Executive Summary

The Association of American Universities (AAU), Association of Public and Land-grant Universities (APLU), Council on Governmental Relations (COGR), the Association of American Medical Colleges (AAMC), and the American Council on Education (ACE), which together represent all major research universities and medical schools in the United States, welcome this opportunity to respond to the NIST Request for Information (RFI) on Federal Technology Transfer Authorities and Processes Docket No. 18022019-819-01). Effective and efficient technology transfer in the public interest is of critical importance to our members.

In our full comments below, we emphasize the following priorities:

(1) No changes to the Bayh-Dole Act are necessary. The statute should be considered a set of core principles that must be protected. Nevertheless, there are a number of additional improvements that could further bolster Bayh-Dole as currently written.

(2) The dearth of funding for university and medical school technology transfer presents a fundamental and ongoing challenge to universities' ability to transfer federally funded technologies, but below we outline a number of possible approaches to improving this situation.

(3) Various "bureaucratic" hurdles – such as invention reporting roadblocks, conflicts of interest rules, and lack of federal agency timeliness and responsiveness to requests for waivers of invention rights under Bayh-Dole – create disincentives for technology transfer by imposing costs and compliance burdens without commensurate salutary benefits for the public.

(4) A robust patent system is essential to a successful technology transfer ecosystem. Uncertainty around Bayh-Dole march-in rights, lack of confidence that patents will be enforceable in fair proceedings in the courts or at the Patent Trial and Appeal Board (PTAB), confusion regarding patent eligibility law, and inconsistency in the government's approach to rights in software, among other issues, have a destabilizing effect on university and medical school technology

transfer efforts and planning.

(5) The tax code presents several potential opportunities for stimulating and supporting technology transfer. We discuss these opportunities below.

(6) Beyond the above, there are numerous mechanisms by which NIST and other federal agencies could improve technology (and knowledge) transfer via universities and medical schools, including: expanding the I-Corps program at the National Science Foundation (NSF) and other federal agencies; creating more flexibility in how SBIR/STTR funds can be used by federal agencies; and developing a targeted federal program focused on funding very early stage POC/translational research funding.

(7) Finally, and most broadly, we urge NIST and other federal agencies to be cautious about construing "return on investment" too narrowly, such as by using success metrics that focus only on the number of patents, start-ups, or licenses produced and/or overall revenue generated by particular institutions. As we explain more fully below, such measures do not offer a complete picture of the socio-economic contributions of university and medical school technology transfer.[1]

Again, our associations appreciate NIST's and the Administration's efforts to substantially improve the transfer of new ideas generated with federal research funds from the lab into the marketplace to enhance the public good. We look forward to continuing to work closely with NIST as it now moves forward to implementing new program initiatives and efforts which result from this ROI initiative. We stand ready to answer any questions regarding the issues and recommendations we raise in our response to the RFI.

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[1] *See* Association of Public and Land-grant Universities, Technology Transfer Evolution: Driving Economic Prosperity (Report of the Technology Transfer Evolution Working Group of APLU's Commission on Innovation, Competitiveness & Economic Prosperity (November 2017), *available at* http://www.aplu.org/library/technology-transfer-evolution-driving-economic-prosperity/file. *See also* Association of Public and Land-grant Universities, Statement to APLU Members of Recommendations on Managing University Intellectual Property (March 2015), *available at* http://www.aplu.org/projects-and-initiatives/research-science-and-technology/task-force-intellectual-property/March2015TaskForceManagingUniversityIntellectualProperty.pdf *and* Association of American Universities, Statement to the AAU Membership on University Technology Transfer and Managing Intellectual Property in the Public Interest (March 2015), *available at* https://www.aau.edu/sites/default/files/AAU-Files/Key-Issues/Intellectual-Property/Technology-Transfer/AAU-Patent-Tech-Transfer-Working-Group-Statement.pdf.

Introduction

The Association of American Universities (AAU), Association of Public and Land-grant Universities (APLU), Council on Governmental Relations (COGR), the Association of American Medical Colleges (AAMC), and the American Council on Education (ACE), write in response to the NIST Request for Information (RFI) on Federal Technology Transfer Authorities and Processes Docket No. 18022019-819-01). Together, AAU, APLU, COGR, and AAMC represent all major research universities and medical schools – including their technology transfer offices – in the United States. We appreciate NIST's intention to evaluate existing practices, policies, regulations, and/or laws that promote the transfer of Federal technologies and their practical application through commercialization by the private sector.

Our member institutions long have engaged in the transfer of federally funded technologies for commercialization. By many measures, these activities have been remarkably successful. They create jobs, contribute to U.S. economic competitiveness and global technological leadership, improve public health, and strengthen national security. To put this in perspective, in 2016 alone, the U.S. Patent and Trademark Office (USPTO) issued U.S. universities 6,452 U.S. patents. Additionally, American universities spun off 962 startup companies (most of which have their primary place of business in the home state of the licensing university) and generated 676 new commercial products.[1] Between 1996 and 2015, domestic university and nonprofit patent licensing activity supported up to 4.3 million jobs and contributed up to $591 billion to our country's gross domestic product and $1.33 trillion to U.S. industry gross output.[2]

Universities have a responsibility to be good stewards of discoveries and intellectual property developed by federally funded research. However, some critics have asserted that universities' technology transfer operations place too much emphasis on maximizing revenues and not enough on moving new ideas quickly into the marketplace. To respond to these concerns and to examine universities' proper role in promoting successful technology commercialization, AAU and APLU each formed high-level working

[1] Association of University Technology Mangers, "2016 Licensing Survey," https://www.autm.net/resources-surveys/research-reports-databases/licensing-surveys/fy2016-licensing-survey/.
[2] Biotechnology Innovation Organization, "The Economic Contribution of University/Nonprofit Inventions in the United States: 1996-2015," *available at* https://www.bio.org/sites/default/files/files/BIO_2015_Update_of_I-O_Eco_Imp.pdf.

groups on technology transfer and intellectual property. After extensive review, both working groups reaffirmed that the primary goal of university technology transfer operations is to advance the public interest.[3,4] The two associations urged university leaders to embrace the role of university technology transfer in promoting innovation and economic prosperity. These recommendations included:

1. Design and implement a clear mission statement for university management of intellectual property in the express interest of the public good;

2. Implement restrictions for university engagement with so-called "patent trolls" which acquire IP rights with no real intention of commercializing the technologies and instead rely solely on threats of infringement litigation to generate revenue; and

3. Broaden metrics and develop new evaluation criteria for university tech transfer units to include measures that do not solely focus on revenue generation or patent counts, but rather on economic and societal impact.[5]

The AAU and APLU working groups' conclusions built upon *Managing University Intellectual Property in the Public Interest*, a 2011 report of the National Research Council (NRC) of the National Academies that examined university intellectual property management practices.[6] The NRC report describes the successes of university technology transfer after the enactment of the Bayh-Dole Act, but also urges universities to be transparent in their commitment to furthering the public good through intellectual property management and to ensure that university policies and practices align with public purposes. The NRC report also backs several of the principles set out in *In the Public Interest: Nine Points to*

[3] Association of Public and Land-grant Universities, Statement to APLU Members of Recommendations on Managing University Intellectual Property (March 2015), *available at* http://www.aplu.org/projects-and-initiatives/research-science-and-technology/task-force-intellectual-property/March2015TaskForceManagingUniversityIntellectualProperty.pdf.

