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June 24, 2008

Dr. Luis M. Proenza
President's Council of Advisors on Science and Technology
New Executive Office Building
Washington, D.C. 20502

Dear Dr. Proenza:

Thank you for your kind invitation to attend the April 8, 2008 meeting and to provide further comment on the recommendations of the 2003 report of the President's Council of Advisors on Science and Technology titled *Technology Transfer of Federally Funded R&D.*

AUTM greatly appreciates the opportunity to provide comments in light of experiences since the report issued. AUTM currently represents 3,500 technology transfer professionals worldwide who are building public/ private sector research, development and commercialization partnerships every day. We look forward to working closely with PCAST to ensure that university inventions make significant impacts in improving the health and wealth of the U.S. public through the development of important new discoveries and in meeting the challenges of the future.

While the PCAST report is almost exactly five years old, its findings remain highly relevant. The report summarized its conclusions to the President as follows:

Federal legislation enacted in the early 1980's allowed universities and businesses to retain intellectual property rights to the results of federally funded R&D. PCAST found this model has not only dramatically improved the Nation's ability to move ideas from R&D into commerce, but also helped enhance the return on this substantial taxpayer investment. The recent past demonstrates a record of commercial successes, including the creation of entirely new technology-based industries that are the envy of the world. Indeed, other nations are striving to replicate our model. As a result, we are not recommending any fundamental changes to our technology transfer mechanisms.

We strongly endorse this recommendation. The U.S. system of university technology transfer remains the envy of the world and is being copied widely abroad by our foreign counterparts. Its fundamental statute, the Bayh-Dole Act, has demonstrated in almost 30 years of operation that it works exceedingly well. As PCAST concluded in 2003, it should not be changed.

However, as the report recognizes, there are many steps that can be taken to improve the overall U.S. technology transfer system and provides a number of recommendations in this regard. AUTM supports these basic recommendations. However, recent changes in

the structure of the Department of Commerce raise serious questions as to how these recommendations can be implemented as outlined in the report to the President.

Listed below are our thoughts regarding the recommendations of the 2003 PCAST report. Because many of the recommendations are closely related, they have been combined under a heading describing a proposed implementation approach.

1. ***Restore the mandated oversight role of the Department of Commerce in technology transfer.***

When Congress enacted the Bayh-Dole Act creating a uniform and streamlined patent policy across all federal agencies, it recognized the need for an oversight role within the Executive branch. These functions were located at the Department of Commerce and were delegated to an Assistant Secretary with policy oversight responsibilities. With passage of the Federal Technology Transfer Act covering federal laboratories, the role of the Department of Commerce was increased to assist all agencies to effectively implement the law as well as reporting to the President and Congress how the law was being applied, its impacts and recommendations for improving it.

Six of the ten 2003 PCAST recommendations build on the Commerce technology transfer authorities to:

- Formalize oversight and accountability of technology transfer;
- Help find best practices and metrics to improve and track performance;
- Develop educational materials assisting other agencies in their complex technology transfer programs;
- Study technology transfer in the global environment, including the impact of important emerging technologies;
- Conduct agency reviews to reduce the time required to complete federal laboratory technology transfer transactions; and
- Create a centralized database at the Department of Commerce assisting the public and private sectors in technology transfer activities by listing available resources, information, educational materials and contacts.

These are all important recommendations that remain highly relevant.

Unfortunately, the abolishment of the Technology Administration of the Department of Commerce in 2007-- and the subsequent loss of the Commerce oversight role in federally-funded technology transfer-- brings implementing the PCAST recommendations into serious question. AUTM and the Council on Governmental Relations communicated our concerns with the loss of the critical oversight role for the Bayh-Dole Act to the Department of Commerce in 2007. These authorities were intended by Congress and President Reagan in his implementation plan to remain at a high policy making level at the Department.

Current proposals to delegate this unique function to the National Institute of Standards and Technology should be reconsidered. While NIST is an outstanding federal laboratory that conducts research and issues awards through its extramural program, it is not positioned to oversee implementation of the Bayh-Dole Act by other agencies, nor undertake the implementation responsibilities outlined by the PCAST report. Implementation and oversight while administering federal funding programs subject to the Act create conflict and difficulty in ensuring independent review and management.

