

APPALACHIAN FERTILITY AND ENDOCRINOLOGY CENTER

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

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

Dear Sirs:

The Food and Drug Administration has recently published in the *Federation* on September 30th, 1999, proposed rules regarding donor egg IVF.

While many of the proposed rules are quite acceptable, a totally unacceptable rule has been proposed. It will require an egg donor to be tested prior to the donor egg cycle and to freeze the resulting embryos and quarantine them until six months later when the egg donor is retested for infectious diseases. While quarantining sperm or semen prior to use for insemination purposes is acceptable to prevent infectious diseases, there has been no evidence that oocytes, embryos or even isolated sperm cells used within IVF-ET are vectors of any infectious disease. HIV or other infectious diseases are not passed by IVF-ET. There have been no scientific papers ever indicating that this is the case nor has anyone ever contacted HIV or any other infectious disease from IVF in the twenty-one years that IVF has been performed.

Quarantining embryos will significantly increase cost and increase numbers of cycles needed to obtain the same pregnancy rate. When embryos are frozen and then thawed, the success rate is at least half as much as it would be in our particular center. There will be unnecessary loss of embryos from the proposed rules required to mandate embryos and, therefore, a terrible psychological result with patients because of this unnecessary rule. This six-month delay would be totally unacceptable for patient anxiety and possibly even increase health risk in women delaying their childbirth. We, therefore, request that this particular aspect of the proposed regulation be removed. It does appear that there is no understanding by the FDA that using semen carries with it a much different risk of transferring disease than the hypothetical risk (so far no risk) associated with use of isolated and washed sperm cells, oocytes and embryos.

Sincerely,



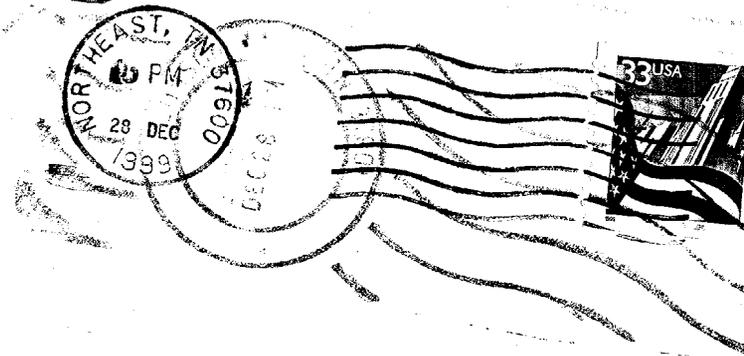
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