



# THE UNIVERSITY OF CONNECTICUT HEALTH CENTER

DEPARTMENT OF OBSTETRICS & GYNECOLOGY MC-6221

December 23, 1999

DIVISION OF REPRODUCTIVE  
ENDOCRINOLOGY & INFERTILITY  
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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 am writing to express my concern and objection to the proposed rule that donor oocytes be used only after they become embryos, are frozen and quarantined for 6 months, the donor has been re-tested for HIV and other sexually transmitted disease, and was found to be healthy.

Reasons:

1. There is no evidence that embryos can be a source of infection for HIV and other sexually transmitted diseases. Therefore, there is no apparent reason for the regulation.
2. Freezing is an additional expense for patients and may make the procedure unaffordable.
3. Success rates with frozen embryos are generally 50% lower than for fresh embryos.
4. Except in states like Massachusetts that mandate insurance coverage for infertility, egg donor cycles are generally quite expensive and are out-of-pocket for patients. In these circumstances, a reduced per-cycle success rate has a huge impact.
5. Freezing kills a portion of embryos. Mandatory freezing would, for many couples, be forcing them to undergo a procedure they regard as morally similiar to abortion.
6. When couples freeze embryos they must also make embryo disposition plans, such as donating or destroying unused embryos if they don't need all the embryos, or if they die or divorce. For some couples, none of the options are acceptable ethically or psychologically, and yet this proposed rule gives them no choices.
7. Most oocyte donation programs already have a long waiting list, generally a year or more. This rule would prolong the wait patients/couples face before they have an opportunity to conceive.
8. If the donor cannot be located for retesting, it would place the embryos in a state of limbo where they cannot be transferred.

Please consider these arguments against the proposal.

Sincerely yours,

Donald Maier, M.D.  
Associate Professor, Obstetrics & Gynecology  
Director, Reproductive Endocrinology & Infertility

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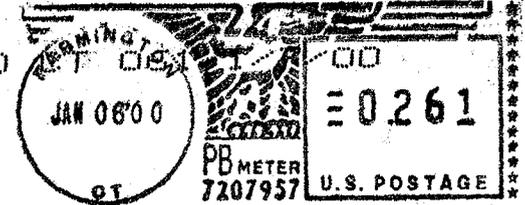
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 AUTHORIZATION 8  
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