CNY Fertility Center

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12-19-99

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

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

I am writing in protest of the proposed guidelines regarding donor embryos. I am against the quarantining of Donor eggs or embryos for IVF-ET. I agree with the comments of the American Society of Reproductive Medicine and Society of Assisted Reproductive Technology.

1. There is no evidence that the oocytes, embryos or isolated sperm cells used with IVF-ET 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 and no HIV has been contracted from IVF in 21 years as far as anyone knows.

2. Quarantining embryos or eggs will significantly increase the costs and will increase the number of cycles required to obtain the same pregnancy rate. The approximate costs of a cycle will increase from $10,000 to more than $15,000 with a significantly reduced pregnancy rate. Thus excluding this treatment option from many infertile couples. The average cost of a baby from this procedure would rise from $30,000 to $150,000.

3. Quarantining embryos or eggs will decrease the success for donor IVF. Frozen embryo cycles have about a 10% success compared to about 30% in fresh cycles.

4. There will be unnecessary deaths of embryos from the proposed rules to mandate freezing. Since only a small proportion of embryos survives the freeze-thaw process fewer couples will experience a successful outcome.

5. Increased delay causes anxiety and possible increased health risks in the woman delaying childbirth.

I believe that the FDA is interfering with the practice of medicine by attempting to require the unjustified quarantining of embryos resulting from donor egg IVF. There is no scientific evidence that the current methods of prescreening oocyte donors for infectious diseases are inadequate. Quarantining would significantly increase costs, reduce success rates, cause significant increase in anxiety and cause unnecessary delay in childbirth in already older women.

It is my recommendation that the FDA not implement this proposed guideline. Thank you for your consideration in this matter.

Sincerely
Linda O'Brien
Linda O'Brien, MA
CNY Fertility Center, Director.

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SYR 132 12/21/99 #8 19:21 MAILED FROM ZIP CODE 13215

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