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Comments of the Pharmaceutical Research and Manufacturers of America in Response to the National Institutes of Health Office of Science Policy's Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning

July 22, 2024

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit these comments in response to the National Institutes of Health Office of Science Policy's Request for Information on its Draft Intramural Research Program Policy: Promoting Equity Through Access Planning ("the Draft IRP Policy").[1] PhRMA believes that federal investment in science and technology and attracting private sector investment to translate early research discoveries into innovative products is critically important for Americans and patients around the globe.

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA's member companies have invested more than $1.2 trillion in the search for new treatments and cures, including an estimated $100.8 billion in 2022 alone.[2] The biopharmaceutical industry is committed to working every day to discover and develop new treatments for patients battling serious and life-threatening diseases such as cancer, heart disease, Alzheimer's as well as many rare diseases.

The U.S. biopharmaceutical industry relies on a well-functioning, science-based regulatory system, strong and reliable intellectual property (IP) protections, and coverage and payment policies that support and encourage medical innovation to thrive. This system, in addition to the collaborative biopharmaceutical research ecosystem that includes both the private and public sectors, yields more innovative medicines than any other country in the world. The American biopharmaceutical research ecosystem is among our country's greatest strengths—in part due to policies enacted by Congress to ensure that federally funded inventions can move from the laboratory to the marketplace to benefit the greater public good.

Last year, PhRMA participated in NIH's workshop, "Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer," and submitted comments as part of that process.[3] The current Draft IRP Policy notes it builds on some of the input provided by participants at this workshop with experiences using "access planning" as a means to address downstream access challenges. Specifically, the Draft IRP policy proposes to require that private industry partnering with the NIH to research and develop drugs, biologics, vaccines or devices utilizing NIH-owned inventions commit at the outset of the partnership to developing patient "access plans" in the licensing process. While we share NIH's concern that too often, patients face barriers to

[1] FR Doc. 2024-11188 Filed: 5/21/2024.
[2] PhRMA, 2023 PhRMA Annual Membership Survey (2023), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/A-C/PhRMA_membership-survey_single-page_70523_es_digital.pdf.
[3] NIH, Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer, July 21, 2023.

accessing the medicines they need, we are concerned that NIH's proposal to improve patient access to products stemming from NIH-owned inventions will produce the opposite effect.

Our biomedical research ecosystem is built on a system of technology transfer that recognizes that appropriate incentives for public-private collaboration need to be in place to ensure discoveries made by NIH and other federal agencies do not simply remain on the shelf not benefiting anyone. This is precisely why key laws have been enacted to support this important goal. Imposing unreasonable terms on licensing agreements between the NIH and private sector partners may only inject broad uncertainty into the process and dampen willingness to partner with the NIH, while doing nothing to address the health care system issues that are the underlying drivers of patient access and affordability. History has demonstrated that placing unreasonable terms on NIH collaborative agreements reduces partnership with the private sector. Thus, while the NIH's stated goal is to ensure the "affordability, availability, acceptability, and sustainability" of products stemming from NIH-owned inventions and to provide an adequate return on taxpayer investment, the more likely outcome is that such future products will never be commercialized or benefit the greater public good.[4] In this sense, the proposed policy could provide the worst possible return on taxpayer investment by undermining a system that has worked incredibly well in encouraging licensing of NIH-owned inventions to generate innovation, while yielding no meaningful benefits to patients or society.

The biopharmaceutical industry is proud to be a key player in the U.S. biopharmaceutical research ecosystem. This ecosystem relies on strong public research infrastructure to generate meaningful scientific exchange and a robust system of technology transfer to facilitate partnership to advance science for the benefit of patients. Our comments seek to:

- Provide greater clarity on the complementary roles served by the NIH and the biopharmaceutical industry in fueling innovation and access to lifesaving medicines.
- Explain why entering into a licensing agreement with the terms laid out in the proposal may prove untenable from the perspective of private industry.
- Explain how the requirements of the access planning proposal leave significant ambiguities and do not align with information that is available to biopharmaceutical companies at the stage at which NIH requires it.
- Explain how biopharmaceutical companies do not have full control over the accessibility of medicines, patient costs, or experiences with medicines.
- Provide historical evidence of diminished willingness to engage in public-private-partnership as a result of unreasonable terms placed on NIH collaborative agreements and express concerns for the future impact the proposal may have on innovation.
- Provide alternative solutions to improve patient affordability and access to prescription medicines while preserving the success of our technology transfer system in driving progress for patients.