This raises a serious potential vulnerability in the U.S. federally-funded technology transfer system. Lack of effective oversight jeopardizes our success just as international competition across the technology spectrum is reaching new heights. We must rely on our proven system of government-university-industry R&D partnerships to be successful in the future as they have been in the past. However, allowing agencies to interpret the various provisions of the Bayh-Dole Act in differing ways risks losing the uniform patent policy that is the fundamental underpinning of our system. It was for this reason that Congress charged the Department of Commerce with ensuring agency compliance with the strictures of the law. This essential safeguard in the system is now missing.

AUTM's central recommendation to PCAST is that the traditional policymaking and oversight role of the Department of Commerce in federally-funded technology transfer be restored as a headquarters function reporting directly to the Secretary of Commerce.

2. Continue the dialogue between industry, universities, and federal laboratories

One of the greatest strengths of the U.S. technology transfer system is its adaptability. The 2003 PCAST report wisely recognizes that differences in industries as well as types of technologies must be recognized in licensing practices. Similarly, it must be recognized that not all universities are alike. There are also differences in how federal agencies behave based on their missions.

Rather than trying to mandate "cookie cutter" approaches through legislation, a more effective approach would be to hold regular discussions between the stakeholders. As I mentioned in my presentation to PCAST, inherent cultural differences between academia and industry must be recognized and understood, and federal laboratories cultivate yet a slightly different culture, based upon our respective mission, principles and infrastructure. For technology transfer to succeed, every party must feel that its needs are being acknowledged. The most important part of any relationship is open communication. Many times this is best done through informal discussions where parties can talk freely. This is something that the Department of Commerce facilitated in the past and PCAST should consider how these discussions could be continued.

3. The U.S. technology transfer system responds well to new challenges

The U.S. system has proven to be the most adaptable in the world. The laws provide tremendous flexibility of approach to accommodate different technologies, fields of use, company types, and business models. This core strength should be recognized so that legitimate stakeholder needs are met, and taxpayers benefit through new products, jobs and increased public welfare.

One example of how the system can voluntarily respond to new pressures is the final recommendation of the 2003 PCAST report on balancing the availability of research tools with the needs of commercial development. NIH's long-standing policy to ensure that NIH-funded research tools are available for further research by the discovering institution as well as other non-profit academic institutions is widely acceptable among the university community. Subsequent studies have shown that some of the concerns about access to research tools that were prevalent in 2003 have not been borne out. As further evidence of the university community's embrace of this concept, several leading universities issued on March 6, 2007, *In the Public Interest: Nine Points to Consider in Licensing University Technology* and AUTM continues to encourage other universities to endorse these points. The document provides guidance on striking the correct balance in the commercialization of university technologies with the needs of an effective academic system for sharing important discoveries.

Central to this document is reserving the right for important research results to be promptly published in peer reviewed journals regardless of patent concerns, maintaining the ability for non-profit organizations to practice resulting inventions for research and educational purposes, and ensuring through appropriate structuring of any license that research tools are made as broadly available as possible. Attached is a copy of the *Nine Points* document.

The result has been a successful balance between the need for advancing knowledge while developing new products from early stage research. Thus, the concerns expressed in 2003 have been answered by the university technology transfer community regulating itself.

Periodically as new technologies emerge, the call for balancing technology transfer needs will again arise. This happened in the early 1980's when biotechnology was in its infancy. Luckily, the U.S. system proved itself equal to the task and a leadership position was achieved in this important new field while fundamental openness of research was maintained. There is every reason to trust the system to produce similar results in the future.

The 2003 PCAST report's recommendations remain highly relevant to this date. PCAST can help in the implementation of its recommendations—and the continuing success of U.S. technology transfer from research organizations—by affirming its report, helping in restoring central oversight of the Bayh-Dole Act, and continuing to provide a forum where research institutions, government agencies and laboratories, and different sectors of industry can continue to interact and learn from each other.

AUTM greatly appreciates having this opportunity to share its thoughts with the President's Council of Advisors on Science and Technology. Please let us know if there is anything we can do to assist you in the future.

Sincerely,

Janna Tom

Janna Tom
Vice President for Public Policy

Attachment: Nine Points to Consider in Licensing University Technology

Cc: Steven Papermaster, PCAST
Scott Steele, OSTP
AUTM Board of Trustees