July 22, 2024

National Institutes of Health (NIH)
Attn: Lawrence A. Tabak, D.D.S., Ph.D.
Principal Deputy Director, NIH

Submitted via Comment Form at: https://osp.od.nih.gov/comment-form-draft-nih-intramural-research-program-policy-promoting-equity-through-access-planning/

RE: AUTM's comments in response to NIH's Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning (Docket No. 2024-11188)

Dear Dr. Tabak:

Please accept AUTM's comments on the NIH's request for information on its proposal to develop and implement a new policy within its Intramural Research Program (IRP) to promote access to products stemming from taxpayer funded inventions and accompanying draft license agreement language that incorporates patient access in the commercialization process for NIH-owned inventions ("**Access Plan Policy**" or "**Proposal**").

AUTM is the non-profit leader in efforts to educate, promote, and inspire professionals to support the further development and deployment of innovations arising from academic research. Our community is comprised of more than 3,000 members who work in more than 800 universities, research centers, hospitals, businesses, and government organizations around the globe.

AUTM's membership has traditionally stemmed—and continues to draw primarily—from academic settings. AUTM members in such academic settings are focused on advancing early-stage inventions and other technologies to the marketplace, primarily through licensing and further development with partners (i.e., implementers). Between 2013 and 2022 (the most recent decade for which we have data), our skilled professionals filed over 160,000 patents for academic inventors and negotiated over 70,000 intellectual property license agreements on behalf of U.S. universities and academic research institutions. About 70% of these licenses are to start-ups and small companies. It is estimated that the American economy has received nearly $2 trillion in benefits from the technology transfer carried out by AUTM members over the past 30+ years.

AUTM members are at the very crossroads of innovation, taking early-stage inventions from the laboratory and helping to translate those inventions into new products and services through commercialization so that all Americans can benefit from them. Thus, we appreciate you considering AUTM's views on this important issue, as the development and commercialization of innovations arising out of NIH's investments in research is critical to retaining America's position as the world leader in innovations that improve human health.

Mandated Access Plans - *Without Incentives* - Will Harm, Not Improve, Patient Access

AUTM strongly believes in promoting public access to inventions and technologies created by innovators of all stripes (e.g., universities, the NIH IRP, small inventors, SMEs, etc.). Thus, we commend the NIH for its efforts to seek constructive ways to enhance the availability, accessibility, and affordability of end-products resulting from NIH-owned inventions, including drugs and other biomedical innovations and particularly for underserved patients in the U.S. and worldwide. Many AUTM members work at or are affiliated with hospitals and clinics that treat patients and, as such, are well-aware of the importance of lower drug prices. Not surprisingly, many AUTM members and their family members are patients themselves and thus have a personal stake in the matter.

While we appreciate the NIH's recognition of the challenges and the delicate balance involved in placing additional requirements on the development and commercialization of federally funded technologies given the existing difficulties in attracting licensees for such innovations, we have concerns with the Proposal as drafted. We fear it may do more harm than good.

1. **Mandating access plans, as proposed, will undermine NIH's goal of improving the availability, affordability, and access of NIH-owned technologies.**

Requiring licensees of NIH-owned technologies to submit and adhere to an access plan, as defined by the Proposal, will significantly undermine the investment NIH has made in these innovations. Such a mandate will create a substantial disincentive for private investment, making it considerably more challenging for these federally funded technologies to attract the necessary funding compared to their non-federally funded counterparts. This disparity will likely result in extended development timelines, if not the complete abandonment of some projects, effectively nullifying the initial federal investment. In short, this Proposal may return us to the days before Bayh-Dole where there were few, if any, end products resulting from government funded early-stage research to access.

At a minimum, this Proposal would run counter to the NIH's own objectives. Therapies from non-federally funded inventions would retain market dominance for longer periods, thereby diminishing competition and ultimately limiting the treatment options available to patients. Fewer treatment options also maintain prices higher than they otherwise would be. This market dislocation will exacerbate the issue of access and affordability for patients. Thus, the intended benefits of promoting affordable access may paradoxically result in fewer, costlier therapeutic options, to the detriment of public health outcomes.

The potential requirement for licensees to provide access plans would undoubtedly force them to consider these critical issues earlier in the development and commercialization process. However, if the Access Plan Policy imposes significant penalties or allows NIH to reclaim the technology from the licensee, it is likely that far fewer federally funded technologies will be further developed and commercialized, ultimately placing underserved patients in a worse position than without such policy. Therefore, we believe that the impact of this policy could be significantly more effective by redesigning it as an incentive program rather than a mandate.

