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Re: Comments on NIH's Workshop: Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer, July 31, 2023

The Association of American Universities (AAU) and COGR appreciate the opportunity to share input on the ongoing discussion regarding NIH's levers to catalyze technology transfer. AAU is an organization of 71 leading U.S. and Canadian research universities that transform lives through education, research, and innovation. COGR is an association of over 200 public and private U.S. research universities and affiliated academic medical centers and research institutes. COGR focuses on the impact of federal regulations, policies, and practices on the performance of research conducted at our member institutions, and we advocate for sound, efficient, and effective regulation that safeguards research and minimizes administrative and cost burdens.

Our combined member universities comprise the majority of competitively awarded federal funding for research that improves public health, seeks to address national challenges, and contributes significantly to our economic strength, while educating and training tomorrow's visionary leaders and innovators. Additionally, many of our member institutions operate hospitals and affiliated health systems throughout the U.S. and are themselves large-scale purchasers of drugs and therapies developed for patients by the commercial market. AAU and COGR member institutions represent multiple stakeholder positions in the NIH research and commercialization lifecycle.

As in all ecosystems, changes to one part of the ecosystem affect other parts as well. Disruptions to the current innovation ecosystem that are hastily designed and implemented will have ripple effects which will discourage research partnerships between federally funded researchers, industry, and other important players in the technology transfer pipeline. Such changes in policy and practice must be done in a deliberate manner to ensure the effectiveness and longevity of the technology transfer and U.S. innovation system. To do otherwise would jeopardize U.S. leadership in biomedical research and innovation, to the detriment of the American people and the world.

In addition to providing these written comments today, our associations echo the sentiments submitted to this solicitation by AUTM, the non-profit leader in efforts to educate, promote and inspire

professionals to support the development of academic research that changes the world and drives innovation forward.

### **The American Innovation Ecosystem & the Role of the NIH**

The United States leads the world in novel biomedical innovation, thanks in large part to strong and sustained government support for research, strong research universities, talented researchers, efficient drug approval processes, and a pricing system that enables companies to earn sufficient revenues to reinvest in future generations of innovation.<sup>1</sup> Indeed, the Bayh-Dole Act, combined with sustained government support for research at NIH, has helped to ensure U.S. competitiveness in biomedical research and technology. It remains critical that this existing policy apparatus and federal support be maintained and strengthened.

The pathway from discovery to commercialization is a years, often decades-long process. The average length of development is 10-15 years from identification of a biomarker to development of a medication through regulatory approval process to market distribution. The expected cost to develop a new drug—including capital costs and expenditures on drugs that fail to reach the market—has been estimated to range from slightly less than \$1 billion to more than \$3 billion, with many different factors that determine the necessary levels of investment. Detailed case studies reveal that public support has played at least some role in virtually all of the 26 most clinically and commercially significant drugs and drug classes approved over the past several decades.<sup>2,3</sup>

NIH's investments in university-based basic research are a part of the innovation ecosystem, setting the stage for the industry-led applied research and development activity that leads to the commercialization of new medicines and treatments. Broad scientific endeavors such as the Framingham study, the Human Genome Project, and research on vaccine development have helped catalyze the identification of novel approaches to improve diagnostics and treatments.<sup>4</sup> The Framingham study led to the identification of cholesterol as a factor for cardiac disease and the development of medications to mitigate risks for strokes and heart attacks.<sup>5</sup> The Human Genome Project, among many other things, facilitated improvements in cancer diagnoses through the identification of genetic variants<sup>6</sup>. Decades-long research

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<sup>1</sup> Ezell, S, The Bayh Dole Act's Vital Importance to U.S. Life-Sciences Innovation System, Information Technology & Innovation Foundation, 2019.

<sup>2</sup> Wouters, OJ, McKee, M, Luyten, J: Estimated Research and Development Investment Needed to Bring New Medicines to Market, 2009-2018. *JAMA*. 2020; 323 (9): 844-853.

<sup>3</sup> NASEM 2020 Workshop "[The Role of NIH in Drug Development Innovation and its Impact on Patient Access](https://doi.org/10.17226/25591)" National Academies of Sciences, Engineering, and Medicine. 2020. The Role of NIH in Drug Development Innovation and Its Impact on Patient Access: Proceedings of a Workshop. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25591>.