[4] Association of American Universities, Statement to the AAU Membership on University Technology Transfer and Managing Intellectual Property in the Public Interest (March 2015), *available at* https://www.aau.edu/sites/default/files/AAU-Files/Key-Issues/Intellectual-Property/Technology-Transfer/AAU-Patent-Tech-Transfer-Working-Group-Statement.pdf.

[5] For example, John Hennessey, former President of Stanford University, often noted that a university's success in technology transfer derived from its technology transfer office's taking risks and moving technology rapidly from the lab to the marketplace rather than concentrating on licensing arrangements structured to maximize revenue. In Hennessey's words: "As universities, we need to emphasize flexibility and appreciate the good things that happen when technology transfers. And the ultimate reward to a broad-minded institution consists of the long-term goodwill and philanthropy, and must always be the greater reward for a university – above and beyond the revenue." *See* Jim Woodell and Tobin Smith, "Technology Transfer for all the Right Reasons" (2017), *available at* https://www.aau.edu/sites/default/files/AAU%20Files/Key%20Issues/Intellectual%20Property/Technology%20Transfer%20For%20All%20The%20Right%20Reasons.pdf.

[6] *See* https://www.nap.edu/catalog/13001/managing-university-intellectual-property-in-the-public-interest.

Consider in Licensing University Technology, a 2007 statement developed by ten leading research universities and endorsed by our associations and more than 100 research universities and other organizations.[7] The *Nine Points* statement articulates a set of "core values" that are consistent with universities', medical schools', and research foundations' missions of learning, discovery, and engagement with societal challenges. Our associations continually encourage our member institutions to review the *Nine Points* statement to ensure continuity between these principles and university policy and practice.

I. What are the core Federal technology transfer principles and practices that should be protected, and those which should be adapted or changed?

The enabling statutory framework for transfer by our members of federally funded technologies is the Bayh-Dole Act of 1980 (35 USC 200 *et seq.*) and it is a widely acknowledged success story. Prior to Bayh-Dole's enactment, inventions developed with government funding in most cases were owned by the government. As a direct result, the majority of these inventions languished "on the shelf," and never resulted in a public benefit. In 1980, the federal government held title to approximately 28,000 patents. Fewer than 5% of these were licensed to private industry for development of commercial products.[8] And, in 1980, fewer than 500 patents were granted to U.S. universities.

The data discussed above show that Bayh-Dole has had a deep and far-reaching positive effect, both in the U.S. and globally. Numerous examples of innovations from university laboratories have had a tremendous, recognizable impact on our daily lives, including 3-D virtual colonoscopies, cochlear implants, the CAT scan, the seat belt, e-ink, plasma screens, and lithium-ion batteries.

The Bayh-Dole Act authorized universities, medical schools, and other non-profit organizations to retain title to their federally funded inventions, subject to certain safeguards to protect the government and public interest. The results have been dramatic, as shown by the numbers and examples cited above. This prompted *The Economist* to remark some years ago that "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole Act of 1980…this unlocked all the inventions and discoveries that had been made in laboratories throughout the United

[7] *See* http://www.autm.net/AUTMMain/media/Advocacy/Documents/Points_to_Consider. pdf.

[8] U.S. Government Accounting Office (GAO) Report to Congressional Committees entitled "Technology Transfer, Administration of the Bayh-Dole Act by Research Universities" (May 7, 1998).

States with the help of taxpayers' money. More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance."[9]

The Bayh-Dole statutory framework, with its carefully constructed safeguards and checks and balances, has proved sound. These include requirements to: disclose "subject inventions" to the Federal funding agency; elect title and file patent applications within certain time periods; grant a royalty-free license to the U.S. government for government use; give preference to small business in the licensing of inventions: require licensees to manufacture products in the U.S.; share income received with the actual inventors and use residual income for research and education purposes; and provide the government with the right to "march in" and require compulsory licenses if there is not reasonable progress towards practical use.[10]

We strongly believe that *no changes* to the Bayh-Dole statute are necessary. The Bayh-Dole Act should be considered a set of core principles that must be protected. Notably, the Bayh-Dole regime has been further strengthened by several improvements in the implementing regulations (37 CFR 401) recently made by NIST. These include providing a clear regulatory requirement for written assignments of inventions by federal contractor employees, updating the regulations for consistency with the America Invents Act (AIA), clarifying the status of provisional patent applications under Bayh-Dole, and providing additional guidance for situations involving Federal co-inventors. We have some suggestions for additional improvements – addressed in Sections II and III below – that we think will even further bolster the implementation of Bayh-Dole *as currently written*. Again, we very much appreciate NIST's efforts to reach out to the stakeholder community to seek input before making these changes.

II. What are the issues that pose systemic challenges to the effective transfer of technology, knowledge, and capabilities resulting from Federal R&D?

A. New Bayh-Dole Implementing Regulations

We believe the changes in the revised Bayh-Dole Act implementing regulations mostly are positive, as discussed above. However, we are concerned about some of the changes, particularly regarding certain time periods specified in the regulations.

[9] Les Nouvelles, *The Bayh-Dole Act Turns 30* (December 2010), *available at* https://c.ymcdn.com/sites/awis.site-ym.com/resource/resmgr/imported/Loise%20Stevens%20The_Bayh-Dole_Act_Turns_30%202010.pdf.
[10] See Council on Governmental Relations, *A Guide to the Bayh-Dole Act and Implementing Regulations* (October 1999), *available at* http://www.umventures.org/sites/umventures.com/files/COGR_Bayh_Dole.pdf.

First, we are concerned about the removal of the 60-day time for funding agencies to request title upon learning of a contractor's failure to disclose an invention or elect title. As we stated when commenting on the proposed changes, with no limit on the time period required for agency action, the result might be to cast an indefinite cloud over the invention title. For example, if a contractor fails to disclose in the two-month window under § 401.14(a)(c)(1) due to lack of information from the inventor on funding leading to the invention, but the contractor later learns about funding and then takes appropriate steps to inform the government to fulfill reporting requirements, the fact that the government can take title at any time over the course of the patent life is troubling. This change presumably means the government could step in and take title at any time, even long after a license has been executed. This will not advance university—industry relationships or promote commercialization.

