

VERKAUF, BERNHISEL & TARANTINO, M.D.'s

Gynecology
Reproductive Endocrinology & Infertility

BARRY S. VERKAUF, M.D.
MARC A. BERNHISEL, M.D.
SAMUEL TARANTINO, M.D.

0470 '99 DEC 28 AM 06

DIPLOMATES AMERICAN BOARD
OBSTETRICS AND GYNECOLOGY
SUBSPECIALTY CERTIFIED,
REPRODUCTIVE ENDOCRINOLOGY
& INFERTILITY

December 20, 1999

Dockets and Management Branch (HFA-305)
Food and Drug Administration
5360 Fisher's Lane, Rm. 1061
Rockville, MD 20852

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

Dear FDA:

We are concerned about the FDA's proposal regarding the cryopreservation of embryos conceived via donor oocyte cycles. The intended purpose for this, the way I understand it, would be to limit the risk of potential HIV transmission. There is, to my knowledge, however, no evidence that oocytes, embryos or sperm cells that are used in IVF act as vectors for the diseases listed in the FDA. There has been no evidence also that HIV or other infectious diseases have been transmitted by any IVF or embryo transfer over the past 21 years.

As director of an ART lab that does over 300 cycles a year, the cost to our patients would rise significantly. The rate of frozen embryo transfer is somewhere between 10-15% and given the fact that our rates are 50-60% with fresh oocyte donation, it would require likely four times the number of cycles to attain the same pregnancy rate.

The additional burden to the patient would be a loss of 30-40% of their embryos because of freezing. It is estimated by the Society for Advanced Reproductive Technologies that 9,000 embryos would be lost during a single year representing a significant biological loss.

In many cases the women who are asking for donated oocytes are in their early to mid 40's. They have some risks associated with that age if they were to conceive. The delays attributed to the quarantining would significantly increase their anxiety and probably their health risks in going through a pregnancy and child birth.

In summary, I believe the FDA's inferences are not accurate. I do not believe that the quarantine of embryos would in a substantial sense reduce the risk of HIV and will very likely decrease success rates, unnecessary wastage of embryos and delay in child birth in a patient who is somewhat advanced in age already.

97N 484S

C201

• 5450 EAST FLETCHER AVENUE
SUITE 280
TAMPA, FL 33613
TELEPHONE (813) 971-0008

REPLY TO:
• 2919 SWANN AVENUE
SUITE 305
TAMPA, FL 33609
TELEPHONE (813) 970-7557

• 1700 McMULLEN BOOTH ROAD
SUITE A7
CLEARWATER, FL 34619

Dockets and Management Branch (HFA-305)
Food and Drug Administration
December 20, 1999
Page 2

On behalf of our ART lab, but particularly on behalf of our patients, I would ask that an investigation be performed as to the risk of HIV transmission from oocyte donation rather than to suggest a resolution of a problem that may not exist. Please let me know if you have any questions in this regard that I might answer.

Sincerely,



Marc A. Bernhisel, MD
Director ART unit, University Community Hospital
MAB/jas

CC: Nancy Anguard, RN, University Community Hospital
Baha Alak, PhD, University Community Hospital Embryology Laboratory

VERKAUF, BERNHISEL & TARANTINO, M.D.'s, P.A.

*Gynecology,
Reproductive Endocrinology & Infertility*
3450 EAST FLETCHER AVENUE
SUITE 280
TAMPA, FLORIDA 33613

Address Service Requested



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

20852/3593 