The complementary roles played by the NIH and the biopharmaceutical industry are essential to fueling innovation and delivering patient access to medicines.

[4] FR Doc. 2024-11188 Filed: 5/21/2024

Policy proposals aiming to ensure federally funded research provides a better return on investment fundamentally misunderstand the biomedical research ecosystem and the respective roles played by NIH and the biopharmaceutical industry in fueling innovation. The current proposal is no exception. While the Draft IRP policy only affects the commercialization of NIH-owned inventions, the proposal should be considered in the context of our nation's broader system of technology transfer in order to understand the repercussions of undermining its success with misguided policies.

According to the NIH Office of Technology Transfer, "technology transfer moves medical innovation from the benchtop through additional research and development, testing, regulatory approval, manufacturing, and finally to distribution as a medical product which will improve the health of everyone."[5] Although many medical discoveries have their origin in the research laboratories at the NIH or through federally funded research at universities and academic medical centers, technology transfer is what allows these discoveries to be developed into medicines and made available to improve public health through licensing and collaboration agreements with the private sector.

Key policy frameworks have been foundational in supporting our system of technology transfer with the private sector and in facilitating commercialization of products. Among these is the Stevenson-Wydler Technology Innovation Act of 1980 which facilitated technology transfer between intramural government laboratories and the private sector. Also enacted in 1980 was the Bayh-Dole Act, which incentivized the private sector to transform discoveries resulting from government funded extramural early-stage research into useful products. Bayh-Dole enabled grant recipients such as universities to retain the title to the patents covering resulting inventions, allowing them to license these patents to private sector partners.[6] The system was further strengthened by The Federal Technology Transfer Act of 1986, which authorized Federal laboratories to enter into cooperative research and development agreements (CRADAs) with private businesses and other entities. Collectively, these policies have proven a remarkable success in facilitating technology transfer and the commercialization of products to the benefit of patients, thereby maximizing taxpayer benefit for government-funded research.

Partnership between the government and the private sector is critical because each plays a fundamentally different but complementary role in the biopharmaceutical R&D ecosystem and in driving scientific advances to the benefit of society. The Congressional Budget Office (CBO) describes this relationship well, noting "the complementary relationship between public and private R&D spending arises mainly because NIH funding focuses on basic research that leads to the discovery of new drugs and vaccines, whereas private spending focuses on applications of such research."[7] While the NIH plays an important role in fostering basic research in genomics,

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[5] NIH, the NIH's Role in Technology Transfer, available at: https://www.techtransfer.nih.gov/nih-and-its-role-technology-transfer

[6] Prior to enactment of the Bayh-Dole Act, the government retained the patents on federally funded inventions – and only 5% of those patents were ever licensed for use in the private sector. In contrast since Bayh-Dole, over 200 new drugs and vaccines have been developed through public-private partnership. *See,* Association of University Technology Manager, Driving the Innovation Economy, Available at: https://autm.net/AUTM/media/SurveyReportsPDF/AUTM_FY2016_Infographic.pdf

[7] CBO, Research and Development in the Pharmaceutical Industry, April 2021, Available at https://www.cbo.gov/publication/57126

molecular biology and other life sciences that have identified new disease mechanisms, these discoveries are far from fully developed therapies, but rather a jumping off point for private industry to invest in the development of a potentially useful medicine for patients.

The biopharmaceutical industry's unique role in the research ecosystem is to utilize its scientific and industrial expertise and invest, at risk, to build upon and further advance basic science research conducted by the federal government to determine if safe and effective treatments can be developed and made available to patients. The federal government cannot effectively research, develop and manufacture vaccines and other new treatments. Rather they rely on the resources, scientific expertise, R&D and manufacturing capabilities, and technological platforms of biopharmaceutical companies to research and develop medicines. And this is good news for taxpayers, as the odds of success in drug development are slim, making the incentives built into our system which encourage public-private collaboration to commercialize new medicines a beneficial feature that shields taxpayers from the substantial risks and costs associated with this endeavor. The private sector investment necessary to develop a new medicine can cost an average of $2.6 billion. These efforts take on average 10-15 years with only 12% of drug candidates entering clinical trials successfully reaching FDA approval.[8]