Second, regarding the required notification period for contractor decisions not to continue non-provisional patent prosecution, we appreciate that NIST split the difference from the former 30 days notification requirement to 60 days, rather than the proposed 120 days. Our view was that 120 days was too long. While 60 days is more reasonable, often decisions to proceed with patents cannot be made until close to the deadlines in order to fully assess market demand. Further, the decision to establish a start-up company around a new university technology requires extensive research, capitalization, and intellectual property valuation. Increasing the notice period for abandoning patents limits the prosecution options available to forming companies, possibly precluding downstream successes. The former 30-day period was most supportive of start-up companies. The new 60-day requirement limits the amount of time to make prosecution decisions and ultimately reduces licensing (or potential licensee) evaluations. In many cases, contractors will have to expend additional resources on responding to deadlines for patents and patent applications that may no longer have commercial value in light of the decisions from the USPTO.

Third, the change that has perhaps caused the most concern in our community is the new requirement for a contractor to file a non-provisional patent application ten months after filing a provisional application. While we appreciate that there is an automatic one-year extension if requested (unless the agency notifies the contractor within 60 days of the request), the basis for this change is not clear. Many of our member institutions have expressed the view that this will substantially increase burdens without any clear benefit to the government. Another related

issue is the lack of a notification requirement for abandoned provisional patent applications where contractors are not abandoning the subject invention itself. This is not clearly addressed in the revised regulations. NIST has encouraged consultation with funding agencies where as a matter of prosecution strategy contractors do not continue prosecution of provisional applications, but the regulations do not specify notification in such circumstances.

B. Lack of Funding to Support University Technology Transfer

Although the Bayh-Dole Act has been critical to the success of university technology transfer, it essentially created an unfunded mandate. No funding was provided for patent costs or other costs associated with the operation of university technology transfer offices established to implement Bayh-Dole, such as efforts to undertake proof-of-concept work on early stage technologies. Studies have shown that a majority of U.S. institutions spend more on technology transfer than the income they generate.[11] This has led to increasing tensions as patenting has become more expensive and other institutional costs continue to increase. Although in theory some portion of facilities and administrative (F&A) cost recoveries could be used for this purpose, the Office of Management and Budget (OMB) caps the amount research universities can recover for administrative costs. Thus, they are essentially unavailable for such use. In short, the current lack of funding in this area poses a fundamental challenge to universities' ability to transfer federally funded technologies.

C. Invention Reporting Roadblocks

We have discussed with NIST the difficulties associated with invention reporting. The additional reporting requirements in the revised Bayh-Dole implementing regulations (401.5(f)) may add to the compliance burdens without increasing effectiveness of reporting, much less technology transfer overall. The iEdison reporting system used by most agencies is a legacy system with many problems. We are aware, however, that NIST and NIH are in the process of rebuilding the system and appreciate NIST's and NIH's efforts in that regard.

Beyond iEdison, there are other problems with current invention reporting. iEdison is not universally used by federal agencies, requiring our member institutions to deal with widely

[11] *See* "How are U.S. technology transfer offices tasked and motivated: is it all about the money?" Research Management Review (2009*), available at* https://www.wpi.edu/sites/default/files/docs/Offices/Intellectual-Property/How_are_US_Academic_Licensing_Offices_Organized_Tasked_Financed_and_Motivated_--_Final.pdf.

different reporting requirements of various agencies. A good example is NASA's New Technology Reporting System.[12] Some of our members have experienced significant compliance issues with that system due to misunderstandings as to what technology must be reported. The Department of Energy has three different reporting portals which are not necessarily consistent with one another. Even where an agency participates in iEdison, it still may require a specific agency invention report. Examples are the Air Force Research Office (DD Form 882) and other defense agencies.

D. Conflict of Interest Rules

The National Academies' 2016 report, *Optimizing the Nation's Investment in Academic Research*, correctly observed that "[Conflicts of Interest] are inevitable at research institutions, whose missions include the promotion of the public good by both creating new knowledge and facilitating the transfer of that knowledge to the private sector."[13] As the Academies note, because the academic mission is to benefit the larger society, academic research institutions and individual faculty and scientists must closely monitor research activities for conflicts of interest, and ensure that, "an individual's decisions or actions are not unduly influenced by considerations of personal financial gain."

Indeed, federal regulators, agencies and universities moved diligently to address and manage the review of such conflicts, beginning with new regulations in the 1990s and subsequent reforms. However, in 2012, the Public Health Service (PHS), responding to intense political and public pressure, revised the regulations around financial conflicts of interest, substantially "ratcheting up" the obligations of PHS-funded research institutions, including those performing research funded through the National Institutes of Health.

Among other requirements, the new rule expanded disclosure and review of researchers' financial interests beyond those related to their funded research to *any* that related to their academic responsibilities, including those for education, administration, and clinical care, and all reimbursements of sponsored travel. The rule requires investigators to disclose all financial interests meeting certain criteria to their institutions, and transfers responsibility for judging whether those interests were related to the investigators' ongoing research from the

[12] *See* https://invention.nasa.gov/.
[13] National Academies, *Optimizing the Nation's Investment in Academic Research* (2016), *available at* https://www.nap.edu/catalog/21824/optimizing-the-nations-investment-in-academic-research-a-new-regulatory.

investigator to the institution. It extended review of financial interests to include compensation received from many nonprofit entities and organizations. Notably, the rule reduced the threshold for a financial interest an investigator would need to disclose to an institution for review from $10,000 to $5,000, without any empirical basis for why the new threshold would be more effective.

Our associations believe that the Public Health Service (PHS) conflict of interest regulations have both dissuaded some faculty from working with industry to commercialize their ideas and placed significant new cost burdens on universities without a concomitant measurable reduction in conflicts of interest.

When the PHS conflict of interest rules were proposed, our associations, along with several other scientific societies, associations, and companies, expressed concerns that the new rules could have a "chilling effect" on universities' and their faculty members' willingness to engage in relationships with industry or other technology commercialization activities.[14] We continue to believe that the PHS disclosure requirements discourage rather than encourage researchers' interest in pursuing activities and relationships that can help lead to commercialization of government-funded ideas.[15]

At the same time, the conflict of interest regulations have added significant additional costs to our institutions for what appears to be a very limited benefit. A study conducted by the AAMC, with the assistance of its member medical schools and teaching hospitals, found that the 2012 rule substantially increased the administrative burden for institutions complying with the new regulation.[16] Despite the increased regulatory burden, the number of actual financial conflicts

[14] "Proposed Revisions to DHHS Conflict of Interest Policies: Concerns About Effects on Commercialization of Research," Summary of public comments on May 21, 2010 Department of Health and Human Services public comments on proposed revisions to "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors" regulations. Compiled by the Association of American Universities, September 9, 2010. *See* https://www.aau.edu/sites/default/files/AAU-Files/Key-Issues/Research-Administration-Regulation/Conflicts-of-Interest/Conflict-of-Interest-Regs-Concerns-about-Chilling-Impact-of-Changes.pdf.

[15] In addition to federal laws and policies, state conflict of interest laws that place additional restrictions on specific research activities or performers also potentially disincentivize productive cross-sector relationships.

