

Dec. 5, 2011

To Whom It May Concern:

On behalf of the Association of University Technology Managers (AUTM), I am pleased to respond to the Office of Science and Technology Policy Request for Information: Building a 21st Century Bioeconomy

AUTM is a nonprofit organization with an international membership of more than 3,000 technology managers and business executives. These members come from more than 300 universities, research institutions, teaching hospitals, government organizations and businesses.

We believe that academic technology transfer can help harness biological research innovations to meet national challenges in health, food, energy, and the environment while creating high-wage, high-skill jobs. To do so, we must provide adequate resources for technology development, reduce risk on the part of industry partners, free up capital for development of technologies and secure funding within the USPTO for the patent approval process. Therefore, we must:

Invest in the Building Blocks of American Innovation

The doubling of funding for basic research at universities and research hospitals will drive economic progress as demonstrated by a recent study published in the *New England Journal of Medicine*. This study demonstrates that over the last 40 years, 153 new FDA-approved drugs, vaccines or new indications for existing drugs were discovered through research carried out in public sector research institutions (PSRIs)¹. The study also found that an increase of 1 percent in the funding of public basic research led to an increase of 1.8 percent in the number of successful applications for new molecular entities. The bottom line: Investment in basic research at universities and research hospitals pays off. Such funding is particularly critical as there is no movement by industry to dramatically increase its funding of early stage research as this is the highest risk research.

The federal government spends more than \$50 billion on scientific research in academic institutions each year; the Bayh-Dole Act was intended to facilitate the transfer of useful inventions that resulted from this research to the private sector. However, Bayh-Dole made no explicit provision for funding the further development and transfer of these technologies. The framers of the Bayh-Dole Act anticipated that operating expenses for technology transfer would be included in the administrative component of each institution's indirect cost base. However, in the early 1990s these costs were capped at 26

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¹ The Role of Public-Sector Research in the Discovery of Drugs and Vaccines, Ashley J. Stevens, D. Phil.; Jonathan J. Jensen, M.B.A.; Katrine Wyller, M.B.E.; Patrick C. Kilgore, B.S.; Sabarni Chatterjee, M.B.A., J.D.; Mark Rohrbaugh, PhD, J.D., The New England Journal of Medicine, vol. 364, February 10, 2011

percent. The result is that a significant portion of technology transfer costs at universities are generally not funded through administrative indirect costs.

Instead, academic institutions have had to provide their own funding for technology transfer activities. A recent study² shows that they spend only 0.59 percent of their research budgets on technology transfer, a seemingly disproportionate figure given the expectation for technology transfer offices.

The study found that for 84 percent of academic institutions in 2006, technology transfer represented a net cost to the institution, and that only 16 percent of technology transfer programs retained enough of the income they generated to cover all the costs of the function. As a consequence, many academic institutions under invest in their technology transfer function and therefore potentially promising technologies are not protected and transferred. Technology transfer should be valued and resourced properly, and each university should have the flexibility to fund technology transfer in whatever way best serves its mission.

Promote Market-Based Innovation

AUTM has worked with the higher education associations in negotiating the recent patent reform bill, the America Invents Act. We believe this Act will accelerate the process of patent approvals, and provide appropriate protection of university technologies so long as adequate funding remains under the control of the Patent Office.

The success of a startup company or small business often hinges on access to small amounts of capital. Making the Research and Experimentation Tax Credit permanent for these businesses will be a welcome relief as will the increased financial support in the Small Business Jobs Act, which the President signed into law last year.

Increase Opportunities for Collaboration with Universities by SBIR and STTR Awardees

In order to reduce the need of early stage small businesses to buy capital equipment and build facilities they cannot afford, we also recommend increasing the percentage of an SBIR and STTR award which may be subcontracted by an additional 20 percent so long as those funds are spent for renting laboratory equipment, test facilities, or prototyping facilities at universities, research hospitals, or government laboratories or for paying staff of those entities to operate that equipment or facilities. Such an increase is supportive of the President's initiative to increase access to Proof of Concept Centers in the US.

Catalyze Breakthroughs for National Priorities

Also encouraging is NIH's National Center for Advancing Translational Sciences (NCATS). It is clear the administration grasps the challenges of translating early stage technologies into usable products and services. Building a center focused on bridging this gap will offer numerous opportunities for technologies that otherwise may never be fully developed. AUTM has long been a supporter of more translational research funds and we look forward to seeing the results of NCATS.

² How Are US Technology Transfer Offices Tasked And Motivated -- Is It All About The Money? Irene Abrams, Grace Leung and Ashley Stevens, Research Management Review, Vol 17 Winter/Spring 2010, in press

Finally, we are concerned about a recommendation in the recent report from President Obama's Council on Jobs and Competitiveness. The suggestion to allow research that is funded with federal dollars to be presented to any university technology transfer office, not just the one where the research has taken place (sometimes referred to as Free Agency) would actually slow the process of commercialization. The Free Agency concept would add a new layer of bureaucracy to the technology transfer process, including the need for agreements between the inventor's institution and the licensing agent which would add considerable time to the technology transfer process BEFORE marketing and licensing could even be started, as well as potentially reducing the inventor's share of royalties through management fees assessed by the licensing agent. The concept also assumes technology transfer offices would want to commercialize another institution's technologies, when in fact MIT, Stanford University and WARF (three of the largest and oldest technology transfer offices) have all publicly stated, "It would be inappropriate for us to handle inventions from inventors outside our own institutions, and we have no interest in doing so." The administration is right to recognize in the RFI that "It is a challenge to commercialize advances in the life sciences because of the risk..." The Free Agency approach to commercialization will create more risk in the eyes of companies which would normally invest in the technologies because untangling title and ownership would be more complicated and fraught with potential legal burdens

Clearly, the members of AUTM share the administration's interest in innovation. We share the priority of accelerating commercialization of university technologies, creating a stronger bioeconomy and are willing partners in seeking out new methods and improving upon standard practices. Thank you for the opportunity to respond to this Request for Information.

Sincerely,

A handwritten signature in blue ink, appearing to read "Robin Rasor". The signature is fluid and cursive, with a large initial "R" and a trailing flourish.

Robin Rasor, CLP, RTTP
President