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DOCKETS MANAGEMENT BRANCH (HFA-305)
Food and Drug Administration
5360 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket # 97N-4845, Suitability Determination for Donors of Human Cellular and Tissue-Based Products.

To Whom It May Concern:

As a reproductive endocrinologist actively involved in assisted reproduction, I have strong objections to certain provisions of Docket # 97N-4845, particularly the proposed requirement to quarantine embryos resulting for donor oocytes for 6 months. This will have a devastating impact on the patients and drive up the costs of donor oocytes and the required technical support. First and foremost, there is no evidence to suggest that HIV is transmitted in oocytes, embryos or isolated sperm cells, (or any other infectious disease, for that matter) nor any reports of HIV contracted through IVF procedures under the current screening process. Thousands of embryos will be lost in the cryopreservation process as well, with a tremendous loss of potential human lives.

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From an economic standpoint, multiple embryo transfer cycles will be required to achieve similar pregnancy rates as the success with a cryopreserved embryo is approximately 50% less than with fresh embryos. Therefore costs will be increased by increased need for cryopreservation and storage

97N 4845

RE: DOCKET #97N-4845

From an emotional standpoint, undue delay in embryo transfer will cause increased anxiety and possible increased health risk to women delaying childbirth.

In summary, there is no scientific justification for the proposed interference by the FDA in the practice of Reproductive Medicine. Quarantining would increase costs, decrease pregnancy rates, and cause unnecessary death of human embryos, as well as delay childbearing in an already older patient. It must be stressed that fresh semen carries with it a much different risk for disease transmission than the hypothetical (and never proven) risk associated with isolated / washed sperm cells, oocytes and embryos. Thank you for your attention and consideration to appropriate modification of Docket #97N-4845.

Very truly yours,

Michael Blot MD