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August 18, 2023

Lawrence A. Tabak, D.D.S. Ph. D.
Acting Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Tabak,

Thank you for the opportunity to submit a written comment on the Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer.

Universities Allied for Essential Medicines (UAEM) is a global, student-driven organization with offices in the United States and members at more than 50 universities around the world. We represent researchers, future physicians, future attorneys, and more who aim to ensure that everyone has access to the medicines they need to survive.

The National Institutes of Health (NIH) are the world's largest government investors in biomedical research and development. With more than \$42 B in funds, the decisions made by the NIH about how to ensure access and affordability for the medicines discovered and developed with these funds set a precedent for other investors from private philanthropy to companies and other nations. No matter how groundbreaking an innovation may be, its potential to save lives can only be realized if people from different socio-economic backgrounds, regions, and communities have access to it. Prioritizing accessibility and affordability is integral to NIH's mission of fostering scientific advances that enhance public health and wellbeing.

We submit the following comment to describe three areas for the NIH to consider in technology transfer: affordable access provisions, reasonable pricing clauses, and ensuring transparency and accountability for the NIH's licensing terms.

Ensuring Affordability

In doling out billions of dollars for the discovery and development of novel health technologies and licensing promising medical products, the National Institutes of Health (NIH) has a responsibility to ensure affordability and access to the American public that ultimately footed the bill. Here we submit two approaches to affordability that should be explored and pursued by the NIH: Affordable Access Provisions, and Reasonable Pricing Clauses.

Affordable Access Provisions:

A vast majority of NIH funding every year goes to university research centers and laboratories with academic affiliations. That means that academic institutions are responsible for the patenting and licensing of a majority of NIH-funded research products. Since the passage of the Bayh-Dole Act in 1980, research institutions take on the responsibility of patenting and licensing NIH-funded research products discovered on their campuses. With the end goal of commercialization, technology transfer officers have felt pressure to deliver exclusive licenses, with terms favorable to industry partners. Yet, when recommendations were made during COVID-19 to make pandemic-related technology licenses less exclusive, more than 96 universities opted to follow new industry-setting guidelines because it was a level playing field, with risks reduced.

To that end, UAEM recommends that the NIH act to level the playing field for university technology managers for access and affordability through contracting requirements such as affordable access provisions. The Affordable Access Plan provision was co-developed by the University of California Los Angeles Technology Development Group,¹ UAEM, and the Medicines Patent Pool. This provision is to our knowledge the first of its kind in exclusive licenses from U.S. universities, and places a forward-thinking but non-prescriptive obligation on the licensee to create and report on an affordable access plan to the university with strategies and timelines to ensure affordable access to licensed products in LMICs. The affordable access plan obligation is only triggered at a point where commercialization is imminent, allowing any licensee sufficient time to generate the resources needed to advance through the many stages of research and development. This provision has been utilized in licensing agreements by UCLA without issue since 2020.

Further, the University of California Berkeley Intellectual Property & Innovative Research Alliance has released their new exclusive license template,² which includes an affordable access plan provision of their own. This provision is substantively similar to the UCLA provision, *but with the important addition of extending the scope of the access plan beyond LMICs to also include underserved communities in the United States, giving the university some level of oversight for the high and rising costs of health products for communities around the country.*

These plans are also being considered in licensing agreements at UC Riverside, Yale University, and Columbia University, to varying degrees. However, these plans are not yet ubiquitous, and UAEM fears that university technology transfer offices may shy away from implementation of these plans or even including them out of fear that it will stymie interest from potential

¹ UCLA Technology Development Group, UCLA Considers Underserved Populations When Licensing Medical Research Discoveries, accessed August 18, 2023, at: <https://tdg.ucla.edu/ucla-considers-underserved-populations-when-licensing-medical-research-discoveries>.

² UC Berkeley Exclusive License Template, accessed August 18, 2023, at: <https://ipira.berkeley.edu/sites/default/files/shared/docs/EXCL%20EQUITY%20therapeutics%20diagnostics%2007April2023.pdf>

licensees, despite the fact that neither UCLA or Berkeley have reported any issues. Given the lack of utilization on behalf of technology transfer officers of past access provisions, frameworks, and policies it is clear that the industry of technology transfer is risk averse when it comes to access provisions in academic licensing agreements.³

If the NIH were to include language akin to an affordable access plan provision when granting funds, this could become part of the standard of practice and thus easier for academic institutions to implement without fear of retribution.

