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July 22, 2024

Monica M. Bertagnolli, M.D.
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Submitted via: <https://osp.od.nih.gov/comment-form-draft-nih-intramural-research-program-policy-promoting-equity-through-access-planning/>

Re: National Institutes of Health (NIH) Office of Science Policy (OSP): Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning, Document No.: 2024-11188

Dear Dr. Bertagnolli:

Intellectual Property Owners Association (IPO) appreciates the opportunity to respond to the Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning (the “Draft Policy”) and provide input on the effects of its proposed “patient access” license terms on private sector licensees who develop and commercialize potentially lifesaving products that may incorporate NIH-owned inventions.¹

IPO is an international trade association representing a “big tent” of diverse companies, law firms, service providers and individuals in all industries and fields of technology that own, or are interested in, intellectual property rights. IPO membership includes over 125 companies and spans over 30 countries. IPO advocates for effective and affordable IP ownership rights and offers a wide array of services, including supporting member interests relating to legislative and international issues; analyzing current IP issues; providing information and educational services; supporting and advocating for diversity, equity, and inclusion in IP and innovation; and disseminating information to the public on the importance of IP rights.

IPO’s vision is the global acceleration of innovation, creativity, and investment necessary to improve lives. The Board of Directors has adopted a strategic objective to foster diverse engagement in the innovation ecosystem and to integrate diversity, equity, and inclusion in all its work to complement IPO’s mission of promoting high quality and enforceable IP rights and predictable legal systems for all industries and technologies.

IPO members invest tens of billions of dollars annually in research and development, employing hundreds of thousands of scientists, engineers, and others in the United States to develop, manufacture, and market innovative new products and services. In a limited number of cases, this

¹ Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning, 89 Fed. Reg. 45,003 (May 22, 2024).

research originates from programs and initiatives funded by the federal government, including inventions made by Intramural Research Program (IRP) scientists. Turning basic research into practical applications and commercial products typically requires enormous investments, years of additional research, development, and refinement, and is often accompanied by missteps and outright failure.

As the Draft Policy recognizes, such “investments are critical to the health of our scientific enterprise, both in terms of supporting research discoveries and by fueling U.S. leadership in the bioeconomy.” IPO provides these comments to assist the NIH with the goal of entering into “effective partnerships [with the private sector] that foster a shared commitment to transforming knowledge into improved health for all.” Bottom line, IPO recommends that NIH withdraw the Draft Policy.

1. Promoting Meaningful Access Approaches.

NIH intends to provide additional guidance to licensees on examples of acceptable, commercially reasonable approaches for promoting access. NIH is seeking input on the range of activities that could be considered and strategies to mitigate access challenges and expand the reach, and benefit, of drugs, biologics, vaccines, and devices stemming from NIH inventions.

NIH’s goal of expanding the reach and benefit of pharmaceuticals and medical devices is laudable, but the Draft Policy’s proposed “patient access” provisions introduce uncertainty for prospective licensees, risking the commercialization and further development of IRP inventions. Thus, we submit that these provisions will not benefit patients.

As the Draft Policy notes, “[t]he process of bringing a new product, through research and development, to market and into the hands of patients is long, fraught with challenges, and expensive.” “On average, it takes 10 to 15 years and costs \$2.6 billion to develop one new medicine, including the cost of the many failures.”² The “[e]stimated average cost of post-approval R&D—studies to test new indications, new formulations, new dosage strengths and regimens, and to monitor safety and long-term side effects in patients required by the [FDA] as a condition of approval—of \$312 million boosts the full product lifecycle cost per approved drug to nearly \$2,870 million.”³ The decision to develop and advance a potentially promising discovery is made with the expectation that the innovator will realize a return reflecting the value of the product to patients and society.

As discussed in more detail below, the Draft Policy creates uncertainty that would chill future commercialization of IRP inventions and result in a loss of access by all.

