

AAU *Association of American Universities*
AAMC *Association of American Medical Colleges*
COGR *Council on Governmental Relations*
NASULGC *National Association of State Universities and Land-Grant Colleges*

August 8, 2007

The Honorable David Wu
Chairman
House Science and Technology Subcommittee on
Technology and Innovation
2338 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Phil Gingrey, M.D.
Ranking Member
House Science and Technology Subcommittee on
Technology and Innovation
119 Cannon House Office Building
Washington, D.C. 20515

Dear Chairman Wu and Ranking Member Gingrey:

On behalf of the Association of American Universities, the National Association of State Universities and Land-Grant Colleges, the Council on Governmental Relations, and the Association of American Medical Colleges, we are writing to thank the subcommittee for its interest in and attention to the role of universities in contributing to U.S. economic competitiveness, and for the recent hearing, “The Bayh-Dole Act (P.L. 96-517): the Next 25 Years.” Given that the testimony and discussion from the hearing will provide a basis for any further deliberation by the subcommittee on this topic, we submit for the record these additional comments.

Our organizations unequivocally affirm the statements made by subcommittee members and the witnesses on the success of Bayh-Dole as a catalyst for innovation and its substantial contribution to U.S. economic growth and competitiveness over the past 25 years. In his testimony, Arundee Pradhan of the Oregon Health & Science University cited several key indicators that are worth revisiting. According to the Association of University Technology Managers (AUTM), over the past nine years approximately 3,600 new products have been introduced as a direct result of university research in a broad array of fields including medicine, public safety, food and agriculture, new materials, semiconductor devices, education, and communications; 527 new products were introduced in 2005 alone. Since 1980, more than 5,000 companies have been started based on university research, contributing to the creation of more than 260,000 new jobs. There are many examples of recent university-led innovation,¹ including

¹ See COGR, *21 Questions and Answers About University Technology Transfer*, <http://www.cogr.edu/>. Also, AUTM, *Better World Report*, <http://www.betterworldproject.net/reports.cfm>.

the start-up medical device firm, CardioMEMS, founded by hearing witness Mark Allen of the Georgia Institute of Technology. This record of economic growth recently motivated the National Governors Association to reaffirm its support for Bayh-Dole.²

We note that, significantly, all of the witnesses testified that they see no need for major legislative changes to Bayh-Dole, and that current issues could be addressed in the implementation of Bayh-Dole's existing provisions or by strengthened government oversight. Unquestionably, difficulties can arise in establishing research relationships between universities and U.S. industry. The concerns expressed in the hearing focused largely on intellectual property practices as an impediment to some university-industry collaborations. However, other overriding aspects of academic culture—and academic freedom—enter into all university arrangements, and directly or indirectly may contribute to the challenges encountered by some commercial firms in these negotiations. Such issues include freedom to publish (including the ability to publish negative results), sustaining an open environment for faculty and students conducive to training new scientists and workers, management of conflicts of interest, honoring philanthropic commitments, and generally safeguarding an institution's academic mission.

The occasional inability of industry and academic institutions to conclude a negotiation does not necessarily indicate a weakness of the system. Most universities, we believe, correctly focus on technology transfer as a public benefit and, consistent with the provisions of Bayh-Dole, work to see that the development of new technologies is not held back by either academic institutions or by industry.

Numerous successful academic-industrial collaborations have been established over the past 25 years and others continue to arise, spanning many industrial sectors and fields of research. We believe that the issues highlighted by some of the witnesses regarding impediments they have encountered in specific circumstances must be viewed with this in mind. This is not to diminish the potential significance of the witnesses' experiences, but we offer a caution that attempting to remedy problems encountered in a few situations may create problems for many other collaborations, most of which appear to work successfully. It also is important to keep in mind that the provisions of the Bayh-Dole Act itself do not directly address mechanisms for industry-university collaborations, nor should they.

Several witnesses commented that university technology transfer to industry appears to work more smoothly for pharmaceuticals and biotechnology than other industry sectors. We are not certain that this distinction is as pronounced as implied in some of the statements at the hearing. However, it is the case that university technology licensing offices tend to have the most experience with these areas of research (as life sciences receive the largest share of federal support for university research). To the extent that this observation is valid, it may support our view that the majority of existing difficulties can be attributed to the technology-transfer learning curve for universities and companies alike.

