

TULSA CENTER FOR FERTILITY & WOMEN'S HEALTH

December 20, 1999

0471 '99 DEC 28 AM 06

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

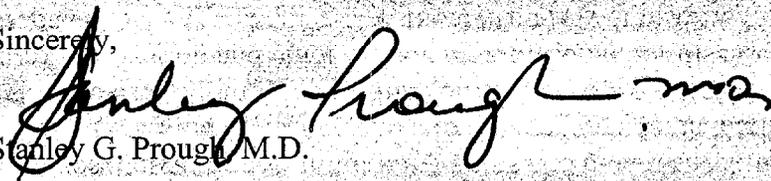
RE: Docket #97N-484S
Suitability Determination for Donors of Human
Cellular and Tissue-Based Products

Dear Sir or Madam,

Under your suggestions for the "Suitability Determination for Donors of Human Cellular and Tissue Based Products", many of the proposed rules are indeed acceptable. However, I do find objectionable the requirements regarding donor egg cycles. The requirement to test an egg donor before the donor IVF cycle, freeze the resultant embryos, quarantine them for six months and then rechecking the donor at that point in time and only then releasing the embryos for transfer is totally unacceptable. There is no evidence existing that shows that oocytes, embryos or isolated sperm cells used in in-vitro fertilization and embryo transfer are vectors for disease transmission under this proposal. As far as I am aware, there is no HIV transmission via IVF or any other assisted reproductive technology in the past 21 years of its existence. To freeze all embryos for a quarantine period will decrease the success rate for in vitro fertilization in that a large number of these embryos will be lost because they do not survive the freeze/thaw cycle. The quarantine of these embryos will significantly increase the cost and the number of cycles needed to obtain the same pregnancy rate. Also, the use of frozen versus fresh embryos is a marked decrease in success rate of probably at least 50% over that of a fresh cycle. Not only that, we must consider along with the financial implications, the emotional and psychological implications of this on the couple.

In summary, I would suggest that this attempt to require quarantine of embryos resulting from donor egg in vitro fertilization in preparation for in vitro fertilization has no scientific basis under your current recommendation. Quarantine would increase costs, decrease the success rate and cause unnecessary loss of embryos as well as a delay in the attempt for pregnancy in an already older patient.

Sincerely,


Stanley G. Proug, M.D.

Cc: Joyce Zeitz
Fax#: 205-978-5005

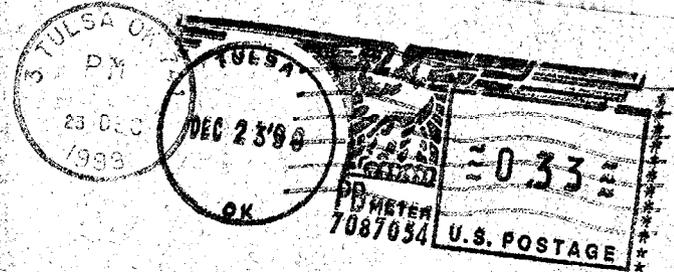
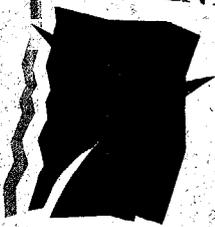
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