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March-in Rights Under Bayh-Dole

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COGR sent comments on march-in rights under the Bayh-Dole Act to the Office of Technology Transfer at the National Institutes of Health

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COUNCIL ON GOVERNMENTAL RELATIONS

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April 5, 2004

Dr. Mark Rohrbaugh
Director of the Office of Technology Transfer
Office of Intramural Research
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852

Dear Dr. Rohrbaugh:

The Council on Governmental Relations (COGR) is an association of 150 of the leading research universities in the United States and several affiliated hospitals and research centers. COGR focuses on understanding federal policies and complying with federal regulations pertaining to sponsored research at universities. Among the most important policies and regulations of interest to our members are those pertaining to the transfer of federally funded research results at universities to the private sector under the Bayh-Dole Act of 1980 (P.L. 96-517; 35 USC 200-212).

The Bayh-Dole Act plays a critical role in enabling university innovations that have been crucial to U.S. economic growth and competitiveness. Bayh-Dole established the major mechanism for successfully transferring federally funded research results from the laboratory to products and services, which benefit all Americans. Bayh-Dole's success is derived from its consistency with America's commitment to free market principles and incentives.

Many studies have demonstrated the phenomenal success of the Bayh-Dole Act. For example, according to an article in the December 12, 2002, *The Economist*, "The Bayh-Dole Act of 1980 is perhaps the most inspired piece of legislation to be enacted in America over the past half-century....this unlocked all the inventions and discoveries that have been made in laboratories throughout the United States with the help of taxpayers' money...."

We understand that NIH has been asked to answer recently submitted petitions for exercise of march-in rights that, according to the authors of the legislation, Senators Birch Bayh and Robert Dole, are based on a fallacious premise. March-in rights accrue to the government only for the purpose of ensuring prompt commercialization of federally funded inventions and to avoid the possibility of companies stifling the development of new products. The legislation does not empower the government in any way to influence or to dictate licensing or commercialization terms for technologies. NIH itself has confirmed this interpretation (NIH Plan to Ensure Taxpayers' Interests are Protected, July 2001).

NIH may feel challenged to review its longstanding interpretation of the conditions under which the government may exercise march-in rights. Given the critical role played by the Bayh-Dole Act in the continuing success of university technology transfer, COGR believes that any proposed change to such a longstanding interpretation should be subjected to close scrutiny. If this were to become necessary, all stakeholders in the continuing success of technology transfer from universities should participate fully in the consideration of the scope of government march-in rights to ensure that the public-private partnership in innovation is maintained.

COGR is concerned that a substantial reinterpretation of the Bayh-Dole's march-in provisions could undermine the ability of universities to make their federally funded technologies available for public use. Any such change in march-in authority or in expanding their exercise by government agencies could result in the loss of the very delicate balance of rights and obligations between the three partners - government, universities and industry - which has been the basis for the success of this legislation. History has proven how important incentives are for encouraging technology transfer from the universities. It would be ironic, indeed, if a change in the current understanding of march-in rights were to impair the dissemination of, and public benefit from, university research results.

For these reasons, COGR urges the NIH to make a strong statement in support of the proper exercise of march-in rights as stated by Senators Bayh and Dole, which was recently reconfirmed in their letter dated April 11, 2002 in the Washington Post. NIH surely is aware of the importance of the Bayh-Dole Act to public-private partnerships in innovation. We see no reason to tamper with this proven platform for promoting government investment in discovery and its application for public use and benefit.

Sincerely,

Katharina Phillips