Supporting the complementary roles of public and private sectors in the drug development process are also important as investment in the NIH basic research has a synergistic relationship with private sector investment generating spillover effects which further fuel innovation generation to the benefit of patients and society. Several studies have demonstrated that increases in NIH-funded basic research results in increased private R&D investment and innovation.[9] In fact, one study found that in the decade following an increase in NIH funding, private R&D spending grew by about eight times as much as the increase.[10] Another study found that each $10 million increase in NIH funding resulted in private sector investment yielding a net increase of 2.7 patents.[11] Moreover, given the NIH licensing agreements yield royalties from the private sector when products are commercialized, successful collaboration also facilitates reinvestment in research at the NIH to explore new discoveries further fueling the advancement of scientific research. Evidence suggests these funds are significant. In fact, GAO has found that the NIH received up to $2 billion in royalties between 1991 and 2019.[12] In this way, not only does this system of technology transfer shield NIH from the significant risks and costs of R&D, but it provides a great return on investment when success is achieved, further funding the NIH in its mission to advance science and the public health.

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[8] DiMasi, J. A., Grabowski, H. G., & Hansen, R. W. (2016). Innovation in the pharmaceutical industry: new estimates of R&D costs. Journal of health economics, 47, 20-33.
[9] Schacht, Wendy H. (2012). Federal R&D, Drug Discovery, and Pricing: Insights From the NIH-University-Industry Relationship, Congressional Research Service Report RL32324.
[10] Toole, Andrew A. (2007). Does Public Scientific Research Complement Private Investment in R&D in the Pharmaceutical Industry? Journal of Law & Economics, 50(1) 81–104, https://doi.org/10.1086/508314.
[11] Azoulay, Pierre et al. (2019). Public R&D Investments and Private-Sector Patenting: Evidence From NIH Funding Rules, Review of Economic Studies, 86(1)117–15. Available at: https://academic.oup.com/restud/article/86/1/117/5038510?login=true
[12] https://www.gao.gov/products/gao-21-52

A rich body of research also underscores the significant amount of private sector investment that is necessary to realize the potential of basic research conducted at NIH. A 2014 study of the most transformational drugs of the 25 prior years, as identified by over 200 physicians, found that the private sector was responsible for the vast majority of the work required to develop a therapy.[13] An analysis of the contribution of NIH funding to new drug approvals between 2010 and 2016 found that although NIH funding contributed to published research associated with every one of the 210 new drugs approved by the FDA in those years, 90% of the NIH funding supported basic research related to the biological targets for drug action rather than the drugs themselves.[14] And an analysis of 23,230 NIH grants awarded in the year 2000 that were ultimately linked through the reported patent filings to 18 FDA-approved therapies showed that NIH funding totaled $0.670 billion, whereas private sector funding totaled $44.3 billion. In other words, the private sector's funding contributions were 66 times greater than the NIH's funding contributions to the development of these therapies.[15] The private sector's substantial investment in research and development of medicines far exceed the contribution of the public sector. But importantly, in the absence of these substantial investments and the risk shouldered by the private sector, the foundational basic research discoveries facilitated by NIH research and grant funding may have never transcended the lab to benefit patients or society.

Entering into a licensing agreement with the terms laid out in the proposal may prove to be untenable from the perspective of private industry.

While improving access to products in which NIH-owned inventions have played a role is an important goal, if the Draft IRP Policy ultimately discourages future licensing with the NIH then the current proposal will fail to achieve this objective. Unfortunately, entering into licensing agreements with the problematic terms laid out in the proposal may be a non-starter for private sector companies.

Many of the strategies that the NIH outlines would be considered acceptable components of an access plan equate to government price controls or biopharmaceutical firms agreeing to sublicense patents and trade secrets to third parties around the globe. For example, NIH has proposed promoting equitable access and affordability in product development and deployment through methods such as committing to keep prices in the U.S. equal to those in other developed countries, or not raising costs above inflation. NIH has also proposed that firms commit to sublicense relevant IP and know-how on a low- or no-royalty basis.[16] These types of provisions reach well beyond standard commercial licensing terms, and do not take into account the many

[13] Chakravarthy R, Cotter K, DiMasi J, et al. (2016). Public- and private-sector contributions to the research and development of the most transformational drugs in the past 25 years: from theory to therapy. Ther Innov Regul Sci. 2016;50(6):759-768.
[14] Galkina Cleary, E., Beierlein, J. M., Khanuja, N. S., McNamee, L. M., & Ledley, F. D. (2018). Contribution of NIH funding to new drug approvals 2010-2016. Proceedings of the National Academy of Sciences of the United States of America, 115(10), 2329–2334. https://doi.org/10.1073/pnas.1715368115
[15] Schulthess D, Bowen HP, Popovian R, Gassull D, Zhang A, Hammang J. The Relative Contributions of NIH and Private Sector Funding to the Approval of New Biopharmaceuticals. Ther Innov Regul Sci. 2023 Jan;57(1):160-169..
[16] FR Doc. 2024-11188 Filed: 5/21/2024

complexities of drug pricing discussed throughout these comments. Accordingly, the NIH appears to overestimate the likelihood that the private sector would agree to such terms in an access plan.

