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COMMITTEE ON THE JUDICIARY SUBCOMMITTEE ON THE CONSTITUTION WASHINGTON, D.C. 20510

July 24, 1978

Dear Colleague: Potent Rights and

We plan to introduce next week the enclosed "University and Small Business, Research Utilization Act," of 1978", and we seek your support as a co-sponsor. The purpose of the bill is to encourage utilization of inventions arising from government-supported university and small business research. The bill addresses a serious and growing problem: Hundreds of valuable medical, energy and other technological discoveries are sitting unused under government control because the government which helped finance their development can not commercialize them and patent rights are not available to encourage private industry to develop them into products available to the public.

Specifically, this bill will allow universities, non-profit organizations and small business, under limited circumstances, to obtain a degree or patent protection on discoveries they have made under government-supported research, if they spend the additional private resources necessary to bring such discoveries to the level of public availability. Patent rights would not be available to large businesses for such inventions. The bill also would create specific exemptions if the contract is for operation of a government-owned research or production facility, if the research is classified, or if there are exceptional circumstances which lead the contracting or granting agency to conclude that granting patent rights would not be in the public interest.

This legislation has broad support among the scientific, academic and small business communities, and it would cost the government nothing. Indeed, the government stands to have part of its research funds replenished under a provision of this bill which would require the patent holder to reimburse the federal research money out of royalties and income.

HOWARD M. METZENBAUM, OHID JAMES B. ALLEN, ALA. JAMEE ABOUREZK, B. DAK. WILLIAM L. BOOTT, VA. DRRIN G. HATCH, UTAH

NELS ACKERSON, CHIEF COUNSEL AND EXECUTIVE DIRECTOR MARY K. JOLLY, STAFF DIRECTOR KEVIN O. FALEY, GENERAL COUNSEL The limited form of protection afforded by this bill is a prerequisite for making government-supported inventions available to the public. Science Magazine described the dilemma now faced by our government and private industry as follows:

> We see a prodigious R & D enterprise, fueled by tax dollars, constrained from diffusing its results because of a public policy barrier. Throughout the enterprise, discoveries sit stranded and aging. Meanwhile, we search for clues to what is wrong with U.S. technological innovation, and how it is that <u>for</u> an industry can undercut American competition and employment. for Click

Although there are several government policies which may have a bearing on this issue and should be studied, the primary policy barrier identified in the <u>Science Magazine</u> article is the federal government's reluctance to grant patent rights for inventions developed under government contract and grant programs.

Inventions derived from government sponsored research often are unintended by-products of the program, and since most government sponsored research is basic research rather than applied research the inventions often are in an embryonic stage of development. Consequently, if the innovation is ever to be developed for public use, substantial additional expenditures for product development and commercialization by the private sector are required. It has been estimated that product development costs exceed the funds contributed by the government toward the initial research leading to such inventions by a factor of at least 10 to 1. This, together with the known failure rate for new products, makes the private development process too risky unless the incentive of limiting patent protection is available for the new product.

The present government patent policies are determined by statute in some departments, but in most departments and agencies they are governed only by regulations and rules. The problem is substantial in HEW, the Department of Defense, the Department of Agriculture, the National Science Foundation and the Department of Energy. But, for the purpose of an example, nowhere is the problem more disturbing than in bio-medical research programs. There is no doubt that people have been condemned to needless suffering because of the refusal of agencies to allow universities, non-profit corporations and small businesses sufficient incentives in the form of patent rights to bring new drugs and medical instrumentation to the marketplace. The exact magnitude of this situation is unknown, but the enclosed partial list of applications that are pending before HEW indicates the potential for human benefit that is being delayed or abandoned.

We believe it is time to overcome this barrier to full public availability of the benefits from our federal research effort and to replace the present inconsistent pattern of departmental and agency policies with a clearly conceived federal patent policy to encourage the movement of useful governmentsupported inventions to the people. To this end we are introducing the enclosed "University and Small Business Research Utilization Act, bf-1978", and we seek your support as a co-sponsor. If you would like to co-sponsor or if you have any questions please see either of us or call Barry Leshowitz at 42028 or Joe Allen at 49263.

Sincerely yours,

Patent Rights and

BOB DOLE

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