patient-listening-sessions

[33] (2023, February 2). *Medicare Drug Price Negotiation Program Patient-Focused Listening Sessions.* Centers for Medicare and Medicaid Services. https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation-program-patient-focused-listening-sessions

- *How can the agency conduct targeted outreach to the population most directly impacted by the initiation of march-in proceedings?*
- *What is the consumer or end-user perspective on whether the product should be subject to march in proceedings?*
- *How will the march-in procedure adjust consumer facing pricing and access structures?*
- *To what extent can the agency ensure consumers or end-users will benefit financially from the march-in process?*
- *Are there previous examples of controlling prices and its impact on the market? How can we learn from these successes/failures?*
- *How will march-in impact product availability?*

As outlined in detail above, NORD has serious concerns about the use of cost alone as a criterion to initiate march-in proceedings. These concerns notwithstanding, based on the current framework it is not clear **how** cost is defined, what parameters define unaffordability, and whether cost savings will be meaningfully passed on to patients and other consumers given the complex nature of our health care system and its various stakeholders.

The pricing of pharmaceutical products lacks transparency and can differ substantially based on payer types, formulary arrangements, rebates, and various other factors external to the manufacturer and the patient. Using a product's list price or wholesale acquisition costs (WAC) is an inefficient proxy for determining whether a product is unaffordable for patients. While, as of 2022, more than 90% of all US residents had health insurance coverage (at least at some point during the year), and the vast majority had some type of prescription drug coverage benefit as a part of their plan, out of pocket costs including co-pays and co-insurance vary widely across plans and even across different parts of the plan year.[34] For instance, amongst patients suffering from cancer or multiple sclerosis, out-of-pocket spending was 25 and 32 times greater respectively for patients with deductibles and co-insurance, compared to those patients suffering from cancer or multiple sclerosis without deductibles and co-insurance.[35] Though fewer than one third of patients in the study who took brand medicines to treat multiple sclerosis filled prescriptions subject to deductibles or coinsurance, these patients accounted for 95% of total out of pocket spending on brand medications for multiple sclerosis.[36] The above example is illustrative of broader trends, and the issue is particularly challenging for rare diseases. Patient out-of-pocket costs for rare disease drugs are frequently significantly greater than for nonorphan

[34] Keisler-Starkey, K. et. Al. (2023, September 12) *Health Insurance Coverage in the United States: 2022*. United States Census Bureau. https://www.census.gov/library/publications/2023/demo/p60-281.html#:~:text=Highlights,91.7%20percent%20or%20300.9%20million).

[35] N.A. (2023) Faced with high cost sharing for brand medicines, many commercially insured patients with chronic conditions use manufacturer copay assistance. Phrma.org. https://phrma.org/-/media/Project/PhRMA/PhRMAOrg/PhRMA-Org/PDF/D-F/Faced-with-High-Cost-Sharing-for-Brand-Medicines.pdf

[36] Ibid

drugs.[37] Placement on the highest (i.e. least accessible) formulary tier is more common for orphan drugs, resulting in higher out-of-pocket cost-sharing compared to non-orphan products.[38]

To further complicate price determinations, different products have different prices across different payer types and different contracts.[39] An illustrative example is the rise of value-based or outcomes-based arrangements in response to recent approvals of cell and gene therapies. Payers, both private[40] and public[41] are entering into contracts with manufacturers that scale payment based on patient outcomes. Even though cell and gene therapy products may carry list prices of seven digits, the actual financial burden to the payer is not representative of this cost. Moreover, formularies are frequently designed to include exclusive contracts with specific manufacturers. As early evidence from the entry of biosimilar medications (i.e., biologic medications that are highly similar to and have no clinical differences from a biological medication that is already approved by the FDA) with a reduced list price demonstrates, these contractual agreements can make market penetration extremely difficult, as demonstrated by their overall extremely limited uptake despite lower price.[42]

The above examples represent only a small portion of the broader drug pricing ecosystem. Specifically, which cost (or costs) the agency considers can have major impacts on which drugs may be deemed unaffordable, and to whom. Moreover, as outlined above, this cost may be essentially meaningless for the patients and families that depend on the drug because it may bear little or no relationship with the actual out-of-pocket costs the patients pay for their treatments.