[16] Implementing the Regulations on Financial Conflicts of Interest: Results from the AAMC Conflict of Interest Metrics Project (April 2015), *available at* https://www.aamc.org/download/429214/data/april2015implementingtheregulationsonfinancialconflictsofintere.pdf.

identified did not show a commensurate increase. The study could not ascertain the degree to which the new rules have discouraged investigators from engaging in activities that could potentially promote the transfer of new knowledge into commercial activity, out of concerns for the additional—and we believe non-productive—requirements of the 2012 rule.

Section 2034(a) of the 21st Century Cures Act requires that the Department of Health and Human Services (HHS) review all conflict of interest regulations and policies of funding agencies, including: the minimum threshold for reporting financial conflicts of interest; the timeline for such reporting by NIH-funded institutions; whether reporting requirements are appropriate for, and relevant to, research funding awards; and whether training modules the NIH has created for financial interest disclosure should be updated.[17]

E. U.S. Manufacturing Requirement Compliance Challenges

We fully support the intent of the U.S. manufacturing requirement (414(i)) of the Bayh-Dole Act). It is an important component of assuring that U.S. taxpayers benefit from the commercialization of federally funded technologies enabled by the Act. However, with increased globalization, it has become more difficult for our member institutions to find licensees able to comply with the U.S. manufacturing requirement. The difficulty is compounded by slow or, in some cases, lack of responses by agencies to waiver requests. Too often these requests appear to vanish into a "black box" within agencies.

F. Waivers of Rights to Inventors

The Bayh-Dole Act permits agencies to allow contractor employee inventors to retain rights to subject inventions. However, scant guidance on this provision is provided in the NIST implementing regulations (37 CFR 401.9). In the experience of our members agencies vary in their timeliness and responsiveness to requests for such waivers of invention rights, when neither contractors nor agencies are interesting in retaining rights. Leaving invention rights in limbo does not enhance inventors' ability to promote commercialization and application of the inventions themselves.

G. University Technology Transfer and Patenting Challenges

[17] 21st Century Cures Act (Public Law 114-255), *available at* https://www.congress.gov/bill/114th-congress/house-bill/34/.

Universities and medical schools depend on a robust, reliable patent system for their technology transfer activities to achieve their societal benefits. Because inventions emerging from university and medical school research tend to be early-stage and high-risk, successful university technology transfer requires an effective patent system that protects these inventions. First, universities and medical schools and their licensees and start-up investors would benefit substantially from greater clarity and certainty regarding the patenting process. Second, universities and medical schools and their licensees and investors must have some assurance that the patents on those inventions will not be subject to misapplications of Bayh-Dole Act march-in rights. And, third, they must have confidence that those patents will be enforceable in fair proceedings, whether in the courts or at the Patent Trial and Appeal Board (PTAB).

1. Bayh-Dole March-in Rights

A misuse of Bayh-Dole march-in rights to control drug prices, will impede the creation of new drugs by discouraging university and medical school licensees from making the substantial additional investments necessary to take federally funded university-based research from the laboratory to the bedside. Universities and medical schools stand unified in their commitment to ensure that university- and medical school-conducted research and technology transfer serve to advance worldwide public health. Accordingly, they strive to transfer their patented discoveries to the private sector under licensing terms and conditions that will best address unmet needs and promote the broad accessibility of health advances. But if the scope of applicability of march-in rights is broadened beyond Congress's original intent, the private sector will be hesitant or unwilling to license federally funded inventions from universities, potentially chilling progress against some of our costliest and most formidable diseases, to the detriment of public health and safety.

The legislative record of Bayh-Dole and subsequent statements by Senators Bayh and Dole make clear that Congress intended the march-in provision to apply only in narrow circumstances, such as when a licensee fails to make a good faith effort to bring an invention to market or if health or other emergencies arise and the licensee is unable to make enough of a product to meet public needs. The march-in provision was never intended to serve as a vehicle for controlling drug pricing. Rather, the statute refers to "practical application," which is defined as providing availability to the public on terms that are

"reasonable under the circumstances." The statute deliberately does not address or define what may constitute a "reasonable price."[18]

Over the years, the National Institutes of Health (NIH) has considered and rejected several petitions asking it to exercise its march-in authority to address drug pricing concerns. In each review to date, NIH has concluded that the "practical application" requirement was satisfied if the patented drug was on the market and available to the public. Unfortunately, NIH and HHS continue to confront congressional pressure to exercise their march-in rights more expansively. This would require an interpretation of the Bayh-Dole march-in provision that is not supported by the legislative history and aforementioned statements by the Act's authors.

It is important to mention here that concerns about misuse of march-in rights are founded on practical experience. In 1995, former Director of NIH Harold Varmus removed the "reasonable pricing" clause from the Public Health Service (PHS) model Cooperation Research and Development Agreement (CRADA) and the PHS model Exclusive License Agreement.[19] Dr. Varmus did so because, over the course of a year of analyzing its CRADA activities, NIH determined that the "reasonable pricing" clause inhibited collaborative public-private research, innovation, and the creation of intellectual property. As Varmus explained in his rescission letter: "One has to have a product to price before one can worry about how to price it, and this clause is a restraint on the new product development that the public identified as an important return on their research investment."

2. Patent Trial and Appeal Board Proceedings

The Inter Partes Review (IPR) process – which universities initially supported because it was intended to streamline patent adjudications – introduced asymmetries into the patent system, such as varying claim construction standards. These asymmetries unfairly disadvantage patent holders and create uncertainty for university licensees that discourages investment in university innovations. Ensuring fairness and increasing certainty for patent

[18] *See, e.g.,* Statement of Senator Birch Bayh to the National Institutes of Health (2004), *available at* http://www.essentialinventions.org/drug/nih05252004/birchbayh.pdf. *See also*, CRS Report, "March-In Rights Under the Bayh-Dole Act" (August 2016), *available at* https://fas.org/sgp/crs/misc/R44597.pdf.
[19] *See* Statement of NIH Director Harold Varmus on Removal of "Reasonable Pricing" Clause from CRADAs (April 1995), *available at* https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf.

holders engaged in IPR proceedings is critical for the university technology transfer process to work as intended to benefit society and the economy.

3. Section 101

Overly broad interpretations of Section 101 have had a detrimental effect on software-embodied inventions. The Supreme Court decision in Alice Corp. v. CLS Bank (134 S. Ct. 2347 (2014)) has cast a cloud of uncertainty over the patent eligibility of software, although there are recent indications that USPTO is undertaking efforts to ameliorate this situation.[20] Universities are a leading source of innovations based on software, such as artificial intelligence. The Alice decision has had a dramatic effect on the validity of software patents. Since Alice, these patents have suffered a very high mortality rate. Hundreds of patents have been invalidated under §101 of the U.S. patent laws in federal district courts. Applying Alice, district court judges have found many of these claims to be patent-ineligible abstract ideas.[21] Coupled with the inconsistency with regard to rights in software in the applicable government regulations (see below), the result is a landscape inhospitable to commercialization that threatens to slow, if not stifle, the bringing to market of ground-breaking technologies such as artificial intelligence (an area in which the U.S. is currently seeking to remain in the lead globally).

