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July 27, 2023

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Bethesda, MD

Re: Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer

Submitted electronically to SciencePolicy@od.nih.gov

The Association of American Medical Colleges (AAMC) appreciates the opportunity to provide feedback to the National Institutes of Health (NIH) for the workshop, *Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer*.

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 157 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened the AAMC's U.S. membership and expanded its reach to international academic health centers.

The AAMC's member institutions perform more than half of the extramural research sponsored by the NIH, and the Association is mindful that the American people invest substantial resources in medical research, especially relative to other areas of science. While profound social and economic benefits accrue from scientific research generally, our advocacy in support of investment in the NIH emphasizes the potential for research discoveries to translate into new treatments and cures for disease. The topic of this workshop is therefore extremely important to fulfilling this promise, and to strengthening our shared, continuing commitment to the social contract supporting medical research. Our comments here focus on several points that we believe should frame productive discussions on catalyzing technology transfer:

I. While the workshop's deliberations necessarily focus on patenting and licensing practices, the most beneficial "product" of NIH research is the scientific knowledge generated and widely disseminated.

Once, a case needed to be made before the public for how laboratory basic research was relevant to advances in health and medicine, but now, after generations, there is a demonstrable track record – from virology to cancer to CRISPR – that discovery and shared understanding of fundamental biology has made nearly miraculous impacts on human health. Along with discovering new molecular entities and pathways that may become targets for pharmaceutical development, NIH-funded scientists have developed new research platforms, new techniques and methods, data resources, and insights into the mechanisms of health and disease. Behavioral and social science research have similar impacts on improvements to human health, although such advances may not typically be reflected in patentable inventions.

Another vitally important form of knowledge transfer are NIH-supported trainees and scientific personnel. Students and post-doctoral scientists at medical schools and universities, often with NIH funding, participate in the leading edge of scientific exploration, and carry this experience across to other economic sectors. Scientists and leaders in US industry and elsewhere are often the products of NIH support and provide the nation with an ample base of human capital to support medical innovation.

II. The current NIH innovation system has seen spectacular successes.

In a recent study, Stevens and colleagues identified 364 FDA-approved drugs and vaccines over more than 40 years to which specific intellectual property (IP) was held by public sector research institutions, including the NIH and US medical schools, universities, hospitals, and research institutions largely funded by NIH.[1] The tally does not include research platforms or similar resources developed by these institutions that enable drug discovery but were not identified with a particular approved drug. In comparing the relative success of the nation's drug development ecosystem, Stevens et al. noted:

> In the context of the global public sector landscape, the US dominates drug discovery, accounting for two-thirds of these drugs and many of the important, innovative vaccines introduced over the past 30 years. Contributions by Canada, UK, Germany, Belgium, Japan, and others each amount to 5.4% or less of the total.[2]

The persistence of disease and burden in so many areas, including orphan diseases, and in areas like addiction, depression, obesity, etc., challenge us to improve and catalyze the innovation process. But reforms should not undermine what has been shown to work well. The success during the pandemic of a public-private partnership building on decades of mRNA research to develop and deploy COVID-19 vaccines in record time, and avert potentially millions of deaths, should be an inspiration for future action.

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[1] Stevens AJ, Benson DE, Dodson SE, Jensen JJ, Rohrbaugh ML. Role of global public sector research in discovering new drugs and vaccines. *Journal of Technology Transfer*, 2023, Apr 27, published ahead of print.
[2] Ibid, p. 1.

III. Intellectual property protections serve many uses, but an essential feature is that IP protections like patents make it possible for private capital to be used to develop a new pharmaceutical or device.

A promising new molecular entity or pathway discovered by academic researchers usually requires much more effort to be developed into an approved drug. Further R&D is required to assess the chemical properties of a drug candidate, to confirm its effectiveness, identify potential interactions and adverse events, and conduct the extensive preclinical and clinical testing necessary for FDA approval. It remains a notoriously expensive, time-consuming process that only a small percentage of promising drug candidates survive, and is therefore a very high-risk investment. Patent protection and exclusivity rights are necessary to attract the private investment that supports most drug development. Even philanthropic, non-profit organizations have used patents in this way; to simply put an entity in the public domain would likely ensure that it remains undeveloped, just as no contractor would build on a vacant city lot without clear title. That said, not every valuable entity or process needs to be patented; the AAMC has supported NIH positions on research tools, biological samples, genomic and other data sharing encouraging use of these resources with or without proprietary encumbrances as possible. The AAMC was also one of the original organizations drafting the Nine Points document on socially responsible licensing of university technology.[3]

The National Institute of Standards and Technology (NIST) within the Department of Commerce recently studied the entire federal system for promoting innovation, including looking at the implementation regulations for the Bayh-Dole and Stevenson-Wydler Acts, and other controlling authorities. The AAMC joined other organizations in this review, and we highly recommend the report for the NIH workshop deliberations.[4] Overall, we agree with the review that the Bayh-Dole Act has been highly effective in promoting tech transfer from sponsored, extramural research.

On the question of exercising Bayh-Dole's march-in authorities over pharmaceutical pricing, the AAMC has consistently supported the NIH and the Federal Government's interpretation of its authority, which we noted most recently in a joint letter with other higher education associations to Secretary Becerra last year.[5] The AAMC has three central concerns over the proposed use of march-in to influence drug pricing. First, the outcome from granting a march-in petition would be uncertain; any exercise over pricing would likely be challenged in the courts, given the legislative record and express statements by Senators Bayh and Dole that the Act's march-in provisions were not intended for inventions widely available on market. Moreover, march-in would not be a comprehensive solution to the problems of excessive drug prices, as it would apply only to the subset of drugs covered by university patents arising from NIH sponsored research, and to which no other significant IP applies. Price issues exist for many drugs that are not related to university patents, including many essential drugs that have been on the market for decades. Our third and most central concern is that the precedent of exercising march-in over market pricing would create disincentives for industry and private investors to license university inventions. In calculating potential risks and returns, private investors might favor non-university, non-NIH funded inventions, even if the target results are less

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[3] https://autm.net/about-tech-transfer/principles-and-guidelines/nine-points-to-consider-when-licensing-university

[4] NIST. Return on Investment Initiative for Unleashing American Innovation. April 2019. https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1234.pdf

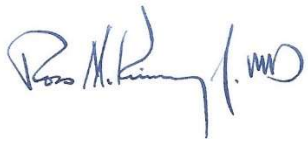
[5] https://www.aamc.org/media/61966/download?attachment

innovative. Rather than incentivizing tech transfer, the action would chill future licensing or industry collaboration, and undermine Bayh-Dole's intent.

In short, we are skeptical that pharmaceutical prices can or should be controlled from the laboratory and would look for alternative solutions to this problem. For example, the Inflation Reduction Act provides the Secretary of Health and Human Services the authority to negotiate drug prices under relevant sections of the Medicare program, and those negotiations are now in process. The USPTO and FDA are also looking at ways the patent system and approval process may be abused to indefinitely extend patent protections and impede the entry of generics to the market.

We are grateful for the opportunity to provide comments, and for continuing engagement with the research community. Please feel free to contact me or my colleagues Stephen Heinig, Director of Science Policy (sheinig@aamc.org) or Heather Pierce, JD, MPH, Senior Director of Science Policy and Regulatory Counsel (hpierce@aamc.org), with questions about these comments.

Sincerely,



Ross McKinney, Jr., MD
Chief Scientific Officer

cc: David J. Skorton, MD, AAMC President and Chief Executive Officer