

# Yale University

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January 13, 2000

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

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

Dear Sirs:

I am writing to call into question the proposed quarantine of six months for the use of embryos resultant from donor oocytes. Although the time delay may be a minimal inconvenience, the tremendous loss of embryos and decreased embryo viability found with cryopreservation will severely restrict to use donated oocytes. We believe that this six month quarantine is unwarranted for the following reasons:

- 1) We have never had a case of HIV or other infectious disease transmitted through embryo transfer. There have been no reports of anyone contracting HIV from in vitro fertilization over the past 21 years.
- 2) Quarantining the embryos will decrease the success rates for donor IVF. Our current success rates per cycle would drop from approximately 30% to approximately 5%, therefore requiring six times as many cycles for a similar pregnancy rate. If the number of embryos transferred were increased to compensate for this decreased pregnancy rate, a tremendous increase in the number of multiple gestations would result. Multiple gestations carry significantly higher risk and greater cost.
- 3) Quarantining embryos will significantly increase the number of cycles needed to obtain pregnancy and therefore the cost. Again, I estimate a six-fold increase in cost to achieve the same pregnancy rate. The cost of one pregnancy will increase from the current range of approximately \$7,000 to 25,000 up to a range of \$42,000 to \$150,000. These costs are prohibitive for most patients. Additionally, if greater number of embryos were transferred to increase the pregnancy rate, the tremendously increased costs of multiples gestations that would result would be far greater than the cost estimated above.
- 4) Since our pregnancy rates drop from 30% to 5% when embryos undergo cryopreservation, there is an approximately loss of approximately 85% of healthy embryos. The unnecessary deaths of these embryos represent a terrible loss of potential human life.
- 5) Finally, the increased delay causes anxiety and perhaps increased health risks from delaying childbearing.

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In summary, quarantining would increase costs, decrease pregnancy rates and cause the unnecessary death of embryos. The risk associated with this quarantine is at this point theoretical, as no cases of HIV have been transmitted in this way.

I would request that you consider an immediate reversal of this rule.

Sincerely,



Hugh S. Taylor, M.D.

Assistant Professor

Division of Reproductive Endocrinology

Department of Obstetrics and Gynecology

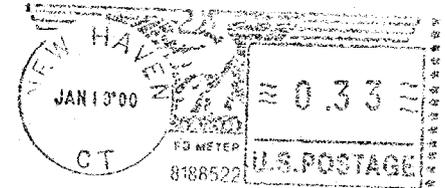
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HST/daf

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