Similarly, judicial interpretations of patent eligibility law under 35 USC 101 have created a measure of confusion and uncertainty for universities that are striving to patent cutting-edge technologies like medical diagnostics. These technologies have the potential to provide more effective care for patients at a lower cost by, among other things, detecting medical conditions earlier, monitoring those conditions more easily, and predicting outcomes more accurately. Medical innovations require significant research for discovery and substantial investments of resources to develop them, to receive regulatory approval for them, and to bring them to the patient or to apply in public health.

4. Rights in Software

[20] *See, e.g.,* "The Berkheimer Memorandum - Good news for software patents in the US" (May 2018), *available at* https://www.lexology.com/library/detail.aspx?g=e792c102-3322-4ae3-a931-353c91a9a7c4.
[21] *See, e.g.,* "Section 101 and the Growing Alice Backlash" (May 2016), *available at* http://www.patentdocs.org/2016/05/section-101-and-the-growing-alice-backlash.html.

The government's approach to rights in software inventions is inconsistent, which has resulted in persistent misunderstandings and uncertainty on the part of our members. Under federal contracts software is treated in a manner similar to technical data (FAR 52.227—14; DFARS 252.227-14), with the government receiving unlimited rights. Under grants, grantees can copyright software with the government receiving a limited license (2 CFR 200.59; 200.315). In either case, award recipients have the right under Bayh-Dole to patent the software. For government contracts with the standard FAR data rights clause, this could lead to conflicting rights and obligations (we are not aware of any actual situations where this has occurred, but because Bayh-Dole is a statutory right it probably would trump the FAR clause).

Presumably it is a judgment call for awardees, but the net result is confusion in the higher education technology transfer community. In many cases, the better decision may be not to seek a patent, particularly given recent Supreme Court decisions that have complicated the ability to patent software as discussed above. But if they choose not to patent the software, it is unclear whether it still needs to be treated in a manner similar to Bayh-Dole subject inventions, since in theory the software could be patented. This is particularly challenging as to whether or not unpatented software must be disclosed similar to the requirements for patentable inventions. According to our member institutions, funding agencies, when asked, have been inconsistent in their responses.

5. Micro-entity Status

35 USC 123(d) defines when a university can claim micro entity status and therefore be eligible for the 75% discount. However, the lack of clarity in 35 USC 123(d) regarding the use of the term "applicant" results in uncertainty about when a university can claim micro entity status (as opposed to small entity status). Because universities and medical schools typically file *on behalf of* their researchers/inventors, this can result in a substantial, and in some cases prohibitively costly, fee differentials for such filings.

H. The Tax Code and Technology Transfer

A number of provisions in the tax code are currently structured in such a way that they impose burdens on – or at least do not promote and support – public-private research partnerships that are a critical component of university and medical school technology transfer activities.

1. Restrictions on Public-Private Use of Tax-Exempt Bond Financed Facilities

Tax-exempt bonds are an important financing tool for universities to build new classrooms and laboratories and to renovate existing campus facilities. Research universities increasingly partner with industry and small technology companies to address tough science and technology challenges, but restrictions on the use of facilities financed by tax-exempt bonds [Internal Revenue Code Section 141(b)] unnecessarily impede the formation and continuation of these innovative partnerships.

At universities and medical schools, activities that might be deemed private business use include (among many others): technology transfer and licensing agreements; sponsored research; clinical trial agreements; and joint ventures. The IRS in 2007 clarified (Revenue Procedure 2007-47) that research in tax-exempt bond financed facilities leading to the licensing of Bayh-Dole rights to private entities does not violate the private business use test. But the remaining private use regulations remain overly restrictive. As a result, some universities opt for taxable bonds or put a percentage of their own equity into the capital budget for facilities, so they can engage in certain research with for-profit entities. Unfortunately, many universities are unable to make such equity investments, which limits their ability to conduct certain cooperative university-industry research that could lead to successful technology transfer.

Moreover, by linking negotiations between universities and private industry to the tax status of a given research facility, private businesses are incentivized to ship their R&D to countries whose governments provide financial support for the facilities where the corporate R&D is carried out and do not intervene in negotiations on intellectual property licensing.

2. Need for an Improved R&D Tax Credit

The federal Research and Development Tax Credit ("R&D tax credit") [26 USC 41(e)(7)(A)] is a business tax credit for qualified research expenses that can be deducted from overall corporate income taxes. Under certain circumstances, businesses can also claim a credit if they fund qualified research at another organization such as a university or other research

organizations. In such instances, a business can claim only 65 percent or 75 percent (as compared to 100 percent for in-house R&D expenditures) of qualifying expenditures toward the tax credit. The 75 percent rate applies only to qualified research organizations (such as universities or research consortiums), which are tax-exempt entities organized primarily to conduct scientific research and which are not private foundations.

Universities benefit indirectly from the R&D tax credit, insofar as the credit encourages industry to take on new research and development challenges that are important to industry but also well-suited to academic research. In addition, when companies contract with universities to conduct R&D, faculty and graduate students benefit from receiving additional complex academic and practical research problems to tackle and, importantly, the financial support to do so. These collaborations also lead to R&D-based employment opportunities for students and graduates, resulting in, among other things, knowledge transfer. And the R&D tax credit also helps to foster start-up companies, many of which are a result of new technologies developed at universities as a result of industry-funded research.

Unfortunately, the R&D tax credit suffers from a number of limitations that prevent the credit from being as powerful a tool as it could be to incentivize university-industry research collaborations. For one thing, the credit too narrowly defines basic research projects as "not having a specific commercial objective." In addition, industry does not receive an additional tax incentive to conduct collaborative research with universities (and, for that matter, federal laboratories).

III. What is the proposed solution for each issue that poses a systemic challenge to the effective transfer of technology, knowledge, and capabilities resulting from Federal R&D?

Below, in *italics*, are our recommended improvements and proposed solutions to the challenges identified in Section II above.

A. New Bayh-Dole Implementing Regulations

(1) Removal of the 60-day time for funding agencies to request title upon learning of a contractor's failure to disclose an invention or elect title.

We appreciate NIST's intent to improve due diligence, but we believe NIST should reconsider reinstating the former 60-day time period for agency action.

(2) Required notification period for contractor decisions not to continue non-provisional patent prosecution.

We recommend that NIST closely monitor the impact of this time period change to determine whether or not there are clear adverse effects.

(3) New requirement for a contractor to file a non-provisional patent application 10 months after filing a provisional application.

We urge NIST to reconsider the 10-month non-provisional patent filing requirement and to address this gap in the regulations related to abandoned provisional patent applications.

B. Lack of Funding for Patent Costs and Technology Transfer

The current lack of funding in this area poses a fundamental challenge to universities' ability to transfer federally funded technologies.