2. Promoting Transparency in the Biomedical Research Enterprise and Return on Investment

The process of bringing a new product through research and development, to market, and into the hands of patients is long, fraught with challenges, and expensive. NIH is interested in hearing from

² *Research & Development Policy Framework*, PHRMA, <https://phrma.org/en/policy-issues/Research-and-Development-Policy-Framework> (last visited July 13, 2024).

³ *Cost to Develop and Win Marketing Approval for a New Drug is \$2.6 Billion*, TUFTS CTR. FOR THE STUDY OF DRUG DEV. 1 (Nov. 18, 2014), https://f.hubspotusercontent10.net/hubfs/9468915/TuftsCSDD_June2021/pdf/pr-coststudy.pdf.

potential partners on how its access plan could incorporate transparent cost accounting measures to assist NIH in driving down costs associated with innovation and making clearer what costs are incurred along the way and how those affect product costs.

Generally, robust markets play an important role in supporting affordable health care and allocating investment to productive economic uses. When capital markets function well, the result is economic growth, job creation, return on investment, and strong competition, which puts more treatments in the hands of patients who need them. On the other hand, insufficient transparency can lead to short-term thinking and a reduction in business investments and overall growth rates. Hence, corporate transparency has generally come to the forefront, particularly with Environmental, Social, and Governance (ESG) policies currently in place.

Some suggest transparency in pricing is the only way to judge whether a drug's price is logical in comparison to the costs. But drug pricing is complicated and impacted by the actions of third parties, including insurance providers, pharmaceutical benefit managers, Medicare, and other governmental organizations.⁴ These complexities can cause the public and media to misinterpret profit margins without considering future projects and investments. Moreover, drug pricing, like any other product pricing, involves information subject to trade secret protection that, if disclosed, would create an environment of unfair competition and potentially harmful products.

According to the Draft Policy, it is “estimated that technology licensed from the IRP supported an average of 74,500 jobs and contributed an average of over \$13 billion to U.S. GDP each year over the last two decades.” Creating a barrier to developing and commercializing IRP technology would have serious economic ramifications. NIH provides many examples of how “inventions made by IRP scientists, which are then patented and licensed to the private sector for commercial development,” have contributed to “the first AIDS drugs (antiretrovirals), vaccines against hepatitis and HPV, treatments for cancer, and diagnostics for HIV and the rare genetic disease, familial Mediterranean fever.”⁵ Given such past successes, there is no short- or long-term benefit to disrupting future commercial development of IRP inventions.

3. Providing Flexibility While Achieving Clear Policy Objectives

NIH recognizes that its licensees, their partners, and the public will need confidence around what this policy requires and the standards that would be used to evaluate plans. The agency is seeking input on how to maintain flexibility for licensees to pursue their specific product development and commercialization needs while simultaneously promoting certainty and transparency on access efforts and policy enforcement.

The Draft Policy explains that “initial agreement terms are intentionally flexible and not prescriptive” and would require “parties [to] commit to revisit access considerations as product development progresses.” For “licenses granted for early-stage inventions,” the terms “would be more flexible to reflect the higher uncertainty associated with technologies that lead to drugs, biologics, vaccines, or devices.” For “late-stage inventions that are closer to market launch,” the Draft Policy contemplates adding “specific, tailored access-oriented provisions,” but is vague about

⁴ Rebecca Robbins & Reed Abelson, *The Opaque Industry Secretly Inflating Prices for Prescription Drugs*, N.Y. TIMES (June 21, 2024), <https://www.nytimes.com/2024/06/21/business/prescription-drug-costs-pbm.html>.

⁵ *Commercializing Inventions*, NAT'L INSTS. OF HEALTH INTRAMURAL RSCH. PROGRAM, <https://irp.nih.gov/our-research/commercializing-inventions> (Jan. 26, 2023).

the terms of such provisions. As a result, a licensee would be left to speculate about when and how the terms of the license agreement may change throughout the life of a license.⁶

Additionally, innovative vaccines, drugs, and medical devices result from integrating multiple technologies covered by intellectual property rights; licenses from multiple licensors are often needed to develop a final product. Licensees of IRP technology will invariably incorporate their own intellectual property and technology to develop and commercialize finished products. Rarely, if ever, will a final product be the result of only NIH-funded technology. Yet once an IRP license agreement is relied on—directly or indirectly—the burdens and uncertainty of the “patient access” clauses will encumber all related technologies and products.

