



0469 '99 DEC 28 AM 106

December 22, 1999

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DIPLOMATE:
AMERICAN BOARD OF OBSTETRICS AND GYNECOLOGY
SUBSPECIALTY CERTIFIED:
DIVISION OF REPRODUCTIVE ENDOCRINOLOGY
FELLOW:
AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS
AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE

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

To Whom It May Concern:

I am writing in regard to the proposed rules concerning the utilization of donor oocytes. I am particularly concerned by the proposed rule requiring testing of the oocyte donor prior to the donor egg cycle, freezing of the resultant embryos and quarantine for six months until the donor can be retested for infectious diseases, and only then allowing use of those embryos. This particular rule will effectively eliminate the use of fresh embryos from donor oocytes. This is the most successful ART procedure performed today. It will require that all patients using a donor egg will only receive embryos that have been frozen for 6 months. The success rate will be decreased by at least 50% and the cost will be increased by several thousand dollars. This clearly is not warranted by the data available today.

There is no current evidence that oocytes, embryos or isolated sperm cells used with IVF-ET are vectors of the diseases listed in the FDA proposal. To my knowledge, no HIV has been contracted from IVF in 21 years. Quarantining of these embryos will only result in increased costs for patients and decreased success rates while causing the unnecessary death of many embryos. This will also delay pregnancy in an already older patient leading to more anxiety in the patient as well as increased risks. There seems to be no understanding by the FDA that using semen carries with it a much different risk for transmission of disease than the hypothetical risk (so far no risk) associated with the use of isolated and washed sperm cells, oocytes and embryos.

I hope that on review you will realize that this portion of the proposed rule should not be implemented.

Sincerely,

George A. Hill, M.D.
Medical Director, Nashville Fertility Center

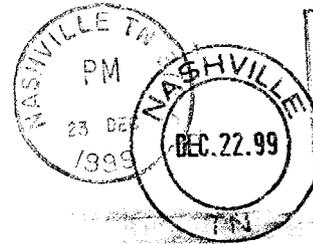
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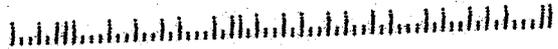
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RETURN SERVICE REQUESTED

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