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Deborah Smith, M.D.

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Department of Obstetrics and Gynecology
Division of Reproductive Endocrinology

December 21, 1999

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

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

To Whom This May Concern:

Our *In Vitro* Fertilization Practice has recently reviewed the new proposed rules titled "Suitability Determination for Donors of Human Cellular and Tissue Based Products". While many of the proposed rules are acceptable, our IVF practice finds it unacceptable to require that donor embryos be frozen and quarantined for six months until egg donor is retested for infectious diseases.

It is our understanding there is no evidence to support that oocytes or embryos used with IVF-ET are vectors of the diseases listed in the FDA proposal. **No HIV has been contracted from IVF in 21 years of experience nationwide.** Quarantining embryos will significantly raise costs by increasing the number of cycles necessary in order to obtain the current pregnancy rate. Success rates for frozen embryo transfers are about one half to one third of the rate for fresh cycles. Therefore, it may take two to three times more cycles for a patient to achieve pregnancy. The proposed ruling will increase the average costs of *In Vitro* Fertilization \$20,000 - \$30,000. It will also create a need for more oocyte donors, placing more "donors" at risk.

In summary, it is our belief that the proposed FDA policy of quarantining embryos would increase costs and decrease success rates unnecessarily. We strongly object to these proposals and hope the new FDA policy will not be adopted.

Sincerely,

Deborah Smith, M.D. by mkm

Deborah Smith, M.D., Assistant Professor
Dept. of OB/GYN Division of Reproductive Endocrinology
Director, IVF Program
UT Southwestern Medical Center at Dallas

DS/mkm

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