This uncertainty is likely to make developing IRP technologies untenable. A typical license agreement gives a prospective or actual licensee certainty over the economic implications of using licensed technology before investing. In contrast, the Draft Policy’s “patient access” licensing terms encumber all subsequent inventions and technology, making it difficult for licensees, such as companies who can develop and market finished products, to invest in further product development. The worst-case scenario, under proposed guidance issued by the National Institute of Standards and Technology (NIST), is that NIH could later decide a price is unreasonable and exercise its march-in rights.

With these provisions, private sector companies developing drug and medical device products utilizing IRP technology are likely to have issues finding willing licensees or acquirers of those products. The adverse impact, in large part, will fall upon start-ups and small companies who typically develop IRP technology until it shows some potential, after which further development rights are acquired by companies with core competencies and resources necessary to develop the technology into a safe and effective medicine through the long, arduous path of conducting additional pre-clinical studies, clinical trials, further product development, scale-up manufacturing, and, hopefully, regulatory approval and commercial launch.

4. Helping Licensees Achieve Access Goals

NIH is interested in hearing ideas about how it may be able to help licensees deliver patient access to products that stem from these agreements. Licensees could include such information in access plans or at earlier states of product development. NIH invites input on additional steps it could take or ways to leverage existing U.S. Government programs and resources to assist in this endeavor.

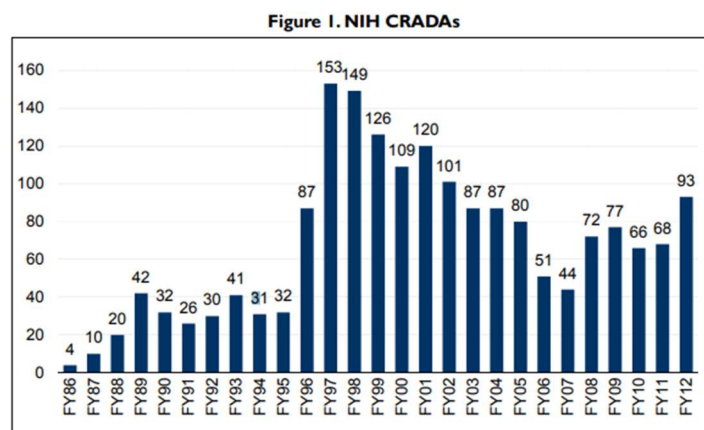
The “access planning” provisions, which seek to “prospectively address downstream access challenges” and “incorporat[e] patient access considerations, at a high level, in agreements related to biomedical research and development” are unworkable and would discourage development of products embodying IRP inventions. There is no way to predict in advance whether a potentially

⁶ In an analogous context, a 2012 Congressional Research Service report notes that “one of the major factors in the reported success of the Bayh-Dole Act is the certainty it conveys concerning ownership of intellectual property.” WENDY H. SCHACHT, CONG. RSCH. SERV., THE BAYH-DOLE ACT: SELECTED ISSUES IN PATENT POLICY AND THE COMMERCIALIZATION OF TECHNOLOGY 9 (2012), <https://sgp.fas.org/crs/misc/RL32076.pdf>. By making the final terms for licensing NIH-funded research “flexible,” the “patient access” provisions in the Draft Policy would have the effect of removing any certainty that a licensee may have when forecasting the ROI for a prospective project.

promising technology will be a commercial success. The failure rate of drug development is exceedingly high—nine of out ten small molecule candidates never reach the market.⁷

NIH Previously Experimented with “Reasonable Pricing” Requirements in CRADAs and Determined That They Stifle Innovation

