



Reproductive Medicine Center

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0299 '99 DEC 28 A9:42

December 21, 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:

I am writing to oppose the proposed regulation requiring freezing of all embryos resulting from egg donation. At the present time, this is an extremely successful procedure offering the possibility of pregnancy to many couples where it would otherwise be impossible. To subject all embryos to cryopreservation prior to transfer would significantly reduce the success of donor programs. We would estimate that it might decrease the likelihood of pregnancy by roughly 50%. At the present time the pregnancy rate in our clinic for donor ova is approximately 50% per cycle. At our center, the donor provides ova for two recipients; i.e. we would expect one-half of the recipients to become pregnant in any given cycle. Subjecting the embryos to freezing and thawing would reduce this to only one in four recipients and lead to the demise of many more embryos and potential human beings.

I am unaware of any evidence that suggests that HIV or other infectious diseases can be transmitted by these embryos. The additional need for freezing would therefore, increase the costs and anxiety for the recipient couple by interposing an additional requirement for which there is no evidence of benefit.

Sincerely,

Theodore C. Nagel, M.D., F.A.C.O.G.

TCN:skf
12/21/99

97N 484S

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359