2. **NIH will greatly improve its chances of success by pairing the access plan requirement with incentives for industry to invest in, develop, and commercialize NIH-owned innovations.**

NIH will significantly boost the availability, accessibility, and affordability of its technologies by incentivizing the private sector to invest in, develop, and commercialize these innovations. For instance, NIH could offer pharmaceutical industry licensees the option to "opt in" to providing an access plan in exchange for benefits such as additional market exclusivity or other regulatory advantages. This approach would not only encourage broader adoption of access plans, but also motivate licensees to implement downstream benefits for underserved patients and their communities.

Licensors of federally funded inventions already encounter significant challenges in finding well-funded, qualified licensees. Recently, concerns have been raised by AUTM members that the National Institute of Standards and Technology's (NIST) request for information regarding the government's march-in rights under the Bayh-Dole Act, based on reasonable pricing, is already adversely affecting their ability to attract private sector companies to collaborate and license their technologies. Adding yet another requirement further weakens patent rights and, without an accompanying incentive, will further diminish the likelihood that NIH-owned technologies will be further developed and commercialized, potentially leaving all patients, particularly those in underserved communities, without any therapeutic options.

Conversely, incorporating an incentive-based approach would encourage private-sector companies to invest in the further development and commercialization of technologies supported by public funding. In the therapeutics context, this would ensure that underserved patients benefit from taxpayer dollars, as these investments would lead to an increased availability of essential treatments in the marketplace. Having more treatments in the marketplace will provide all patients, particularly those in underserved communities if an incentive is provided in exchange for agreeing to an access plan, with more available, accessible, and affordable drugs.

There are numerous examples of successful federal incentive programs that could serve as models for this redesigned initiative, including those listed below.

- **Orphan Drug Act (ODA):** 21 U.S.C. § 360aa et seq., see also 21 CFR Part 316;
- **Fast Track Designation:** Food and Drug Administration Modernization Act of 1997, 21 U.S.C. § 356, see also 21 CFR Part 312, Subpart E;
- **Breakthrough Therapy Designation:** Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012, Section 902, see also 21 CFR Part 312;
- **Accelerated Approval:** 21 U.S.C. § 356(c), see also 21 CFR Part 314, Subpart H (for drugs) and 21 CFR Part 601, Subpart E (for biologics);
- **Priority Review:** Prescription Drug User Fee Act (PDUFA), 21 U.S.C. § 356, see also 21 CFR Part 314, Subpart D;
- **Rare Pediatric Disease Priority Review Voucher Program:** 21 U.S.C. § 360ff, see also FDA Reauthorization Act of 2017;
- **Humanitarian Device Exemption (HDE):** Safe Medical Devices Act of 1990, 21 U.S.C. § 360j(m), see also 21 CFR Part 814, Subpart H;
- **Qualified Infectious Disease Product (QIDP) Designation:** Generating Antibiotic Incentives Now (GAIN) Act, 21 U.S.C. § 355f, see also 21 CFR Part 312;
- **Regenerative Medicine Advanced Therapy (RMAT) Designation:** 21st Century Cures Act, 21 U.S.C. § 356(g), see also 21 CFR Part 312.

By leveraging similar incentive-based approaches, NIH can create a more impactful program that ensures the broad and equitable access to NIH innovations while fostering the continued development of groundbreaking therapies.

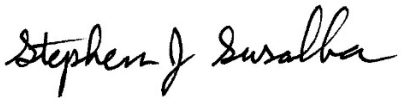
3. **NIH should apply the Access Plan policy in a targeted fashion, limiting it to the IRP and focusing on technologies and therapeutic categories where the cost-benefit analysis is most favorable.**

Should NIH proceed with adopting an Access Plan policy (with or without any potential incentive), AUTM highly recommends that it be limited to the IRP and applied on a per grant or per invention basis. This approach would acknowledge that an access plan may not be necessary for, nor conducive to, achieving NIH's objectives in every biomedical application. Broadly imposing an access plan requirement on all NIH-owned inventions is likely to unnecessarily hinder commercialization across NIH's entire IP portfolio without delivering a corresponding benefit to patients and taxpayers. In the same vein, given its relative size, the effect of expanding the Proposal to the NIH's extramural research program would exponentially increase its harmful effects on U.S. technology commercialization. It would likely return us to the pre-Bayh-Dole era, thereby forsaking all of the good it has brought to the United States' economy and the world.

Conclusion

In sum, while mandating access plans may be well-intentioned, the proposed approach would likely undermine NIH's goals of improving availability, affordability, and access to NIH-owned technologies. Without accompanying incentives, these requirements may stifle the development and commercialization of vital therapeutics. To advance its mission, the NIH should pair the access plan requirement with incentives that encourage industry investment and development. Additionally, the NIH should apply the requirement to the IRP alone and only to those technologies or therapeutic categories where the harmful effects on technology commercialization will be minimal. This approach will better align with the NIH's objectives, fostering innovation and ensuring the benefits of federally funded technologies reach those most in need.

Sincerely,



Stephen J. Susalka, Ph.D.
Chief Executive Officer