The risks posed to companies considering investing into further commercializing NIH-owned inventions also appear to be overlooked in the DRAFT IRP Policy. The policy raises the possibility that a license could be terminated or at risk of non-compliance or breach after significant company investment. Yet, the initial terms of the licensing agreement may not reflect the realities later in the development process or after commercialization. Given the ambiguity surrounding how NIH will evaluate access plans based on the ultimate "affordability, availability, acceptability, and sustainability" of products commercialized from NIH-owned inventions, it is unclear that compliance with such terms even represents an achievable goal.[17] Therefore, as termination of the licensing agreement may jeopardize millions or even billions of dollars of investment to further commercialize a product, it would be unrealistic to presume that a biopharmaceutical firm would take on the additional risk of partnering with the NIH if the policy were finalized.

The NIH also notes a licensee agreeing to access planning as part of a licensing agreement may be required to confer with the NIH as the licensed product progresses under the access plan and consider in good faith any request to review with the licensee reasonable modifications.[18] In other words, before entering into such an agreement, licensees must consider the likelihood that the NIH may continually seek to modify the terms throughout the development process. If subsequent modifications proved to be unworkable to the licensee, the company would have to abandon the licensed product after considerable investment to commercialize the product—again highlighting the challenges a company would face in agreeing to such terms in the licensing process.

Additionally, the proposed policy appears to require that licensees share proprietary information with NIH as part of the access planning process, imposing significant risks for the private sector. The agency notes it seeks "cost accounting" measures from its partners and information about costs incurred in the R&D process to help drive down costs—seemingly ignoring that R&D cost information is highly confidential, proprietary, and commercially sensitive information for biopharmaceutical companies.[19] Moreover, it is unclear how this R&D cost information is relevant to the access planning process or the ultimate affordability of a medicine.

The Draft IRP further raises concerns as it is unclear whether the access planning requirements are binding beyond the expiration of underlying NIH-owned patents. If the NIH is seeking to assert broad control over products based on, in some cases, their limited patent ownership over a small subset of a product's intellectual property, this policy would significantly undermine the value of all subsequent IP resulting from investments made by the private sector innovators.

Investment in R&D to advance a drug candidate from clinical trials to regulatory approval already is a highly uncertain process with low probabilities of success. Imposing additional uncertainty in the agreements between the industry and the NIH would only disadvantage the NIH from a licensing perspective. If the Draft IRP Policy is finalized, the additional risk that biopharmaceutical

[17] FR Doc. 2024-11188 Filed: 5/21/2024
[18] FR Doc. 2024-11188 Filed: 5/21/2024
[19] FR Doc. 2024-11188 Filed: 5/21/2024

companies, particularly publicly traded companies, would have to take on in order to partner with the NIH may prove unsurmountable for many considering entering into these agreements.

The requirements of the access planning proposal leave significant ambiguities and do not align with information that is available to biopharmaceutical companies at the stage at which NIH requires it.

Even if a biopharmaceutical company were willing to undertake the risk of partnering with the NIH and agree to access planning terms, the requirements of what is demanded of companies as part of the process is at odds with the information that is available to biopharmaceutical companies at the stage at which the NIH requires it. When a company is commencing pivotal phase III clinical trials, it is unlikely that they have much more than some epidemiological and market data to assess if there is a potential market for the potential drug candidate/asset. Moreover, at this stage there is little certainty around key access considerations, since many will be tied to the outcomes of the trial which would inform the ultimate drug labeling. For these reasons, the patient population and the corresponding indications may not be fully known to the company, making NIH's expectations of what is feasible under the access planning requirements unrealistic.