<sup>4</sup> Collins, Francis S., Opportunities for Research and NIH. *Science* 327,36-37(2010). DOI:[10.1126/science.1185055](https://doi.org/10.1126/science.1185055)

<sup>5</sup> Franklin, S. S., and Wong, N. D. (2013). Hypertension and cardiovascular disease: contributions of the Framingham heart study. *Global heart*, 8(1), 49–57. <https://doi.org/10.1016/j.gheart.2012.12.004>

<sup>6</sup> Hood, L., Rowen, L. The Human Genome Project: big science transforms biology and medicine. *Genome Med* 5, 79 (2013). <https://doi.org/10.1186/gm483>

on vaccine efficacy helped catalyze mRNA approaches to vaccine development<sup>7</sup>, which allowed Operation Warp Speed to develop, test, and bring to market revolutionary vaccines in response to COVID-19.

NIH's support for basic research related to the biological target, rather than the development of a specific drug, is consistent with its national service and public health mission to promote and facilitate pre-competitive research aimed at advancing the health and well-being of the American people. NIH has historically remained removed from the drug development and marketing process, which should be rightfully left up to private industry. This is why, of the 356 drugs approved and brought to market from 2010 to 2019, all were brought to market in the United States by a biopharmaceutical company, rather than by an academic, governmental, or non-governmental organization.<sup>8</sup>

### **Role of University-Industry Collaboration**

Universities are hubs for research, discovery, and innovation. Very often, academic researchers identify a new idea or concept that has potential for development into a commercial product. University-industry collaborations and partnerships are critical for realizing the public benefits of federally funded research. Initial discovery is critical, but potential impact for the public requires proof that concepts work in humans and years of further investment and development by industry. The expertise, infrastructure, and capital required to bring a medication or technology to commercial market is most often a function of industry investment, which neither the federal government nor research universities are able to bear.

Technology transfer of NIH-funded research between universities and industry allows research to catalyze into the development of potential biomedical innovations. Technology transfer can be operationalized through a variety of mechanisms, such as licensing agreements, assignment of intellectual property rights, material transfer agreements, and collaborative research agreements. The most utilized technology transfer vehicle is licensing.

Examples of technology transfer success stories from universities to industry partnerships leading to biomedical innovation include:

- Emory's development of an HIV medication that disrupts viral DNA from replicating. Emory licensed its discovery in 1996 to a biotech company for further development. Emtriva™ was eventually brought to market in 2003 by Gilead pharmaceuticals.<sup>9</sup>

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<sup>7</sup> Clin, J., Invest. 2021;[131\(19\):e153721](https://doi.org/10.1172/JCI153721). <https://doi.org/10.1172/JCI153721>.

<sup>8</sup> Cleary, Ekaterina, Jackson, Matthew J. and Ledley, Fred, Government as the First Investor in Biopharmaceutical Innovation: Evidence From New Drug Approvals 2010–2019 (August 5, 2020). Institute for New Economic Thinking Working Paper Series No. 133 <https://doi.org/10.36687/inetwp133>

<sup>9</sup> Schinazi, R., & Liotta, D. (n.d.). *HIV Antiretrovirals*. Emory University Office of Technology Transfer. <http://www.ott.emory.edu/about/success/hiv.html>

- University of Wisconsin Madison researchers developed a synthetic form of Vitamin D to better control calcium imbalance in patients on kidney dialysis. Paricalcitol (sold commercially as Zemplar™) was brought to market by AbbVie Inc.<sup>10</sup>
- University of California, Berkeley researchers searched for ways to suppress the proliferation of melanoma cells by activating the patient’s own immune response.<sup>11</sup> Researchers identified a checkpoint molecule (CTLA-4) that suppressed immune response to cancer cells. When CTLA-4 was targeted by monoclonal antibodies, immune cells could better attack cancer cells. Over a decade later following investments by four companies, Yervoy™ was approved by the FDA.<sup>12</sup>

### Placing Arbitrary Pricing Constraints on Potential Commercial Products Will Disrupt Innovation

There is a long history of discussions to include “reasonable pricing” provisions by the NIH Patent Policy Board. In 1989, provisions were adopted to address the pricing of products licensed from federal health research agencies. Reasonable pricing clauses, as has been demonstrated previously by [NIH policies from 1989-1996](#), create an untenable risk calculation to investors and collaborators which discourage them from tapping into federally supported research discoveries made at universities. Given the cost of developing and bringing a medication to market, companies have been and will continue to be reluctant to enter a “reasonable pricing” agreement with the NIH years before a medication has proven that it can be successfully commercialized.

