



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

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Office of the General CounselPublic Health Division  
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June 24, 1997

Donald R. Ware, Esq.  
Foley, Hoag & Eliot, LLP  
One Post Office Square  
Boston, MA 02109-2170

Dear Mr. Ware:

I am responding to your June 20, 1997 letter to Ms. Barbara McGarey in which you object to the National Institutes of Health (NIH) receiving any further submissions from CellPro in connection with its march-in petition and argue that "any decision to initiate a march-in proceeding based upon information submitted by CellPro to which Hopkins has not had an adequate opportunity to respond would be inconsistent with the regulations and administrative due process."

In our view, both parties have been given ample opportunity to set out their respective positions to the agency. The regulations, 37 CFR § 401.6(b), simply state that the agency shall "request informal written or oral comments from the contractor as well as information relevant to the matter." They do not anticipate responsive litigation-style briefing between parties or any right by the contractor to have the last word. Accordingly, we do not intend to tell either Hopkins or CellPro that further submissions are not permitted. We selected July 2 as a deadline for submissions because we felt that date would ensure sufficient time for review prior to the decision by NIH. However, if any submission made by one of the parties by July 2 raises matters that we believe requires response by the other party, we will either pose questions to that party directly or provide additional time for a reply, provided that sufficient time will remain for our consideration of the reply.

Sincerely,

Handwritten signature of Robert B. Lanman in cursive.

Robert B. Lanman  
NIH Legal Advisor

cc: B. McGarey

