U.S. Chamber of Commerce

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July 22, 2024

The Honorable Monica M. Bertagnolli, M.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Re: Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning

Dear Director Bertagnoli:

The U.S. Chamber of Commerce ("Chamber") Global Innovation Policy Center ("GIPC") appreciates the opportunity to comment on the proposed plan to promote access to taxpayer-funded inventions created through the National Institutes of Health's ("NIH") intramural research and development program ("Proposal").

Throughout our history, U.S. intellectual property ("IP") protections have provided a pathway for innovation that brings new medicines, goods, and services to the market at competitive prices and with wide accessibility. As will be discussed, the proposal runs counter to this history and is not based upon an empirical, fact-based approach. Moreover, the NIH has failed to identify a problem that it wishes to solve.

The Chamber supports efforts to help ensure every American has equitable access to life-saving medicines. However, we are concerned this request for information ignores the overwhelming success of NIH and private sector firms working together to drive American life science innovation and could undermine medical research and development. Like many recent rulemakings from this Administration[1], we believe this request for information is premised on a false narrative that, translated into policy, would lead to fewer life-saving drugs and less access to treatments for Americans.

We believe this request for information is an attempt by the NIH to pursue an agenda—based on a misrepresentation of the respective roles of public and private funding of science, research, and development—that would upend the successful legal frameworks that facilitate public-private partnerships and product commercialization. The Chamber's views on this proposal can be summarized in three main points:

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[1] *See* comments from the US Chamber of Commerce and Global Innovation Policy Center to USPTO Director Kathi Vidal regarding Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting, Docket No. PTO-P-2024-0003, July 2, 2024; *see also* Comments from the Global Innovation Policy Center to USPTO Director Kathi Vidal regarding USPTO Initiatives To Ensure the Robustness and Reliability of Patent Rights (87 Fed. Reg. 66,282, November 3, 2022), February 1, 2023.

I. The request for information has failed to demonstrate a problem and the proposal is not supported by independent, objective, and verifiable facts;

II. There are several vague, ambiguous, and unclear terms in the proposal that make it difficult in practice for private sector partners to understand exactly what the agency intends to achieve

III. If implemented, this policy would set a precedent for the application of similar requirements to the agency's extramural research program, which would represent a return to failed policies of the past that hinder life science innovation and result in reduced patient access and choice.

The Chamber's concerns are outlined in more detail below.

I. The proposal is not supported by independent, objective facts demonstrating a systemic problem.

Federal rulemaking and policy should be evidence-based and grounded in the most reliable and up-to-date data available. The use of rigorous, empirical research stands as the most effective yardstick for determining the viability and necessity of any proposed policy. However, the current proposal fails to provide and factual evidence or data that identifies a problem or issue that the agency should seek to resolve.

While advocates for weakened patent rights for life-saving treatments routinely cite misleading studies that parrot false narratives regarding intellectual property (IP) as a barrier to patient access[2], these studies have been rightly criticized for their inaccurate use of underlying data, lack of transparency, and flawed methodology and have been found to be unreliable by not only outside experts but also the government's expert agency itself, the United States Patent and Trademark Office. [3]

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[2] *See Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices*, The Initiative for Medicines, Access & Knowledge; *See also* Evergreen Drug Patent Search Database, University of California College of Law.

[3] USPTO's Drug Patent and Exclusivity Study, available at https://www.uspto.gov/sites/default/files/documents/USPTO_Drug_Patent_and_Exclusivity_Study_Report.pdf; *see also* Brad Watts, *Debunking Myths: USPTO's Report on Life Science Patents,* July 1, 2024, available at Debunking Myths: USPTO's Report on Life Science Patents | U.S. Chamber of Commerce (uschamber.com); Adam Mossoff, *Unreliable Data Have Infected the Policy Debates Over Drug Patents*, The Hudson Institute, January 2022; Erika Lietzan & Kristina M.L. Acri née Lybecker, *Solutions Still Searching for a Problem: A Call for Relevant Data to Support "Evergreening" Allegations,* Fordham Intellectual Property, Media & Entertainment Law Journal, Vol. 33, Sep. 26, 2022; *Ltr. from Senator Thom Tillis, Ranking Member, Senate Judiciary Committee Subcommittee on Intellectual Property to Tahir Amin*, January 31, 2022; Professor Kristen Osenga, *Are "patent thickets" to blame for high drug prices,* Richmond-Times Dispatch, Nov. 30, 2022.

If anything, the Chamber's own empirical research shows that market restrictive policies ultimately lead to fewer treatments, less choice, and longer wait times for patients.[4] For example, if market restrictive policies continue to be implemented in the United States, American consumers can expect to see a decrease in clinical trial research in some therapeutic areas by as much as 75%.[5] Worse still, in other developed economies, it's been observed that market restrictions on life-science innovators can lead to fewer choices for patients even after new medicines are developed.[6] Additionally, these restrictions can cause delays, sometimes up to 500 days, before patients can access these new treatments.[7] This is the type of empirical evidence the agency should be considering, not the debunked claims of anti-intellectual property activists.[8]

II. The proposal is laden with terms that are imprecise, equivocal, and murky, and if implemented would create practical challenges for private sector partners to discern the agency's exact objectives or requirements.