Furthermore, it is unclear whether access plan submissions would become a required activity for every additional indication following initial FDA approvals. If NIH were to require access planning for each additional indication, companies may be discouraged from pursuing additional indications for new patient populations or disease areas. Such a disincentive may particularly impact underserved patient populations, including those in which patient populations sizes are small. Historically, post-approval R&D that leads to subsequent indications has been critical to advancing treatments for patients with rare diseases.[20] Because fewer than 10% of rare diseases have an available treatment option, R&D to advance new treatments for underserved populations affected by these illnesses may be disproportionately impacted.[21]

Biopharmaceutical companies do not have full control over the accessibility of medicines, patient costs, or experiences with products.

PhRMA shares NIH's commitment to ensuring patient affordability and access to medicines. However, the access planning proposal presumes that biopharmaceutical companies have control and insight into the ultimate accessibility and affordability of their medicines both in the United States and around the globe in a manner that is unrealistic.

Patient affordability and access in the United States in particular is often determined by the nuances of specific health insurance coverage, payer policies, benefit design and formulary decisions driven by health insurers and pharmacy benefit managers (PBMs). Unfortunately, large health plans and their PBMs, as well as hospital conglomerates, increasingly play a role in patient

[20] Miller, K.L., Lanthier M. (January 2024). Orphan Drug Label Expansions: Analysis Of Subsequent Rare And Common Indication Approvals. Health Affairs. Available at: https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2023.00219
[21] FDA, Rare Disease Cures Accelerator, Available at: https://www.fda.gov/drugs/regulatory-science-research-and-education/rare-disease-cures-accelerator#:~:text=However%2C%20of%20the%20approximately%207%2C000,and%20progression%20of%20each%20disease.

affordability and access to medicines. PhRMA believes NIH cannot ignore these influences in the context of the current access planning proposal.

In recent years, the largest PBMs—three of which control 80% of the entire market—have combined with health insurers, pharmacies and provider groups to form vertically integrated organizations with enormous influence over which medicines patients can access, where they can access them, and the affordability of those medications.[22] [23] Total rebates, discounts and other payments from brand manufacturers to PBMs, payers, providers, government and others reached $256 billion in 2022.[24] Yet, even as rebates and fees are growing year after year, the number of patients that face high out-of-pocket costs for their prescription medicines has increased significantly as PBMs and health insurance companies have shifted more costs onto patients through the increased use of deductibles and coinsurance for prescription medicines. These benefit designs have increasingly exposed patients to high out-of-pocket costs because they base cost-sharing on the undiscounted list prices, even though the net prices available to PBMs and health plans are often significantly lower.[25] In fact, nearly 50% of commercial and 92% of Part D total patient out-of-pocket spending for brand medicines are based on list price.[26] [27]

To address this continued erosion of health insurance coverage, many drug manufacturers offer to help patients access the medicines prescribed by their doctors through cost-sharing assistance and patient assistance programs. Research has found that those who use patient assistance were up to 47% more likely to stick with their treatment.[28] Yet, insurers and PBMs are adopting tactics that can deny patients the benefit of this assistance through the use of accumulator adjustment programs, copay maximizers and other schemes designed to extract the value of patient assistance. These tactics get in the way of helping patients afford and access the medicines prescribed by their doctors.

Unfortunately, evidence suggests health plans, PBMs, large hospital systems, and others in the supply chain continue to find ways to benefit from spending on medicines to bolster their own profitability, which often negatively impacts patient access and affordability. For example, hospitals have rapidly consolidated over the past decade, buying up physician practices and merging with other hospitals. As a result, these hospital systems can leverage their size and lack of market

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[22] Fein, A. "The 2023 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers," Drug Channels Institute. March 2023.
[23] Federal Trade Commission, "Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies," Interim Staff Report, July 2024. https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf
[24] Fein, A. "The 2023 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers," Drug Channels Institute. March 2023.
[25] MedPAC, Assessing postsale rebates for prescription drugs in Medicare Part D, April 13, 203. https://www.medpac.gov/wp-content/uploads/2022/07/Tab-F-DIR-data-April-2023-SEC.pdf
[26] IQVIA. "Medicine Spending and Affordability in the U.S.," August 2020. https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us
[27] PhRMA. "Trends in Out-of-Pocket Spending for Brand Medicines in Medicare Part D." https://www.phrma.org/Report/Trends-in-Out-of-Pocket-Spending-for-Brand-Medicines-in-Medicare-Part-D
[28] Hung A, et al. Impact of financial medication assistance on medication adherence: a systematic review. J Manag Care Spec Pharm. 2021 Jul;27(7):924-935.

competition to mark up the cost of medicines by an average of 500% from what they paid to acquire the medicine.[29]

A central driver of hospital consolidation and increasing costs is the 340B drug pricing program. Congress created the 340B program in 1992 to provide access to discounts on outpatient medicines for certain health care safety-net providers treating large numbers of uninsured or otherwise vulnerable patients.[30] To achieve that goal, hospitals and clinics that meet certain eligibility criteria receive steep discounts on outpatient medicines from manufacturers. The average discount on 340B medicines is nearly 60%,[31] and in some cases, the discounts bring the price of a medicine down to just a penny.

