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11930 '99 DEC 30 AM 10:05

December 17, 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 was recently notified by the Society for Assisted Reproductive Technology that the Food and Drug Administration is proposing that fresh donor eggs would no longer be available for couples who need required donor eggs to achieve pregnancy. I find this proposal most objectionable and totally unacceptable.

The reasons that this is unacceptable are:

- 1) There is no evidence that oocytes, embryos, or isolated sperm cells used with in vitro fertilization and embryo transfer are vectors of infectious diseases.
- 2) Quarantining embryos will significantly increase costs and will increase the number of cycles needed to obtain the same pregnancy rate.
- 3) Quarantining embryos will decrease the success rate of donor IVF.
- 4) Many embryos will not survive the freezing/thawing process, therefore, will be wasted.
- 5) Increased delays will cause anxiety and possible increased health risk to women delaying childbirth.

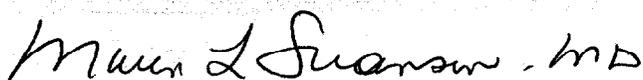
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Page 2  
December 17, 1999

The proposal as it is stated at the present time demonstrates that the FDA really has no understanding of the in vitro fertilization process. It is my opinion that this represents unnecessary intervention on those of us who practice reproductive medicine.

Sincerely,



Marvin L. Swanson, M.D.  
Program Director  
McFarland Clinic Assisted Reproductive Program

MLS:sea

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