In Fiscal Year (FY) 1990 – 1995, NIH incorporated a “reasonable pricing” clause into its Cooperative Research and Development Agreements (CRADAs), collaborative agreements that govern how the public and private sectors work together on research projects.⁸ “While there was no statutory requirement mandating this type of clause, it was instituted in response to public and political pressures resulting from concern over the cost of AZT, a drug used in the treatment of HIV infection.”⁹ Under the clause, a company taking an exclusive license in an NIH invention could be compelled by NIH to submit documentation showing a “reasonable relationship between the pricing of the product, the public investment in that product, and the health and safety needs of the public.”¹⁰ This caused the number of new CRADAs to decrease substantially, ultimately resulting in fewer collaborative research projects.¹¹ NIH removed the “reasonable pricing” clause from its CRADAs in FY 1995 when it became clear that the clause stifled innovation, as reflected in the figure below from the Congressional Research Service.¹² The Draft Policy, whose “access planning” licensing terms are more onerous, will lead to the same predictable harm and simply should not be implemented.



Source: National Institutes of Health, Office of Technology Transfer http://www.ott.nih.gov/about_nih/statistics.html.

To make the determination that the clause should be removed, NIH applied a rigorous, science-based approach, and sought input from scientists, patient advocacy groups, and representatives of academic institutions and industries (*i.e.*, a broad scope of stakeholders).¹³ Ultimately, the then-Director of the NIH, Dr. Harold Varmus, concluded:

⁷ Duxin Sun, Wei Gao, Hongxiang Hu & Simon Zhou, *Why 90% of Clinical Drug Development Fails and How to Improve It?*, 12 ACTA PHARMACEUTICA SINICA B 3049, 3050 (2022), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9293739/pdf/main.pdf>.

⁸ NAT'L INSTS. OF HEALTH, THE NIH EXPERIENCE WITH THE REASONABLE PRICING CLAUSE IN CRADAs FY1990-1995 1 (2021), <https://www.techtransfer.nih.gov/sites/default/files/CRADA%20Q%26A%20Nov%202021%20FINAL.pdf>.

⁹ WENDY H. SCHACHT, CONG. RSCH. SERV., FEDERAL R&D, DRUG DISCOVERY, AND PRICING: INSIGHTS FROM THE NIH-UNIVERSITY-INDUSTRY RELATIONSHIP 16 (2012), <https://sgp.fas.org/crs/misc/RL32324.pdf>.

¹⁰ NAT'L INSTS. OF HEALTH, *supra* note 8, at 2.

¹¹ *Id.*

¹² SCHACHT, *supra* note 9, at 17.

¹³ *Id.* at 17–20.

An extensive review of this matter over the past year indicated that the pricing clause has driven industry away from potentially beneficial scientific collaborations . . . without providing an offsetting benefit to the public Eliminating the clause will promote research that can enhance the health of the American people.¹⁴

It is important to note that CRADAs during this time did not include a requirement that licensees “submit a plan outlining steps they intend to take to promote access to products to regulate price”—*i.e.*, “access planning”—which is even more burdensome than the prior CRADA “reasonable pricing” requirement. It stands to reason the negative impact of the Draft Policy is likely to exceed that of the failed “reasonable pricing” requirement for CRADAs and will stifle partnerships designed to transform knowledge generated from NIH research into commercial products that will improve health for all.