There are a number of possible approaches to improving this situation. One possibility might be for the government to provide some supplemental funding specifically for commercialization activities. NIST/Commerce might consider establishing a separate pool of funds for this purpose.

As such approaches are considered, models such as NSF and NIH i-Corps programs, and Commerce's Regional Innovation Strategies Program, offer insights into ways in which supplemental and complimentary investments in downstream activities can yield advancements in commercialization efforts.

Another possible approach would be for the Federal government to provide funding either directly to universities or for regional not-for-profit entities for activities to help patented inventions cross the so-called "valley of death." For instance, Federal agencies such as Commerce, NIST, OSTP, or NIH / NSF / ARPA-E / DOD could provide best practices and financial support for regional- and topic-specific programs, such as executive-in-residence programs for coaching and mentorship; "venture exchange" programs for matching venture-backable entrepreneurs to high-potential university and Federal lab startups; and boot camps / virtual proof-of-concept accelerators. There are many examples of successful programs at both the university and regional level that could be examined as possible models for emulation or scale.

Furthermore, many low-cost programs to boost tech transfer efficiency and effectiveness already exist at universities across the country, and the knowledge of how to launch and manage these programs are commonly shared across peer institutions at meetings such as AUTM, LES, and smaller gatherings such as IvyTech, the New York Academic Consortium, and others. Even a small increase in the funding to Federal lab tech transfer offices to enable them to more fully participate in the existing opportunities for best practice sharing might lead to significant increases.

For instance, Columbia University runs or co-runs (with other NYC institutions including NYU, CUNY, Cornell Tech, and Stony Brook) five virtual lab-to-market accelerator programs. For each of these accelerators, teams form around promising university research inventions (in cancer; therapeutics; devices, diagnostics, and imaging; clean energy; and media), then receive education relevant for commercialization and entrepreneurship; connections to experienced mentors; small amounts of validation funding for developing prototypes; and the opportunity to pitch to appropriate investors and industry representatives. The programs share a shared infrastructure and a common set of timelines, processes, mentor networks, marketing platforms, event management approaches, and other best practices, which will allow the individual

accelerators to focus on industry-specific needs in order to be as efficient and effective as possible with minimal funding.[22]

Similarly, a group of universities including Columbia, Yale, MIT, Stanford, Harvard, Penn, and others formed the Academic Venture Exchange (AVX), a platform by which venture-backable serial entrepreneurs can be matched with high-promise potential startups emerging from the university research labs. To date, AVX has 250+ entrepreneurs and 125+ university startups in the system, which has led to 650+ initial discussions, 8 CEO-to-startup matches, and another 25 matches pending. Building on learnings from AVX, similar platforms have now been launched for regional- and topic-specific programs, including the New York Cleantech Venture Exchange and the New York Life Science Venture Exchange.

C. Invention Reporting Roadblocks

There are a number of problems with current invention reporting that add to compliance burdens without increasing the effectiveness of reporting, much less technology transfer overall.

Timely and accurate invention reporting should be an essential component of an effective Federal technology transfer system. A single, coherent streamlined government-wide reporting process would greatly improve compliance. The process should be overseen by an entity that has adequate resources and sufficient authority. Agencies that seek to impose additional or different requirements should be required to specifically justify the added requirements to that entity, subject to public comments.

D. Conflict of Interest Rules

Although it is imperative to identify and manage conflicts of interest that could affect research

[22] For more information on these lab-to-market accelerators, see "University Technology Accelerators: Design Considerations and Emerging Best Practices" (June 2017), *available at* https://bit.ly/2JZbgN0.

integrity or the safety of human subjects, the regulations surrounding conflicts of interest have become more burdensome and erected disincentives to responsible collaborations with industry without demonstrating greater effect.

We are hopeful that the agency-level review will result in a system – ideally one that is uniform across agencies – that responsibly addresses conflicts of interest that could be detrimental to research integrity or the safety of human subjects, while recognizing the validity and importance of principled partnerships with industry. The government must seek to better align its current PHS conflict of interest policies with its interest in seeing the commercialization of, and ROI on, its NIH research investments.

E. U.S. Manufacturing Requirement Compliance Challenges

With increased globalization, it has become increasingly difficult for our member institutions to find licensees able to comply with the U.S. manufacturing requirement. The difficulty is compounded by slow or, in some cases, lack of responses by agencies to waiver requests. Too often these requests appear to vanish into a "black box" within agencies.

We suggest that agencies be required to provide some response to these requests within a specific time period, perhaps 60 days. If agencies do not provide a response within that time period, or if they respond in the negative without providing a clear explanation, institutions should have the ability to appeal to NIST.

F. Waivers of Rights to Inventors

In the experience of our members, agencies vary in their timeliness and responsiveness to requests for waivers of invention rights under the Bayh-Dole Act, when neither contractors nor agencies are interesting in retaining rights.

We suggest that NIST develop additional guidance to help facilitate and streamline the process for waiving rights to inventors.

G. University Technology Transfer and Patenting Challenges

1. Bayh-Dole March-in Rights

   Universities and medical schools and their licensees and investors must have some assurance that the patents on those inventions will not be subject to misapplications of Bayh-Dole Act march-in rights.

   We believe it would be helpful for NIST to reaffirm that the National Institutes of Health's response to previous march-in petitions is the correct understanding of the scope and appropriate uses of march-in rights.[23] *This would help to alleviate the uncertainty around march-in rights that can have a chilling effect on university technology transfer. Any such reaffirmation would also help to ensure consistency in the interpretation and application of the Bayh-Dole Act across federal agencies.*

2. Patent Trial and Appeal Board Proceedings

   Universities and medical schools – along with the licensees and investors – must have confidence that their patents will be enforceable in fair proceedings, whether in the courts or at the Patent Trial and Appeal Board (PTAB).

   Accordingly, we have recommended to the U.S. Patent and Trademark Office (USPTO) a number of changes to the PTAB and IPR proceedings, including:

   - *Harmonize the IPR claim construction standard with that of the federal courts and the International Trade Commission by applying the Phillips standard rather than the Broadest Reasonable Interpretation (BRI) standard. We support the USPTO's current proposal in this regard and agree that it will promote consistency in claim construction between the PTAB and proceedings in district court or at the ITC, as well as increase efficiency.*

   - *Harmonize the burden of proof standard applied in IPR proceedings with the burden of proof standard applied in district courts.*

[23] *See, e.g.,* https://www.keionline.org/sites/default/files/Final-Response-Goldman-6.20.2016.pdf. *See also* https://energycommerce.house.gov/hearings/implementing-21st-century-cures-act-update-fda-nih/.

- *Close the "integrity loophole" problem by restoring the traditional right of patent holders to sue for damages if their patents are subject to reexamination on the basis of false evidence or other abuses**,** harmed by fraud on the court, or abuse of process.*

3. Section 101

   Current patent eligibility law under 35 USC 101, as interpreted by the courts, has created a challenging environment of confusion and uncertainty for universities that are striving to patent certain cutting-edge technologies.