As NIH is aware from other efforts to impose price controls on medications, there is a tradeoff between prices and innovation. The [Congressional Budget Office](#) estimated that a legislative proposal introduced by Rep. Nancy Pelosi (D-CA) The Lower Drug Costs Now Act of 2019 (H.R. 3), would reduce the number of drugs available for the market over the next 10 years.<sup>13</sup>

Current calls for Congressional scrutiny of potential levers to reduce the cost of medications, specifically challenges to provisions of the Bayh-Dole Act, will detrimentally disincentivize investment and collaboration as it relates to federally funded research and university-industry partnerships. Without economic incentives to further research, develop, and clinically test university discoveries through private investment, those discoveries will remain in the laboratory and not proceed to the commercial

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<sup>10</sup> University of Wisconsin Madison. (2008). Synthetic vitamin D protects bone strength in kidney failure patients. Better World Project. <https://autm.net/about-tech-transfer/better-world-project/bwp-stories/paricalcitol-zemplar%E2%84%A2>

<sup>11</sup> Fernandes, M. P., Oliveira, C., Sousa, H., & Oliveira, J. (2023). New Approaches in Early-Stage NSCL Management: Potential Use of PARP Inhibitors and Immunotherapy Combination. *International journal of molecular sciences*, 24(4), 4044. <https://doi.org/10.3390/ijms24044044>

<sup>12</sup> Hoos, A., Ibrahim, R., Korman, A., Abdallah, K., Berman, D., Shahabi, V., Chin, K., Canetta, R., & Humphrey, R. (2010). Development of ipilimumab: contribution to a new paradigm for cancer immunotherapy. *Seminars in oncology*, 37(5), 533–546. <https://doi.org/10.1053/j.seminoncol.2010.09.015>

<sup>13</sup> Swagel, L. P. (2019, October 11). Effects of Drug Price Negotiation Stemming From Title 1 of H.R. 3, the Lower Drug Costs Now Act of 2019, on Spending and Revenues Related to Part D of Medicare. Washington, DC; Congressional Budget Office.

market. This will result in the creation and distribution of far fewer life-saving drugs and therapies for both the American people and the world.

In addition, these impacts will be concretely felt at the local and regional levels throughout the country, as university-industry collaborations would decline significantly. Because such collaborations attract capital and translate to a wide array of regional economic benefits at the campus level and beyond, the brunt of this impact will be felt not just in key metropolitan areas but in other more rural areas as well and will come at a time when catalysts for regional economic development in the innovation economy is a national economic priority and national security concern (i.e., regional innovation initiatives in the Inflation Reduction Act (IRA) and the CHIPS & Science Act via the National Science Foundation, and the Economic Development Administration (EDA) via the U.S. Department of Commerce).

### **NIH Levers to Catalyze Technology Transfer**

NIH currently has additional levers at hand that may reduce costs in drug development and increase rates of commercialization success. Continued and increased support of these existing levers offers the optimal public policy solution for catalyzing technology transfer. These existing levers include:

- The NIH's National Center for Advancing Translational Sciences (NCATS) seeks to improve the "bench to bedside" translational process and utilizes a variety of tools such as streamlining enrollment in NIH-Funded clinical trials through the SMART IRB program and improved data collection.
- The development of additional artificial intelligence tools, approved by NIH, to help scientists analyze large data sets would improve identification of biomarkers that can be utilized by industry.
- Proposals to expand NCATS both in terms of personnel and role inside NIH would be effective in bringing greater knowledge and efficiency to biomedical translation.
- NIH's Centers for Accelerated Innovations (CAI) and its recently established REACH: Research Evaluation and Commercialization Hubs, which combine public-private expertise to evaluate and develop discoveries for commercialization has shown early promise in efforts to reduce the time period from discovery to therapeutic product.
- NIH's Small Business Innovation Research Program and Small Business Technology Transfer Program (SBIR/STTR) has expanded the provision of vital early-stage capital for technology transfer and commercialization efforts specifically in biomedical innovation. Additionally, recent enhancements to SBIR/STTR's guidance on partnership identification and business development have helped researchers in need of advice on how to better navigate the innovation pipeline.

Other federal agencies such as the Food and Drug Administration and the U.S. Patent and Trademark Office can work more closely with NIH stakeholders to enhance regulatory engagement during the drug development process. This could streamline and make the process of bringing a drug to market more efficient.

## **Conclusion**

We strongly believe that building upon existing NIH programs, as well as cross-collaboration with other federal agencies to improve and streamline the research, regulatory, and approval processes, will bring the best outcomes in catalyzing technology transfer efforts by the NIH overall.

Thank you for the opportunity to engage with NIH regarding its role in the development pipeline. AAU and COGR look forward to future conversations on discovery, innovation and enhancing the health of the nation.