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Hartford Hospital, Hartford, Connecticut

December 23, 1999

Docketts Management Branch
(HFA - 305)
Food and Drug Administration
360 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket #97N-484S
Suitability determination for donors of human cellular and tissue base projects

To Whom It May Concern:

This letter is written to express my strong objection to the recent requirement regarding freezing and subsequent quarantine of donor eggs prior to transfer to the appropriate recipient. This rule will have a significant negative impact on the many patients who undergo therapy requiring donor embryos. There is no evidence stating that donor oocytes have been implicated in transmission in HIV or other infectious disease. No scientific papers supporting this allegation have been documented and as far anybody knows no instances of HIV transmission from donor eggs has been documented since this procedure has been instituted greater than 20 years ago.

Quarantining embryos and transferring only frozen embryos will have a significant impact on both healthcare costs and pregnancy rates. Pregnancy rates from transfer of frozen embryos are significantly lower than transferring fresh embryos. The pregnancy rate from transferring frozen embryos is approximately $\frac{1}{2}$ that of frozen embryos. This will significantly increase the cost to these patients and also increase anxiety and possibly health risks in women delaying childbirth. Although it is clear that quarantining and freezing sperm is warranted and is necessary and excepted practice. Quarantining and freezing oocytes carries a much different risk for transmission of disease and in my opinion it is an unjustified practice that will have a significant negative impact.

Sincerely,

Linda M. Chaffkin, M.D.
Associate Director
Hartford Fertility and Reproductive Endocrinology Center, P.C.

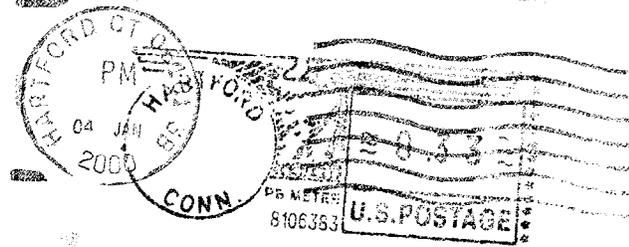
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