Unfortunately, the 340B program of today is unrecognizable in both character and size when compared to the targeted program Congress originally created, with more hospital conglomerates and for-profit companies using these discounts for themselves, leaving vulnerable patients behind.[32] For example, large hospital systems that generate significant profits on 340B discounted medicines may use these profits to expand care in wealthier areas while underinvesting in hospital locations in lower income areas, which often serve patients of color.[33] For-profit pharmacies, often affiliated with large PBMs, also profit from the 340B program. However, evidence shows the 340B discounts received by these pharmacies are rarely shared with patients.[34] At this point, it seems patients are the only ones not benefiting from the billions of dollars in discounts manufacturers provide each year to fund the 340B program.

We share these trends not only because they underscore the many ways that biopharmaceutical companies do not have full control over the ultimate affordability or accessibility of their medicines, but to demonstrate that it is not possible to address these challenges through the Draft IRP Policy or without taking a holistic look across our health care system. Misaligned incentives in our healthcare system increasingly have enabled hospital conglomerates and big health insurers and their PBMs to increasingly maximize revenues at the expense of patient affordability and access. Even if biopharmaceutical companies were to engage in licensing agreements with access planning requirements, the reality is biopharmaceutical companies can't fully control downstream limitations on access to medicines or out-of-pocket costs faced by patients. Likewise, NIH's ability to accurately assess a biopharmaceutical product based on elements of "affordability, availability, accessibility, and sustainability" under the access planning process may be significantly limited—

[29] Moran, Hospital Charges and Reimbursement for Medicines: 2023 Update Analysis of Markups Relative to Acquisition Costs. August 2023. https://themorancompany.com/wp-content/uploads/2023/08/PhRMA-Hospital-Charges-Report-August-2023.pdf
[30] See 42 U.S.C. § 256b (the "340B statute").
[31] Brownlee A, Watson J. "The Pharmaceutical Supply Chain, 2013-2020." Berkeley Research Group, January 2022. https://ecommunications.thinkbrg.com/44/2328/uploads/brg-pharmaceutical-supply-chain-2022.pdf?intIaContactId=lXKabwLWBtOm%2fz%2fpgW%2btPQ%3d%3d&intExternalSystemId=1
[32] A Fein, The 340B Program Climbed to $44 Billion in 2021—With Hospitals Grabbing Most of the Money, August 2022
[33] K Thomas, J Silver-Greenberg, How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits, New York Times, September 2022.
[34] IQVIA White Paper. Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies? October 2022

only further discouraging biopharmaceutical companies from engaging in licensing agreements with NIH.

History demonstrates that placing unreasonable terms on licensing agreements diminishes willingness to engage in public-private partnership.

Imposing access planning requirements on licensing agreements to further commercialize NIH-owned inventions may not achieve NIH's goal. Rather it may only discourage future collaboration between the public and private sectors and reduce access to useful products generated from taxpayer funded research.

Policy proposals to place unreasonable restrictions on agreements with the private sector have been tried before with disastrous results for patients and taxpayers. In 1989, the NIH imposed "reasonable pricing" conditions in all Cooperative Research and Development Agreements (CRADAs) between federal labs and outside parties to conduct research or development. The policy was revoked in 1995 after public meetings were held with companies, patient advocates and researchers after which the agency concluded that these pricing conditions significantly chilled collaboration between the public and private sectors.[35] In his announcement of the decision, then Director of the NIH, Harold Varmus, M.D., said, "an extensive review of this matter over the past year indicated that the pricing clause has driven industry away from potentially beneficial scientific collaborations with [public health service] scientists without providing an offsetting benefit to the public." Dr. Varmus further said, "eliminating the clause will promote research that can enhance the health of the American people."[36] After the removal of the clause, there was a subsequent rebound in CRADAs.[37]