Reasonable Pricing Clauses

Between 1989-1995, the use of responsible pricing clauses in cooperative R&D agreements (CRADAs) was used by the federal government in contracts with the pharmaceutical sector⁴. This policy was incited by patient and family turmoil during 1987, when the pharmaceutical company Burroughs Wellcome launched a new AIDS drug developed with the help of NIH scientists at a cost of \$10,000 per year⁵. This price point caused protests from AIDS activists which led to Congressional hearings conveyed by Henry Waxman (D-CA) resulting in the NIH inserting "fair" pricing clauses into the standard CRADA. From its inception, reasonable pricing clauses became a point of contention between the NIH and pharmaceutical manufacturers⁶. The event that led to the removal of the "fair" pricing clause in CRADAs was the legal dispute between Myriad Genetics and the National Institute for Health Sciences (NIEHS). In 1992, a collaboration began between researchers from the NIEHS and Myriad Genetics to locate the *BRCA1* breast cancer gene which was achieved after two years. The issue of the use of responsible pricing arose after hesitancy from corporate investors, Myriad refused to enter a CRADA with the NIEHS⁷. This led to the NIEHS researchers receiving acknowledgement as inventors but not listed as patent recipients. This led to the presumption that NIH collaborations would not be sought in the future by the private pharmaceutical sector if responsible pricing provisions were included in future CRADAs.

³ Contreras, J. - Univ est' - University T iversity Technology T echnology Transfer and the er and the Nine Points Document – An Empirical Assessment. *University of Utah College of Law Research Paper No. 476 12(2) U.C. Irvine L. Rev. 435 (2023)*

⁴ Jorge L. Contreras, "What Ever Happened to NIH's 'Fair Pricing' Clause?," Petrie-Flom Center Blog, Harvard Law School (August 4, 2020)
<https://blog.petrieflom.law.harvard.edu/2020/08/04/nih-fair-pricing-drugs-covid19/>.

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⁶ Jorge L. Contreras, "What Ever Happened to NIH's 'Fair Pricing' Clause?," Petrie-Flom Center Blog, Harvard Law School (August 4, 2020)
<https://blog.petrieflom.law.harvard.edu/2020/08/04/nih-fair-pricing-drugs-covid19/>.

⁷ Jorge L. Contreras, "What Ever Happened to NIH's 'Fair Pricing' Clause?," Petrie-Flom Center Blog, Harvard Law School (August 4, 2020)
<https://blog.petrieflom.law.harvard.edu/2020/08/04/nih-fair-pricing-drugs-covid19/>.



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Despite the lack of reasonable pricing terms for NIH-funded projects in recent years, universities across the U.S. have been utilizing reasonable pricing terms in various licensing arrangements. In 2023, UAEM has worked to expand on existing efforts and establish affordable access plans, to help create pathways to enforcing affordability at the university licensing level. The University of California Los Angeles created an affordable access plan provision in 2019, and Berkeley expanded upon this policy earlier this year. These provisions create an affordable access plan for medicines in lower- and middle-income countries, and Berkeley's policy requires these plans be developed for vulnerable communities in the U.S. as well.⁸ Additionally, the Innovative Genomics Institute at Berkeley just recommended reasonable pricing for the future of genetic therapies, the cutting edge of biomedical innovation, even going as far as to recommend a cost-plus model for future technologies.⁹

Additionally, during the COVID-19 public health emergency, where significant federal funds were used to bring COVID-19 treatments and vaccines to market, the federal government negotiated terms that are akin to reasonable pricing clauses. In advance purchase agreements between Novovax and the Department of Defense, the company agreed to give the U.S. the "lowest, best price" for five years for any doses administered in the U.S. Pfizer agreed to a most-favored nations clause that would allow the U.S. government to get a lower price if an economically equivalent nation (one of six high-income countries) were able to negotiate a lower price. These terms were not only accepted by these companies, but guaranteed the federal government and U.S. consumers would have timely and affordable access to COVID-19 technologies while these cutting edge technologies were coming to market.

