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Lyric Jorgenson, PhD  
Acting NIH Associate Director for Science Policy  
National Institutes of Health  
Office of Science Policy  
6705 Rockledge Drive  
Suite630  
Bethesda, MD 20892  
[SciencePolicy@od.nih.gov](mailto:SciencePolicy@od.nih.gov)

AUTM's Written Comments Regarding the Workshop on Transforming Discoveries into Products:  
Maximizing NIH's Levers to Catalyze Technology Transfer

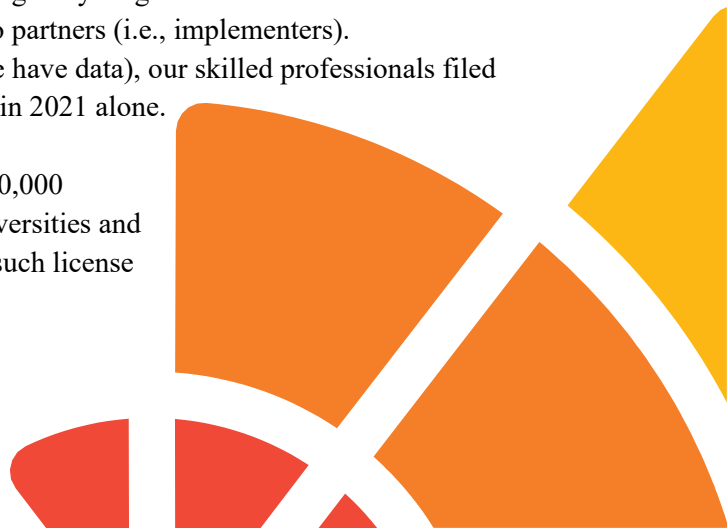
Dear Director Jorgenson:

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

AUTM is the non-profit leader in efforts to educate, promote, and inspire professionals to support the further development of academic research that drives innovation and changes the world. 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 members are primarily from academic settings (67%). 15% are practicing attorneys; 5% are from industry; and 22% of our members are international.

AUTM members in academic settings are focused on advancing early-stage inventions and other technologies to the marketplace primarily through licensing to partners (i.e., implementers). Between 2012 and 2021 (the most recent decade for which we have data), our skilled professionals filed over 150,000 patents for academic inventors and over 16,000 in 2021 alone.

Between 2012 and 2021, our U.S. members negotiated over 60,000 intellectual property license agreements on behalf of U.S. universities and academic research institutions, and in 2021 alone over 8,000 such license agreements.



For these reasons, AUTM has valuable insights and an important voice regarding all aspects of technology transfer including the critical decisions about what to patent and what to license as well as how to do so in the most efficient manner.

## **Introduction**

AUTM believes strongly in the importance of catalyzing technology transfer. Technology transfer has resulted in immeasurable societal benefits since 1980 when the Bayh-Dole Act ushered in the current technology transfer system. Studies have shown that since 1980, technology transfer has resulted in billions of dollars of private-sector investment, thousands of new companies formed, countless high-paying jobs, and the introduction of hundreds of new products and services that have improved the standard of living of Americans and contributed significantly to the growth of the American economy.

This history demonstrates the quantitative and qualitative benefits of increased technology transfer. AUTM believes that additional efforts to make technology transfer more efficient and more prevalent will lead to even more life-changing and economy-boosting innovations.

The good news is we know how to ensure the continued growth of technology transfer because we can look back and identify what has worked—namely, promoting innovation, ensuring strong and reliable property rights in inventions, allowing partnerships with industry for testing and development of such inventions, and access to the free market for the products that ultimately emerge from this process. The best way to promote these foundational elements of technology transfer is to provide as much predictability as possible in our currently balanced, yet fragile, innovation ecosystem. This includes supporting and defending strong patent rights and the Bayh-Dole Act while opposing the inclusion of reference price provisions in government funding, collaboration, and license agreements.

The Bayh-Dole Act (the “Act”) has been in existence for more than 40 years now and, for most of those years, the Act has been faithfully executed, the United States has had the world’s strongest patent system and, save for a 5-year period in the early 1990s, has promoted free market access by avoiding the imposition of reference price provisions.

As recommended below, efforts to weaken technology transfer should be rejected. The Act’s march-in provisions were not designed to (and would not) lower drug prices. The same is true of efforts to weaken patents or burden technology licenses with provisions directed to reference pricing. Such efforts will harm innovation and will not have the desired effect of lowering drug prices.

## **Recommendations**

AUTM recommends that the NIH’s Office of Science Policy (OSP) take a leadership role on this issue to support strong patent rights, enable robust technology licensing rights, and oppose any policies or regulations that would weaken the American innovation ecosystem. This leadership will maximize NIH’s own technology transfer, which would provide a significant carryover effect for all technology transfer. NIH OSP leadership will go a long way toward supporting the limitless benefits of technology transfer.

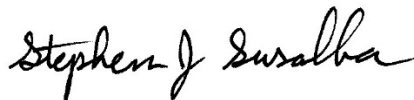
AUTM recommends that the NIH OSP support the NIH in (i) maintaining its consistent stance that the march-in provisions of the Bayh-Dole Act are not to be used as a mechanism to attempt to lower drug prices and (ii) continuing to reject all such petitions. Eliminating the threat of price-based march-in will remove a major obstacle to the partnerships that are necessary to further develop and commercialize the promising new technologies that come out of federally funded research laboratories.

AUTM also recommends that the NIH OSP insist on maintaining the ability of federally funded research organizations to grant licenses, including exclusive licenses, to their partners and the private sector. Exclusivity is sometimes an essential component of the commercialization process—without it, partners would be understandably leery of investing the time and resources necessary to develop a successful product. And without such investment, the technology stays in the lab and never becomes a product with the potential to benefit society.

Finally, AUTM recommends that the NIH OSP strongly oppose any inclusion of reference pricing language in government funding, collaboration, or license agreements. Including such language in any of those agreements will devastate university technology transfer as well as government technology transfer by impeding both universities and government research facilities from entering into the private-sector partnerships necessary to turn early-stage technologies into products and services. Such a result would cause great harm to the U.S. economy and, as just one example, to patients around the world who desperately await new treatments for devastating diseases—such as cancer, Alzheimer’s Disease, heart, lung, and kidney disease—and for ever-evolving pathogens.

Thank you again for the opportunity to comment on this crucially important issue. AUTM looks forward to further engagement with the NIH both now and in the future.

Sincerely,

A handwritten signature in black ink that reads "Stephen J. Susalka". The signature is written in a cursive, flowing style.

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