

Docket Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852  
email: FDADOCKETS@oc.fda.gov

3572 '00 JAN -7 10:56

Docket No. 97N-484S

I am writing to voice my objection to the proposed FDA regulations. I am a gay man, someone whom the FDA and CDC classify as "high risk for HIV". Although I am an "anonymous donor" my identity will be revealed to the mother when the child is three months old. Although I am not a legal parent, I am the birth parent and will have contact with my children throughout our lifetimes. I would not be a sperm donor if I thought that I would be putting anybody at risk. I know that my sperm is frozen and quarantined for six months prior to its use. I also know that the window period for HIV is 2-3 months. Given these safeguards, this is how I have chosen to reproduce. Now the FDA wants to try to take this option away from me. All of the women who may choose to use my sperm know that I am a gay man. They even know my intimate sexual practices.

The proposed regulations do not protect the public. The safety precautions already in place do that. What these regulations do is violate my civil rights as to how I choose to have children in my life and the civil rights of the women who may wish to choose me as a donor. Given the six month quarantine, men who have sex with men are not "high risk donors". In fact the only case that the CDC was able to identify as someone who did not turn positive on the HIV antibody test within a six month period was an otherwise healthy heterosexual man who was infected by his wife. Given that, the FDA should consider barring sexually active heterosexual men from being sperm donors. I strongly urge the FDA to reconsider these regulations as they have no credible scientific basis and would violate my civil rights to choose a safe and reasonable method to reproduce.

Sincerely,

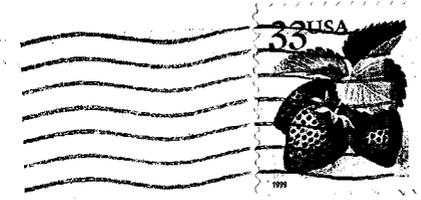


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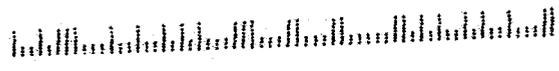
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HOUSING AUTHORITY OF THE  
COUNTY OF SAN MATEO  
264 HARBOR BLVD., BUILDING A  
BELMONT, CA 94002-4017



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**Reproductive Science Center®**  
of Boston

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3679 00 JAN -7 P2 04

December 21, 1999

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

**RE: Docket No. 97N-484S**  
**Suitability Determination for Donors of Human**  
**Cellular and Tissue Based Products**

To Whom It May Concern:

We are responding to you because we are deeply concerned over new proposed rules which may adversely affect and impact on patient care. Our understanding is that the new proposed rule would require an egg donor to be tested prior to in vitro fertilization cycles and the resulting embryos would be frozen and quarantined until the egg donor is then again retested and is found to be negative for infectious diseases. This would place egg donors on a similar status as sperm donation.

We strongly object to these rules on several different levels. Firstly, there is no evidence that any woman who has been the recipient of donated oocytes has ever become infected with HIV or any infectious disease. We challenge you to provide evidence that such diseases have been transmitted.

In addition, this will effectively reduce the pregnancy rates by approximately 50%. The tremendous cost in both dollars as well as lost embryos is enormous and would have a tremendous impact on the financial and emotional health of individuals who have already been subject to long waiting lists and the emotional hardships imposed by the egg donation process.

In summary, we are unanimous in our objection to these seemingly arbitrary rules without scientific basis. We ask you to rethink your strategy and to provide scientific evidence to base these proposed changes on.

Sincerely,

Patricia M. McShane, M.D.  
Medical Director

PMM/po

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Specialists in Physician-Assisted Reproduction

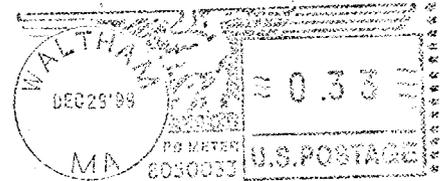
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