With all of this in mind, it is imperative that the NIH consider reasonable pricing terms and strong licensing mechanisms to ensure that U.S. taxpayers no longer pay the highest prices in the world for prescription drugs while also footing the bill for discovery. Even without new legislation, the NIH has the ability to utilize March-In Rights as spelled out in Bayh-Dole, or enact a Royalty-free right to practice in order to increase competition and lower the cost of medicines. This is particularly important while considering the impact of NIH-funded medications that have been over-patented with increasing prices, despite a lack of true innovation.

Ensuring Transparency

Greater transparency about the NIH's operations and licensing transactions is crucial to patients, consumer advocates, and academic specialists in technology transfer. The University of California Berkeley publishes draft licensing agreements and terms on its website to show

⁸ Policy available at Berkeley IPIRA, here:

<https://ipira.berkeley.edu/sites/default/files/shared/docs/EXCL%20EQUITY%20therapeutics%20diagnostics%2007April2023.pdf>. Discussion of policy at UAEM Webinar "A New Standard in University Licensing," Available here: <https://www.uaem.org/tools/recording-a-new-standard-in-university-licensing>

⁹ Making Genetic Therapies Affordable and Accessible, Report, available at: <https://innovativegenomics.org/atf-report/>.

future licensees and other institutions what its best practices are. This practice should be standard for the NIH's licenses as well.

We encourage the NIH to solicit feedback from the public about its policies regarding the accessibility of different types of information about patenting, licensing, and accessibility of products developed with NIH funding.

Greater information about NIH licenses must be made accessible to the public. If confidentiality concerns are justified, they may be appropriate to address through narrow redactions. But at some point, confidentiality concerns are no longer justifiable, and the public should receive full access, as it does to documents pertaining to national security.

While licenses are in effect, the public is entitled to know basic licensing information—such as royalty rates. Making this information available will allow the public to assess the impact of NIH investments and make more informed policy decisions. It will also facilitate accountability to the public and trust in the agency's operations.

Transparency will also increase the efficiency of licensing markets. Royalty rates are routinely disclosed in the course of patent litigation because they are evidence used to prove damages. Making this information available will reduce the cost of obtaining such information through litigation and make it more difficult for companies to use litigation costs to inflate patent licensing fees. This will make licensing markets more efficient, open to competition, and fair to small and new entrants which are most sensitive to litigation costs. Additionally, in the event that the U.S. government does decide to practice its right to government patent use, as described in 28 U.S.C. 1498, a public record of NIH licensing royalty rates would potentially prove useful in setting reasonable royalties when that use is challenged in court.¹⁰

In addition, we recommend that the NIH ensure transparency on a number of factors outside of licensing and royalty agreements, and have included the following as areas to consider broader transparency:

Trial costs

Any NIH-supported clinical trial should be required to report its total costs and the share funded by the federal government, using a standardized accounting format.

¹⁰ Brennan, Hannah, Kapczynski, Amy, Monahan, Christine H., Rizvi, Zain. A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health. *Yale Journal of Law & Technology*. 2017. Available at: <https://openyls.law.yale.edu/handle/20.500.13051/7810>



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Drug pricing and market information

We urge the NIH to implement the provisions in [WHA72.8](#), which the World Health Organization (WHO) has developed specifically to improve the transparency of markets for medicines, vaccines, and other health products.

Enforcement of existing disclosure requirements

The NIH can and must do more to enforce the obligation to disclose federal funding in patent applications. There must be consequences for those who violate their disclosure obligation.

Conclusion

UAEM applauds the NIH's efforts to open up public comment on technology transfer and innovation. The agencies efforts have clearly demonstrated an effective system to drive biomedical products and health technology to commercialization. It is our view that the NIH's impact on both taxpayers and the public's health more broadly have been limited by licensing terms and transparency that favors commercial interest over the public. The proposals we have set forward in this comment, especially adoption of an affordable access plan provision, are friendly to both the public's interests in new medical innovations, and to the commercialization of those products.

Sincerely,

A handwritten signature in black ink, appearing to read 'Justin Mendoza', is written over a white background.

Justin Mendoza, MPH

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