The suspension of the Institutional Patent Agreement (IPA), which was created by NIH in 1968 at the behest of President Lyndon Johnson and the recommendation of Elmer Staats, Comptroller General of the United States, is similarly illustrative.¹⁵ As Howard Bremer testified before Congress, “[a]fter the IPA went into effect, patent applications by universities increased by 300 percent, and of the 329 inventions managed by universities in the first five years, 122 were licensed, including 78 exclusively.”¹⁶ But in 1975, U.S. Department of Health, Education, and Welfare Secretary Joseph Califano suspended the IPA program to return to case-by-case review, similar to what is currently proposed. Secretary Califano, in effect, marched-in on American Science and Engineering for CAT scanners, premised on a concern over health care costs. The pace of subsequent innovation slowed dramatically as university inventions again became “entangled in a lengthy bureaucratic process and the development of important treatments was delayed.”¹⁷

NIH’s goal should be protecting U.S. innovation and benefiting patient access by encouraging partnerships between NIH and private industry. As the Association for University Technology Managers (AUTM) stated in a 2024 letter to NIST concerning the proposed revised framework for exercising march-in rights, requiring reasonable pricing is directly in conflict with the intent and the government’s own interpretation of the Bayh-Dole Act.¹⁸ NIH’s proposed policy change would similarly undermine forty-three years of government interpretation and Bayh-Dole’s purpose of promoting public-private collaboration.

Access planning places the economic hurdle of promoting equity for underserved communities on institutions that are ill-equipped to assess and create functional plans for such. Universities are simply not equipped to promote equitable access and affordability in product development and deployment to make such demands of industry, which will walk away from licenses and investment. Although some major institutions have vast resources, universities with limited technology transfer programs may not, putting them at a disadvantage to better endowed universities.

¹⁴ Press Release, Nat’l Insts. of Health, NIH News 1 (Apr. 11, 1995), <https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf>.

¹⁵ See STEPHEN EZELL, INFO. TECH. & INNOVATION FOUND., THE BAYH-DOLE ACT’S VITAL IMPORTANCE TO THE U.S. LIFE-SCIENCES INNOVATION SYSTEM 24–25 (2019), <https://www2.itif.org/2019-bayh-dole-act.pdf>.

¹⁶ *Id.* at 25.

¹⁷ *Id.*

¹⁸ Ass’n for Univ. Tech. Managers, Comment Letter on Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (Jan. 23, 2024).

Financial resources for technology transfer groups are limited, so plans to include “partnering with public health, non-profit, or patient advocacy organizations” would be fiscally implausible. Technology transfer would also be confounded by addressing “accessibility as a design objective,” given that universities are not responsible for manufacturing and distribution. Licensing could become more convoluted and drive away interested licensees because of requested commitments to manufacturing, supplying, and donating for a product that may never be brought to market.

Diminished industry-university collaboration would likewise result in a loss of spillover to the communities at large. The ITIF report states:

In this sense, publicly funded basic research generates more than just papers, knowledge, and postgraduates; public-sector funds increase the productivity of the industry as a whole by facilitating an environment of readily valuable basic science. Public research within the life sciences industry leads to the development of “infrastructure knowledge,” or skills acquisition, techniques, and research tools that increase the expected rate of return for private-sector R&D projects.¹⁹

Knowledge and economic spillovers from such collaborations have been shown to crowd-in, not crowd-out, more innovation.²⁰ The loss of such spillovers would slow innovation, impact the local community around every university, and over the long-term, could promote stagflation.

Additionally, such licensing requirements would fail to impact many drugs. One paper suggests only 9% of government funded drugs are tied to at least one patent.²¹ Most drugs have more than one patent and a significant amount of know-how that is not encompassed by any patent.²² However, the threat of such licensing would likely drive industry away from collaborations given the risk-cost benefits of investment.

5. Establishing License Obligations Depending on the State of Technology Development

Generally, as a product moves closer to market, the odds of successful commercialization improve, and NIH’s proposed policy would take this into account. If the agency has advanced products to the point of a first pivotal clinical trial (e.g., Phase III or the equivalent) – licenses covering those products would include specific, tailored access-orientated provisions that should be clear and understandable. NIH is seeking further input on specific provisions that would meet these objectives.

Whether a new medicine will be commercialized remains unpredictable through all stages of drug development. For example, drug candidates and vaccines regularly fail Phase II clinical trials for

¹⁹ ROBERT D. ATKINSON, INFO. TECH. & INNOVATION FOUND., HEALTHY FUNDING: THE CRITICAL ROLE OF INVESTING IN NIH TO BOOST HEALTH AND LOWER COSTS 13 (2019), <https://www2.itif.org/2019-healthy-funding.pdf>.

