

*The Fertility Institutes*

*Tarzana, Encino, Antelope Valley, Beverly Hills, Westlake Village, Las Vegas, Guadalajara*

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*Jeffrey Steinberg, M.D.*

*Medical Director*

December 17, 1999

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5360 Fishers Lane, Room 106.1.  
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 in response to the proposed FDA rules regarding donor egg In Vitro Fertilization.

I must raise a specific objection to the proposed requirement calling for the frozen quarantine of embryos involving oocytes obtained from donor sources.

It should have been quite obvious to any panel considering such an illogical restriction that there is **no** credible scientific documentation available that supports or legitimizes the proposed rule. That the proposition was made in the absence of such documentation raises concern over who is steering the regulatory "ship" that will have, such an enormous impact on the lives of so many infertile couples destined to be adversely affected by this proposed ruling.

Specifically, there is currently no valid scientific evidence linking the use of donor oocytes to the transmission of the diseases listed in the FDA proposal. In our California experience, oocyte donor screening is so extensive that the donors generally appear to be far less a vector risk than many of the spouses themselves.

The freezing and quarantine of embryos will significantly impact the costs and success of the procedures in which the oocytes are utilized. We estimate that the costs for achieving a successful pregnancy with donor oocytes will rise in our program, from \$12,400.00 to \$21 650.00. This results from the multiplicity of negative factors imposed upon our efforts as a result of proposed rules, including a halving of our per cycle pregnancy rates.

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The proposed cryopreservation mandate will also result in the **death of a significant** number of embryos subject to the freezing requirement. The loss of embryos that would have survived a **fresh transfer but are lost as a result of damage in the cryopreservation process has been and remains a significant concern in all IVF programs.**

Infertility patients are human beings facing one of the most physically and psychologically trying of medical conditions: That a government body, charged with the duty of assuring the continued **well being** of such people would overlook the volumes of medical evidence available on this issue and issue instead a proposal not backed by any credible scientific documentation raises serious concern over a number of issues.

I feel the FDA has, in this instance intruded without justification or reason into the practice of medicine. This intrusion **serves to jeopardize the chances of a successful treatment outcome for thousands of Americans who look to this government body for an evidence based, researched and validated opinion on medical procedures:**

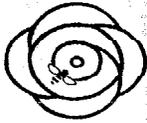
I urge the FDA to reconsider their opinion, focusing their attention on the, **marked difference between semen and that of washed oocytes and embryos as vectors of disease. This distinction does not call for opinion, but merely for careful analysis of the available data. This is a black and white scientific call. The shades of gray that the FDA is often called upon to evaluate do not exist in this instance. If the data is evaluated closely, as it has been repeatedly by those of us in the field, the proper decision, backed by scientific investigation and evidence, is there for all to see.**

I thank you for your concern and efforts **on behalf of the millions who have been affected, and the millions more who will be affected by infertility and the advances made by those of us in the field charged with the care of these people.**

Sincerely,

A handwritten signature in black ink, appearing to read "Jeff Steinberg". The signature is fluid and cursive, with the first name "Jeff" and last name "Steinberg" clearly distinguishable.

Jeffrey Steinberg, M.D., FACOG  
Director

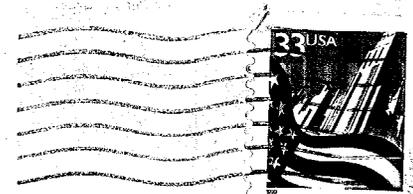


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