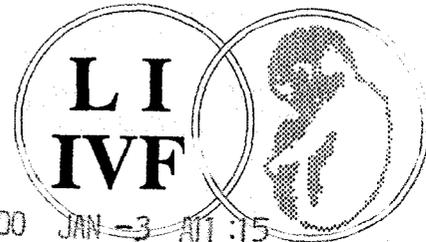


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DANIEL KENIGSBERG, MD



1417 '00 JAN -3 AM 1:15

December 17, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5360 Fishers Lane
Room 1061
Rockville, MD 20852

Dear FDA:

I am writing regarding Docket #97N-484S, Suitability Determination for Donors of Human Cellular and Tissue Based Products. Within this document, there is a recommendation that embryos that result from oocyte donation have mandatory cryopreservation and quarantine for six months. Although this is analogous to donor sperm recommendations, it is not analogous in terms of the definite decrement and efficacy of not using fresh embryos, as opposed to frozen embryos, and it vastly will increase the already substantial cost for these procedures. Furthermore, although there have been documented cases of infectious disease transmission from donor sperm used fresh, I am not aware of any infectious disease transmission from donor oocytes. Furthermore, in the pre-cryopreservation days of donor sperm, the extensive infectious disease screening now applied to donors of all gametes was not universally practiced.

Therefore, I would urge you not to require the cryopreservation of embryos resulting from donor oocytes. Although there are theoretical concerns, there is no evidence of the transmission of infectious disease from these procedures using current standards of donor screening. The imposition of the proposed standards will most definitely decrease efficacy, increase cost and otherwise cause definite harm to patients who have, thus far, been completely unharmed from these procedures practiced under the ASRM guidelines.

Sincerely,

Daniel Kenigsberg, M.D.

DK/cjm

cc: Joyce Zeitz

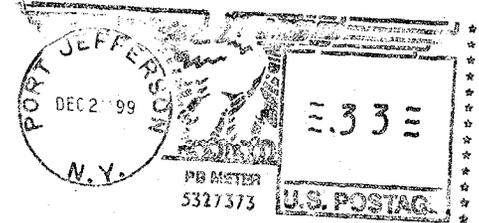
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97N 484S

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Address Correction Requested



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