²⁰ EVERETT EHRLICH, UNITED FOR MED. RSCH., AN ECONOMIC ENGINE: NIH RESEARCH, EMPLOYMENT, AND THE FUTURE OF THE MEDICAL INNOVATION SECTOR 14 (2011), https://unitedformedicalresearch.org/wp-content/uploads/2012/07/UMR_Economic-Engine.pdf; see also David C. Mowery & Arvids A. Ziedonis, *Numbers, Quality, and Entry: How Has the Bayh-Dole Act Affected US University Patenting and Licensing?*, in 1 INNOVATION POLICY AND THE ECONOMY 187, 205 (Adam B. Jaffe, Josh Lerner & Scott Stern eds., 2001).

²¹ Lisa Larrimore Ouellette & Bhaven N. Sampat, *The Feasibility of Using Bayh-Dole March-In Rights to Lower Drug Prices: An Update*, in NBER WORKING PAPER SERIES, at 14 (Nat’l Bureau of Econ. Rsch., Working Paper No. 32217, 2024).

²² Ass’n for Univ. Tech. Managers, *supra* note 18, at 8–10.

unforeseen reasons, including: (1) previously unknown toxic side effects (50%); (2) the trials show insufficient efficacy to treat the medical condition being tested (30%); or (3) commercial viability looks poor (15%). For cardiovascular drugs, “44% of late trial failures are due to poor efficacy and 24% are due to safety concerns.”²³ The probability of a vaccine progressing from Phase II to Phase III is about 38%.²⁴ By the time clinical studies reach Phase III, it would be easy to assume that failure rates are relatively low, given that all the data gathered in earlier trials and pre-clinical testing is used to validate a drug’s chances of meeting its efficacy goals. But according to one study, around 50% of Phase III trials fail.²⁵ Against this backdrop, requiring licensees to articulate “clear” and “specific” plans based on the stage of development would be near impossible and would likely deter interest from prospective licensees, who are often reluctant to pursue early-stage research due to the uncertainty and risk.

Additionally, that a licensee’s obligations may vary depending on technology development seems arbitrary and vague for the grantee as well as the licensee. According to some in the industry, even the threat of such subjective actions through march-in has already driven away venture capital.

The proposed requirement would cause NIH to be out of step with other government funding agencies responsible for medical research dollars including the Veterans Affairs, Department of Defense, and the Drug Enforcement Agency, which is under the Department of Justice. It would also place a burden on grantees not present under Bayh-Dole for government money on these other agencies. The resulting disparity in grant money requirements is contrary to the legislative intent of Bayh-Dole to standardize the administration of government funding and licensing. It is unclear whether the proposed change here would also govern patents falling under the Stevenson-Wydler Act of 1980.

6. Assessing Policy Impact

NIH is seeking input on how to assess compliance with the proposed policy and potential metrics for assessing its impact.

IPO recommends that NIH withdraw the proposed policy.

Sincerely,



Krish Gupta
President

²³ Gail A. Van Norman, *Phase II Trials in Drug Development and Adaptive Trial Design*, 4 JACC: BASIC TO TRANSLATIONAL SCI. 428, 429 (2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6609997/pdf/main.pdf>.

²⁴ Amanda MacPherson et al., *Probability of Success and Timelines for the Development of Vaccines for Emerging and Reemerged Viral Infectious Diseases*, 174 ANNALS OF INTERNAL MED. 326, 329 (2021), <https://www.acpjournals.org/doi/epdf/10.7326/M20-5350>.

²⁵ Chris Lo, *Counting the Cost of Failure in Drug Development*, PHARM. TECH. (June 19, 2017), <https://www.pharmaceutical-technology.com/features/featurecounting-the-cost-of-failure-in-drug-development-5813046/?cf-view>.