The NIH's proposed policy change outlines broad goals such as affordability, availability, acceptability, and sustainability of products. However, nowhere in the document does the agency provide clarity as to the specific, actionable guidelines for licensees. Private sector actors cannot reasonably operate with such significant ambiguity. The ambiguous terms contained in this proposal would lead to varied interpretations and inconsistent implementation, making it challenging for the business community to align their strategies with NIH's expectations.

Moreover, the policy's requirements for access plans are also not clearly defined. While the NIH proposes that licensees submit plans outlining steps to promote patient access, the criteria for what constitutes an acceptable plan are left open-ended. This lack of clarity could result in confusion and uncertainty among licensees, who will likely struggle to understand what is required of them to comply. The flexible approach suggested by the NIH, though well-intentioned, may inadvertently create a landscape where licensees are unsure of the standards they need to meet.

Additionally, the tiered approach to licensing, which varies based on the stage of technology development, adds another layer of complexity. The policy suggests more specific provisions for late-stage inventions and flexible terms for early-stage inventions, but it does not provide clear guidelines on how these provisions will be tailored or enforced, which could lead to arbitrary decision-making[9] and difficulties for private sector actors in planning and

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[4] *See From Innovation Oasis to* Research *Desert: The Impact of Price Controls on Clinical Research and Development,* available at How Government Price Controls Impact Patients, Medical Innovation | U.S. Chamber of Commerce (uschamber.com).

[5] *Id.*

[6] *GIPC 2023 Patient Access Report*, available at Patient Access Report | U.S. Chamber of Commerce (uschamber.com).

[7] *Id.*

[8] *See* Watts, supra note 3.

[9] For example, what if the NIH doesn't like an applicant's access and pricing plan? Who makes that decision, the NIH project manager, a peer review panel, or the division director the? Additionally, does

executing their commercialization strategies. The lack of concrete metrics for assessing compliance and impact further exacerbates these challenges, making it difficult for licensees to navigate the policy effectively.

If the agency were to move forward with this proposal, which the Chamber strongly opposes, it should at least address the varying levels of ambiguity, vagueness, and arbitrary, open-ended terms which are subject to agency interpretation as a threshold matter. However, it is worth noting that even if the agency provides further clarity on the proposal, the proposed approach could lead to fewer products reaching commercialization and contributing to the public good.[10]

III. If implemented, this policy could pave the way for similar stipulations in the agency's extramural research program, potentially resurrecting outdated policies that stifle life science innovation and limit patient access and options.

The request for information and the proposed amendments appears to be confined to the agency's internal research program. However, the Chamber isconcerned that if these proposed changes are put into effect, they could potentially be used as a basis for expanding similar requirements to the agency's external research program. Specifically, the Chamber is concerned that this is the first step in a larger effort to reintroduce "reasonable price clauses" and impose additional price controls on lifesaving and life-altering medical innovations.

Reimposing "reasonable price clauses" is simply another tested and failed policy that will hinder life science innovation and result in patients having less access and less choice. When such price clauses were implemented in the past, they harmed life science innovation by causing valuable private sector industry partners to withdraw from public-private partnerships, eviscerating the vast resources previously committed to developing new, innovative products. The Clinton Administration recognized that "reasonable price clauses" had caused private sector actors to forfeit beneficial research partnerships with the federal government, thus depriving the public of any benefit. After the Clinton Administration repealed this clause in 1995, there was a four-fold increase in public-private collaborations and a "doubling of individual collaborating companies."[11]

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this proposal envision the NIH allow an applicant to revise their submission, or will the access and pricing plan originally submitted be the deciding factor in whether the license is awarded or not? Relatedly, what happens if the applicant is unable to achieve its proposed access/pricing plan? Will the NIH revoke the license? These are but of the few questions that the vague, open-ended nature of this draft proposal raise for private sector actors looking to partner with the NIH.

[10] This is because company access considerations vary by product, asset, therapeutic area, manufacturing needs, and disease burden, among other issues. Having a standardized checklist, which is a likely outcome of this proposal, may impact the initial willingness to invest in commercializing an NIH-licensed product.

[11] *The NIH Experience with the Reasonable Pricing Clause in CRADAs FY1990-1995*, National Institutes of Health, November 15, 2021, available at https://www.techtransfer.nih.gov/sites/default/files/CRADA%20Q%26A%20Nov%202021%20FINAL.pdf.

Given this history, to the NIH should refrain from reimposing these tested and failed policies in either the agency's intramural or extramural research programs. Doing so would only harm the very individuals such policies allegedly intend to help: American patients. Instead of focusing on these failed policies, the NIH should encourage, protect, and promote the valuable public-private partnerships that lead to more research, development, and innovation.

IV. Conclusion

The Chamber appreciates the opportunity to submit these comments to NIH. While the Chamber supports policies that lead to increased access to medicines for American patients, we cannot support efforts this that will ultimately undermine private sector actors and lead to fewer medicines, treatments, and cures. Respectfully, we request this proposal be withdrawn and the agency instead focus on increasing private sector collaboration.

Sincerely,

Tom Quaadman
Executive Vice President
Global Innovation Policy Center
U.S. Chamber of Commerce