Near the end of the hearing, industry witnesses expressed the view that the Bayh-Dole Act inadvertently creates expectations among universities that industry should assign them intellectual property rights resulting from industry-sponsored research, contrary to industry preference. These witnesses also noted that federal tax issues may arise if universities pre-commit rights to technologies based on research conducted in facilities supported with tax-exempt debt financing. They suggested that these issues might need clarification. Even absent Bayh-Dole or tax concerns, universities are usually not at liberty to

² National Governors Association, Policy Position EDC-04.5.4, July 24, 2007, <http://www.nga.org/portal/site/nga>.

assign patent title or ownership rights because such actions might prevent continuation of important lines of research and have an adverse impact on faculty or students. There also is potential for conflicting obligations because university laboratories typically are supported by multiple sponsors, including federal, state, and local governments, philanthropic foundations, their own endowments, and commercial and non-profit organizations, all of which contribute to university research. We do not believe that amending Bayh-Dole or federal tax law could safeguard these academic concerns or resolve the issue of assigning ownership rights to a specific company when several sponsors may have contributed to the new technology. While assertions were made at the hearing about the behavior of institutions in other countries with which some U.S. firms seek collaborations, it is not clear that practices of those institutions have relevance for U.S. universities. Rather, our sense is that more nations are adopting policies similar to Bayh-Dole. Moreover, we are not aware of any data that support assertions that adverse negotiations with U.S. universities are causing industry to “off-shore” research and development (R&D) that otherwise would be performed at U.S. institutions.

We agree that, to the extent real deficiencies are encountered in technology transfer, universities and their federal and industry partners have the ability and bear the responsibility to optimize the process and protect the public’s interest. In the spirit of protecting the public good, several academic organizations convened recently to develop a white paper on best practices in licensing, “In the Public Interest: Nine Points to Consider in Licensing University Technology,” which was published in March.³ Among other elements, the paper affirms that university licenses should not excessively restrict other areas of R&D and should protect, in drug development for example, the interests of vulnerable populations and developing countries. In the months since the participating organizations developed these principles, additional universities and associations (including AUTM) have signed on to the document. Other academic coalitions, or AUTM, may develop similar statements of good practices and related resources to help academic institutions strengthen their professional capacities for negotiations with industry (e.g., helping to minimize unwarranted variances in academic licensing practices that may contribute to perceived difficulties). The university community and industry also have made several efforts to develop common frameworks for collaboration. These include activities undertaken by the Business-Higher Education Forum and, more recently, the University-Industry Demonstration Partnership. The cultural differences between universities and industry, given their different missions, make these activities particularly challenging. However, the dialogue has been ongoing and, as noted, there are many examples of successful collaborations.

In conclusion, we believe that by focusing specifically on programs and mechanisms that promote industry-academic-federal collaborations, and by continuing to champion increased funding for the National Science Foundation and other federal science agencies, the subcommittee and the full committee have the best opportunity to promote the next generation of innovation. In our view, these approaches provide more productive alternatives for encouraging innovation and U.S. competitiveness than changes to the proven, successful structure of the Bayh-Dole Act itself. We note especially Chairman Wu’s opening statement that the subcommittee also will hold a hearing on the Stevenson-Wydler Act, which will examine the progress of industry collaborations with federal laboratories. We look forward to that discussion.

³ Available at AUTM, http://www.autm.net/ninepoints_endorsement.cfm.

We are, again, grateful to the subcommittee for its consideration of these views, and would gladly respond to questions or provide other assistance as requested.

Sincerely,



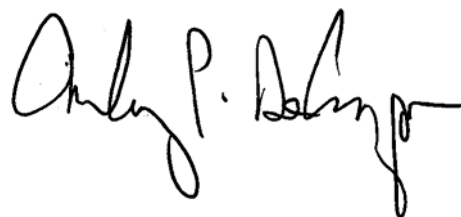
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