   We encourage NIST and Congress to consider a number of recent proposals made by the American Intellectual Property Law Association (AIPLA), the Intellectual Property Owners Association (IPO), and the American Bar Association (ABA) Section of Intellectual Property Law, to replace existing Section 101 with alternative language that we believe would help to reform Section 101. In short, these proposals contend that an invention should be considered patentable subject matter unless it exists in nature independently of human activity or it can be performed solely in the human mind; in addition, they assert that the question of whether or not an invention is implemented via conventional means is irrelevant to whether or not that invention constitutes patent eligible subject matter. The existing standards of novelty (Section 102), nonobviousness (Section 103), and written description (Section 112) would remain in place, thus preventing undeserving technologies from receiving patent protection.

4. Rights in Software

   The government's approach to rights in software inventions is inconsistent, which has resulted in persistent misunderstandings and uncertainty on the part of our members.

   Clarifying guidance from NIST would be helpful, especially as to disclosure requirements in situations where the awardee chooses to copyright or provide open access but not patent the software. Moreover, NIST could, under the auspices of Section 1(b)(6) of Executive Order 12591, seek to coordinate with other federal agencies to develop a uniform policy to allow federal contractors to retain rights to software, engineering drawings, and other technical

data generated under federal grants and contracts.

5. Micro-entity Status

   The lack of clarity in 35 USC 123(d) regarding the use of the term "applicant" results in uncertainty about when a university or medical school can claim micro entity status (as opposed to small entity status).

   Universities and medical schools would greatly welcome clarity regarding whether or not they are eligible for micro entity status under 35 USC 123(d).

H. The Tax Code and Technology Transfer

Restrictions on Public-Private Use of Tax-Exempt Bond Financed Facilities

Restrictions on the use of facilities financed by tax-exempt bonds [Internal Revenue Code Section 141(b)] unnecessarily impede the formation and continuation of these innovative partnerships.

A solution to this problem would be to ease and simplify the tax code's restrictions on tax-exempt bonds that unduly limit innovative partnerships between universities and businesses. One possible approach is presented by H.R. 1819 of the 114th Congress, which would have amended the Internal Revenue Code by creating more flexible standards under which public-private research activities at tax-exempt bond financed research facilities could occur and also clarifying determinations of whether collaborative agreements were eligible to draw on tax-exempt bond financing. Another possible approach would be to create an exception to the private business limits for research arrangements relating to basic research at tax-exempt bond-financed research facilities where (1) the research facility is owned by a 501(c)(3) nonprofit entity and (2) that nonprofit entity has entered into a bona fide, arm's-length contract with a private business sponsor of basic research regarding the terms for sharing the economic benefits of any products resulting from the research (including provisions for intellectual property).

Need for an Improved R&D Tax Credit

Even though the current R&D tax credit works reasonably well, it could do much more to

provide incentives for companies to partner with universities for R&D.

To facilitate increased collaborative efforts between universities and industry, language in the basic research tax credit [26 USC 41(e)(7)(A)] – *which narrowly defines basic research projects as "not having a specific commercial objective" – should be broadened. At a minimum, Congress should be encouraged to delete such language from current law and allow any research expenditures at universities to qualify for the basic research credit. Moreover, and ideally, industry should receive an additional tax incentive to conduct collaborative research with universities and federal laboratories. This could be done by doubling the existing credit from a 20 percent flat credit to a 40 percent flat tax credit.*

IV. What are other ways to significantly improve the transfer of technology, knowledge, and capabilities resulting from Federal R&D to benefit U.S. innovation and the economy? What changes would these proposed improvements require to Federal technology transfer practices, policies, regulations, and legislation?

A. Identify and Disseminate Effective New and Innovative Technology Transfer Practices

Universities are developing and implementing many novel approaches to increase and accelerate commercialization opportunities. Many such innovations are highlighted in APLU's recent report Technology Transfer Evolution: Driving Economic Prosperity. Universities have: worked to implement streamlined licensing terms, created gap funds, developed space and other offerings for entrepreneurs, designed new organizational and structural models for technology transfer, and much more. One way to significantly improve the transfer of technology is to study what is working and what is most effective among the many innovations in technology transfer currently being undertaken. Efforts can then commence to diffuse and disseminate the most effective strategies.

To support ongoing innovation and improvement of technology transfer practices, federal government entities can address the solutions detailed above. Additionally, NIST and other federal agencies can support studies of effective practices and follow-on dissemination and also provide support for scale-up across universities as well as federal laboratories. As an example, NIST recently awarded the University of Michigan a grant to study effective commercialization practices at APLU's Innovation and Economic Prosperity (IEP) Universities.

B. Broaden How We Think About and Assess Successful Technology Transfer and University Support for Economic Development

In a 2010 memo to the Office of Science and Technology Policy, our associations expressed concerns that too much weight has been assigned to the role of number of patents, licensing, and revenue generation in defining university success in technology transfer and economic development. In that memo we noted that "….the statistics on university licensing revenues contained in the annual AUTM Licensing Activity Survey have too often been used as metrics by the media and others, including state governors, to determine the 'success' of university technology transfer and commercialization efforts." To address this concern, we called for the development and use of a broader set of new metrics that would more accurately and appropriately "reflect the range of university contributions to local, regional, and national economies."[24]

Since 2010, both APLU and AAU have undertaken efforts focused on developing a broader and more comprehensive set of metrics to assess and evaluate university technology transfer and economic development activities. These metrics tend to focus on 'impact' as opposed to 'income' and are at times not at all easy to measure[25]

As the federal government looks to assess and evaluate the ROI from federal investments in university research, we would caution against using too narrow a set of metrics. Measures that focus only on technology transfer; the number of patents, start-ups and/or licenses produced; or overall revenue generated by particular universities do not provide a complete picture of the socio-economic contributions of university technology transfer.

Although technology transfer is one means by which universities support economic development, its role in this complex equation has often been over-emphasized. Indeed, university returns on federal research investments take many forms other than direct technology commercialization, some of which are not easily measurable. These returns on federal research investments range from the

[24] *See* https://www.aau.edu/sites/default/files/AAU%20Files/Key%20Issues/Budget%20%26%20Appropriations/FY17/Joint-Univ-Assn-Comment-Letter-onOSTP-NEC-RFI_10May2010.pdf.

[25] See APLU's New Metrics Field Guide, APLU's Innovation & Economic Prosperity Universities Program, and AAU's Indicators of a Successful University Technology Transfer Office.

education and training of students to faculty consulting to the generation of new fundamental knowledge and the open publication of research results, which industry has heavily relied upon in patents and for the development of new products.[26]

Universities and medical schools have themselves worked to develop metrics for success of technology transfer and for proper contextualization of tech transfer in broader knowledge transfer and socio-economic development. As university-level efforts continue, we find that different and complimentary sets of measures emerge for technology commercialization, industry/entrepreneur engagement and partnerships, and economic development. Because all of these activities and resulting outcomes measures are highly sensitive to individual universities' missions, size, resources, geography, and a variety of other factors, it is most appropriate for further development of appropriate measures to happen at the individual university level. While the federal government may find it helpful to develop broad measures of technology transfer and economic development, it would be unhelpful and likely lead to inaccurate conclusions if federal measures where imposed on universities.