Beyond the effect the Draft IRP Policy may have on technology transfer to facilitate the development of intramural research conducted at the NIH, we urge the agency to consider the compounded effect of implementing this policy in light of the additional uncertainty posed by the National Institute of Science and Technology's (NIST) proposed march-in framework. The Draft Framework blatantly misinterprets the Bayh-Dole Act and ignores decades of policy precedent by encouraging federal agencies to explicitly consider the price of a product incorporating federally funded inventions when evaluating the statutory march-in criteria. If finalized, NIST's proposal would likely discourage companies from investing funds in an already risky endeavor. The negative consequences of this uncertainty could send the U.S. innovation ecosystem back to a time before Bayh-Dole when government-funded research sat on a shelf, undeveloped and unused. If both of these proposals are implemented, the likelihood that taxpayer funded discoveries made at NIH or via federal funding at research institutions around the country would be licensed and transformed into useful products benefiting the greater public good may be severely diminished.

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[35] National Institutes of Health. (1994). Reports of the NIH Panels on Cooperative Research and Development Agreements: Perspectives, Outlook, and Policy Development. Available from: https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH%20CRADAReportonReasonable-PricingClause1994.pdf

[36] Press Release, NIH News, April 11, 1995. Available from: https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf

[37] https://www.techtransfer.nih.gov/licensing

There are alternative solutions to improve patient affordability and access to prescription medicines while preserving the success of our technology transfer system which enables innovation to thrive.

We share NIH's concern that too often patients are unable to access the medicines they need. We do believe, however, that policy proposals that would discourage licensing of NIH-owned inventions by imposing burdensome requirements on licensees in the private sector does not provide a meaningful strategy to address this concern. Biopharmaceutical innovation offers the best opportunity to address our nation's most pressing health care challenges and improve the health of all Americans. Addressing misaligned incentives in our healthcare system which drive affordability challenges can help meaningfully support patient access to new medical innovations while taking meaningful steps towards achieving NIH's goal.

For example, requiring PBMs and health insurers to share the savings they receive on medicines directly with patients at the pharmacy counter would also lower patient out-of-pocket costs and help realign payer incentives. Additionally, ending list price-based PBM compensation in favor of flat fees can help to reduce PBM incentives to prefer higher price medicines over lower cost alternatives. Patients with deductibles and coinsurance could also benefit from expanded coverage of lower price medicines in the form of lower out-of-pocket costs.

Addressing misaligned incentives driven by the 340B program would also represent a meaningful step forward in improving patient access and affordability. A combination of lax eligibility standards for 340B hospitals, little oversight into how 340B funds are used, and a lack of program requirements to share savings on medicines with low-income and uninsured patients are among the key factors that have contributed to the way the program has distorted the health care market at the expense of patients. Changes are needed to ensure the 340B program is working for patients instead of driving up costs for everyone while being co-opted by big hospitals and for-profit companies to pad their bottom lines.

NIH's Draft IRP proposal does not provide a solution to the affordability and access policy issues that the Administration and Congress have failed to address. While we realize the aforementioned reforms are not within NIH's capabilities to address, we offer them as a reminder of actionable policies that can have a meaningful impact on patient affordability and access without broadly discouraging licensing with the NIH in the process.

Conclusions

Our collaborative biopharmaceutical research ecosystem relies on our nation's system of technology transfer and the success of this system is a driving factor behind U.S. global leadership in biomedical innovation. This system is among our nation's greatest strengths due in large part to historic policies that have recognized the importance of ensuring federal funded inventions can move beyond the research laboratories at NIH to benefit the greater public good. Policies which have placed unreasonable terms on collaborative agreements between the public and private sector have demonstrated what may happen if this policy is finalized. As stated throughout our comments, we are concerned that NIH's Draft IRP Policy would discourage collaboration between the NIH and the private sector, jeopardizing future patient access to new medicines in which NIH-

inventions have played a role. Even worse, the proposal would do this without meaningfully addressing the sources of patient affordability and access that patients struggle with today, including in the underserved communities who are most severely impacted. We urge NIH to change course and abandon this policy as the combined effect of finalizing the Draft IRP Policy along with other harmful policies advanced by the Administration—namely, NIST's march-in framework—may undermine the future of public-private collaboration and successful technology transfer in the United States, ultimately reducing access to innovation to the detriment of patients and society.

Respectfully Submitted,

/s/	/s/
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