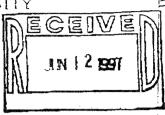
COLUMBIA UNIVERSITY

ARBY WER OF YORK

CRESIDENT S ROOM

June 10, 1997



Dear Harold:

You have been asked by CellPro Inc. to exercise "march-in rights" under the Bayh-Dole Act in its dispute with Johns Hopkins University over patents for stem cell transplantation technology. I write to urge you to deny CellPro's request.

The central purpose of the Bayh-Dole Act was to encourage the commercialization of federally funded university research by creating a set of incentives for the establishment and implementation of university-industry partnerships. By providing patent protection to universities and by assuring the exclusivity of licensees who invest substantial sums in product development, the Act creates an environment in which research results can be rapidly and efficiently transformed into useful products. To guard against the possibility that a university might not take steps to license its inventions or that a licensee might not make efforts to design and develop useful products, the Act contains a "march-in rights" provision. But neither of these two conditions apply in this case. Johns Hopkins has, in fact, licensed the technology and the licensee, Baxter Healthcare, has developed a product that is pending FDA approval. The federal district court has determined that CellPro has infringed on the Johns Hopkins' patents in marketing a therapeutic device based on the patented invention. Because potients are currently receiving treatment using the CellPro product, Johns Hopkins has proposed that CellPro be allowed to continue selling the technology until the FDA approves a licensed system for sale.

The Bayh-Dole Act has been successful in assuring public access to the results of federally funded research. There is no reason to call upon the "march-in" provision in a case in which a university-industry partnership has resulted in licensing and product development just as envisioned by the Act. In addition to penalizing those who have acted under the letter and spirit of the Act, a decision to invoke the "march-in" provision would threaten the future effectiveness of the Act by creating an atmosphere in which both universities and industries will be forced to question whether the protections of the Act will, in fact, be provided. Incentives for developing useful technologies that could flow from university research would be weakened and the potential public beneficiaries of the technologies would be the losers.



Harold Varmus, M.D. Director National Institutes of Health Building 1, Room 126 Bethesda, MD 20892

bcc: John Brody

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