C. Provide Additional Support to Help Universities to File for Foreign Patents

Universities have a strong interest in protecting their intellectual property from theft both domestically and abroad. To that end, we would like to explore new government funding mechanisms that could be utilized to extend protections overseas for university inventions and intellectual property. This might include, for example, the development of a specific funding streams that would provide additional government support for universities to file foreign patents applications.

D. Expand I-Corps program at the National Science Foundation (NSF) and other federal agencies.

[26] National Science Board, "Private Use of Public Science," Science & Engineering Indicators, Chapter 6, 1998, Arlington, VA: National Science Foundation, 1998 (NSB 98-1) See: https://wayback.archive-it.org/5902/20150629142654/http://www.nsf.gov/statistics/seind98/pdf/c6.pdf.

The NSF I-Corps program helps train and prepare scientists, engineers, and graduate students to extend their focus beyond the university laboratory and to accelerate the economic and societal benefits of basic research projects that have commercialization potential. The American Innovation and Competitiveness Act enacted into law in 2017 authorized the I-Corps at NSF and encouraged its expansion. Since its creation in FY2011, several other federal agencies have funded I-Corps cohorts. We urge NIST and the administration to continue to support the I-Corps program at the NSF and to encourage that other federal research agencies establish and expand I-Corps programs.

E. Provide for additional flexibility in how SBIR/STTR funds can be used by federal agencies by reauthorizing and making the SBIR Administration Funding Pilot Program (AFPP) permanent.

One unfortunate casualty of the 2016 SBIR/STTR reauthorization act was the Administrative Funding Pilot Program (AFPP). This program had permitted federal agencies to use 3% of their SBIR/STTR funds for administration of SBIR and STTR programs including providing administrative support for services that helped to advance technology transfer and to better leverage the SBIR/STTR programs to advance commercialization. From narrowing the “valley of death" by speeding up the acquisition process to improving outreach and assistance through increased support services and training, the AFPP was viewed by most all as a successful change to the SBIR/STTR program. We would encourage NIST and the Administration to support reauthorization on the AFPP and to push to make this program a permanent feature of the SBIR/STTR program.

F. Development of a new institutional awards program to support proof of concept (POC) and transitional research funding grants to support faculty with technologies and ideas with commercial potential.

Despite the existence of the SBIR/STTR programs, there still exists a gap in the funding needed to begin to push new ideas and technologies across the “valley of death”. This gap often prevents universities and their faculty from moving research discoveries with commercial potential successfully into the marketplace. Given the high-level of risk associated with early stage technologies, companies, angel investors, and venture capitalists are often unwilling to invest in the early-stage proof of concept (POC) research, data generation, modeling and market analysis required to explore the commercial value of such advances. While the current SBIR/STTR programs

begin to address this issue, they fall short of providing very early stage support for POC/translational research required to help a faculty entrepreneur get to the point of deciding if it is even worth creating a company around a new technology/discovery in order so that they can apply for an SBIR or STTR award.

To address the gap, we propose the development of a targeted federal program focused on funding very early stage POC/translational research funding. Such a program would not only help more projects cross the Valley of Death but would also help enhance the infrastructure (e.g. expertise, personnel) and facilitate the cultural change necessary for universities to better support successful technology transfer and increase the ROI from discoveries generated with federal grant funding.

Existing models for such a program include:

- The European Research Council (ERC) proof of concept funding initiative;[27]
- The Wallace H. Coulter Foundation's Translational Research (for individual researchers) and Translational Partnership (for institutions) Awards for proof of concept research in biomedical engineering.[28]
- Programs supported with philanthropic funding at MIT's Deshpande Center,[29] the University of California San Diego's von Liebig Center,[30] and the University of Southern California's Stevens Center;[31] and
- The National Institutes of Health (NIH) Research Evaluation and Commercialization Hub (REACH) program previously authorized under Section 5127 of the 2011 SBIR/STTR Reauthorization Act (P.L. 112-81).[32]

The Technology and Research Accelerating National Security and Future Economic Resiliency Act of 2013 (TRANSFER Act) (H.R. 2981)**,** introduced in the 113th Congress by Representatives Chris Collins (R-NY) and Derek Kilmer (D-WA) and approved by the U.S. House of Representatives, represents one

[27] *See* https://erc.europa.eu/funding/proof-concept.
[28] *See* http://whcf.org/coulter-foundation-programs/translational-research/coulter-translational-partnership-tp-and-research-awards-ctra/.
[29] *See* https://deshpande.mit.edu.
[30] *See* http://jacobsschool.ucsd.edu/ige/commercial/vlc.shtml.
[31] *See* https://stevens.usc.edu/.
[32] *See* HHS Funding Opportunity Announcement on NIH Research Evaluation and Commercialization Hub (REACH) Awards (April 25, 2014), *available at* https://grants.nih.gov/grants/guide/rfa-files/rfa-OD-14-005.html.

possible way in which such a POC/translational research program could be funded.[33] The TRANSFER Act would have allowed government agencies to spend a portion of their funds set aside for the STTR program to support a new POC institutional awards program. In the past our associations have expressed our support for the TRANSFER Act.[34] Alternatively, if some portion of STTR funds are not to be used to support such a multiagency early stage POC program, we would recommend that NIST independently establish such a program with new funding provided for and appropriated by Congress. Such a proposal has been advanced by Ashley J. Stevens in an April 23, 2018 memo to Dr. Copan.

Conclusion

Our associations appreciate the efforts of NIST and the administration to increase the ability of universities and federal laboratories to effectively transfer new ideas generated with federal research funds out of the lab and into the marketplace to enhance the public good. We look forward to continuing to work closely with NIST as it now moves forward to implementing new program initiatives and efforts which result from this ROI initiative. We also welcome the opportunity answer any questions the agency has regarding the issues and recommendations we have raised in our response to the RFI.

[33] The Technology and Research Accelerating National Security and Future Economic Resiliency (TRANSFER) Act, H.R. 2981. *Available at* https://www.govtrack.us/congress/bills/113/hr2981/text.

[34] See: TRANSER Act Letter to Rep. Chris Collins, Rep. Derek Kilmer, Rep. Lamar Smith, Rep. Eddie Bernice Johnson, Rep. Larry Bucshon, and Rep. Daniel Lipinski, August 1, 2013. https://www.aau.edu/sites/default/files/AAU%20Files/Key%20Issues/Research%20Administration%20%26%20Regulation/Letter-Transfer-Act-of-2013-Support-8-01-2013.pdf.