DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of the General C

Public Health Division
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June 13, 1997

Donald R. Ware, Esq.
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One Post Office Square
Boston, MA 02109-2170

Dear Mr. Ware:

The National Institutes of Health (NIH) is in the process of reviewing the various submissions that you have made on behalf of The Johns Hopkins University in connection with CellPro Incorporated's petition requesting that the Department of Health and Human Services exercise its march-in rights under the Bayh-Dole Act, 35 U.S.C. 200 et seq., in connection with certain patents owned by Hopkins. In this regard, we have various questions, which are set forth below.

As you know, CellPro has asserted that if the injunction proposed by Johns Hopkins issues in its present form, CellPro's ability to remain in business will be impaired or that it may even be forced to close down its operations. In your June 2, 1997 letter to Wendy Baldwin, you state that if CellPro abandons a site that does not currently have a Baxter system:

> Baxter will install its device at the CellPro site free of charge and will provide that site the same support CellPro was providing on the same contract terms. It will also provide all necessary clinical, regulatory, and technical support to put the Baxter system into operation as quickly as possible.

We assume that you are making this commitment as an alternative to modifying the proposed injunction. While we are encouraged by this commitment by Baxter, we have some questions and concerns regarding its implementation. Have you considered whether the Food and Drug Administration (FDA) would permit such a substitution of the Baxter device for the CellPro device and what regulatory approvals would be required? Also, have you considered the need for and time required to obtain Institutional Review Board approval for any ongoing clinical trials where the Baxter device would be substituted for the CellPro one? In addition, can you inform us at what institutions the Baxter device is currently in place and, if such figures are available, the number of patients that have been treated at such sites? Moreover, how will Baxter cover any

patients who are not enrolled in clinical trials? In sum, we are interested in learning in greater detail how and in what time frame Baxter's proposal could be accomplished, if necessary, and the extent to which it would, in fact, cover the public health need for this technology.

In addition, we note the recent news about Baxter's proposed alliance with VIMRx to form a new cell therapy company. According to the June 12, 1997 press release, a definitive agreement is not expected until the third quarter of 1997. Nonetheless, in the event that Baxter's device is not approved at that time and no other resolution of the current dispute has been reached, can you please explain how Baxter intends to fulfill its commitment to install its device any place the CellPro device has been removed if Baxter is only a minority owner with one representative on the board of directors of the new company.

We would greatly appreciate hearing your response to these issues. To the extent that you answers to these questions may, in part, be covered by information that you have already provided, please reference that information rather than sending us duplicates.

Sincerely,

Robert B. Lanman
NIH Legal Advisor