University Working Group Observations on NIH Report on Return on Investment in Drug Research

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The National Institutes of Health has delivered to Congress a report mandated by last year's Labor/HHS appropriations bill. The report is available on the NIH website at: http://www.nih.gov/news/070101wyden.htm.

We commend the NIH for its thoughtful and comprehensive response to Congress' request for analysis of the public interest in securing an appropriate return on the nation's investment in basic research.

- This is an excellent report and one that illuminates the essential role of publicly funded research in drug development.

Key among the NIH's conclusions is the finding that, two decades out from the inception of Bayh-Dole, the nation's system of biomedical discovery and technology transfer is working well.

- As a direct result of Bayh-Dole, academic institutions across the country have established a strong national technology-licensing infrastructure that encourages the practical application of basic research results for the broad public benefit.

- These patenting and licensing efforts have fostered the commercialization of innumerable technological advances that positively affect the lives of millions of people across the nation-yielding products and processes that diagnose disease, reduce pain and suffering, and save lives.

- As a by-product, such innovation has stimulated economic development at local, regional and national levels.

In terms of return on investment, the NIH confirms that taxpayers are realizing significant returns under the current system. After analyzing the available literature, the report notes that the studies are consistent in that they find "that there are both monetary and intangible benefits of remarkable value that are gained from federally funded biomedical research."

The NIH report also reminds us that the question of the taxpayers' return on investment in biomedical research was debated both at the time the Bayh-Dole Act was under consideration and in the years following passage of the law.

- Various changes to the current system for patenting and licensing federal research results have been considered, including proposals to recoup the federal investment for technologies that reach commercialization and proposals to enforce reasonable pricing for those technologies.

- The NIH's discussion of these proposals makes clear that such modifications could undermine the significant public benefit our nation now enjoys.

Two additional, major findings included in the report warrant special attention.

- While federal support has been essential to advances in medicine and biology, direct contributions to therapeutic products have been limited. One important corollary is that actual financial return to NIH grantees and contractors are relatively low. For example, the report's analysis of pharmaceutical sales data shows that, of a total of 47 FDA approved drugs meeting the threshold of $500 million per year in annual sales in the U.S., NIH could identify only four that were developed with NIH grant support.

- Second, that same analysis shows the difficulty of tracing the linkages from basic research to royalties. According to NIH, determining which of the 47 drugs that have reached the $500 million per year threshold can be tied back to NIH funded intellectual property was difficult, in part because the implementing regulations of Bayh-Dole do not require that that information be provided. According to the report, this lack of information is a key obstacle to systematic analysis of questions such as those posed by Congress in calling for the present report.

In conclusion, we applaud the NIH's analysis of return on investment and we commend the agency for carefully and comprehensively examining this important issue. This report will help the public understand the substantial return our nation enjoys from federal investments in biomedical research.

The report illuminates the wisdom of Congress in crafting the seminal legislation that created our nation's system of innovation, education, and discovery.

Universities support access to publicly funded products and technology and to affordable prescription drugs. In the current context, however, it is essential to understand that neither the NIH nor our own institutions have a role in affecting the price of drugs.

We appreciate the benefits of enhanced data tracking and reporting in illuminating the significant contributions NIH makes to FDA-approved drugs. We plan to work with the NIH to formulate such systems in ways that minimize administrative costs and burdens. A single government-wide system to report data on federally funded inventions for all agencies would be preferable.

We support also the NIH's call for continuing dialogue in this arena and we stand ready to join our colleagues in discussion of ways to preserve and to enhance our nation's remarkable biomedical enterprise.