ASSISTED REPRODUCTIVE TECHNOLOGY

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9377 '99 DEC 22 A10:29

December 20, 1999

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

Re: Docket #97N-484S, Suitability Determination for Donors of Human Cellular and Tissue-Based Products

To Whom It May Concern:

We are greatly dismayed at the proposal of the FDA to require quarantine of donated human eggs through embryo cryopreservation.

There is no evidence that oocytes, embryos or isolated sperm cells used with in vitro fertilization/embryo transfer are vectors of the diseases listed in the, FDA proposal. HIV or other infectious diseases are not passed by IVF-ET. No specific papers claiming this have been found. No HIV has been contracted from IVF in 21 years as far as anyone knows.

Quarantining embryos will significantly increase costs and will increase the numbers of cycles needed to obtain the same pregnancy rate. Quarantining embryos will decrease the success rate for donor IVF.

There will be unnecessary deaths of embryos from the proposed rules to mandate freezing.

Additionally, increased delay causes anxiety and"&&ble increased health risks in the woman delaying childbirth.

We request that you re-assess this proposal. Thank you.

Sincerely,

Kathryn L. Honea MD Virginia L Houserman, MD. Cecil A. Long, MD

Kathryn L. Honea, M.D. Virginia L. Houserman, M.D. Cecil A. Long, M.D.

/mh 97N 484S

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