Require <u>all</u> impacted agencies to collaborate in the determination of whether march-in proceedings should be initiated, and the subsequent fact-finding and decision-making process.

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[37] Tisdale, A., Cutillo, C.M., Nathan, R. *et al.* The IDeaS initiative: pilot study to assess the impact of rare diseases on patients and healthcare systems. *Orphanet J Rare Dis* **16**, 429 (2021). https://doi.org/10.1186/s13023-021-02061-3

[38] Faden, L., Huskamp, H. (2010) *Rare Diseases and Orphan Products: Accelerating Research and Development.* Institute of Medicine Committee on Accelerating Rare Diseases Research and Orphan Product Development. https://www.ncbi.nlm.nih.gov/books/NBK56190/

[39] Cubanski, J. et. Al. (2019, May 20). *How Does Prescription Drug Spending and Use Compare Across Large Employer Plans, Medicare Part D, and Medicaid?* KFF. https://www.kff.org/medicare/issue-brief/how-does-prescription-drug-spending-and-use-compare-across-large-employer-plans-medicare-part-d-and-medicaid/

[40] Cherian, J. (2022, December 21). *Evolving outcomes-based arrangements with cell & gene therapies.* IPG Health. https://ipghealth.com/news/evolving-outcomes-based-agreements-with-cell-gene-therapies

[41] CMS. (2024, January 20). *Cell and Gene Therapy (CGT) Access Model.* Centers for Medicare & Medicaid Services. https://www.cms.gov/priorities/innovation/innovation-models/cgt#:~:text=millions%20of%20dollars.-,The%20Cell%20and%20Gene%20Therapy%20(CGT)%20Access%20Model%20aims%20to,for%20states%20and%20ties%20payment

[42] Cohen, J. (2023, December 4). *Humira Biosimilars Not Gaining Traction Epitomizes Dysfunctional U.S. System.* Forbes. https://www.forbes.com/sites/joshuacohen/2023/12/04/humira-biosimilars-not-gaining-traction-epitomizes-dysfunctional-us-system/?sh=6f7085422b8f

Proposed questions:

- *How will relevant agencies need to adapt guidance and regulation to cope with changes produced by the use of march-in?*

NORD strongly urges NIST to delegate the development of applicable criteria for march-in rights to the heads of all impacted agencies, supplemental to its sector agnostic guidance. Within the prescription drug sector alone, a multitude of agencies, including CMS, FDA, NIH, VA, and the U.S. Patent and Trademark Office (USPTO) all impact important aspects of the healthcare ecosystem and have valuable and unique perspectives to offer on the applicability of march-in criteria. Only requiring the involvement of a single agency to determine the benefits and potential risks associated with march-in proceedings can lead to an incomplete picture that may have devastating impacts across the whole ecosystem.

In addition, codifying requirements to extend the Intra-Agency Working Group for Bayh Dole (IAWGBD) to specific cases where march-in rights may be applied will be crucial to appropriately predict the intended and unintended impacts of any march-in proceedings, in particular if cost is the only or primary consideration for the proceeding.

Conclusion

NORD thanks NIST for the opportunity to provide comments on this important draft guidance, and we look forward to working with the agency and all key stakeholders on increasing the clarity of the appropriate use for march-in rights. With any questions regarding our above comments, please contact Karin Hoelzer, Director of Policy and Regulatory Affairs, at khoelzer@rarediseases.org, Hayley Mason, Policy Analyst at hmason@rarediseases.org or Mason Barrett, Policy Analyst at mbarrett@rarediseases.org.

Thank you for your consideration,

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