

the **CENTER** for **REPRODUCTIVE HEALTH**  
320 21st Avenue North • Nashville, TN 37203  
Phone 615.321.8899 • Fax 615.321.8877

**Jaime Vasquez, MD** • Medical Director  
*Diplomate American Board Obstetrics & Gynecology  
Subspeciality in Reproductive Endocrinology & Infertility*

1999 DEC 30 10 21

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:

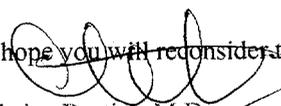
I object to your Federal Register publication "Suitability Determination for Donors of Human Cellular and Tissue-Based Product" of September 30, 1999. Your statement that only frozen, quarantined embryos are suitable for embryo transfer has no basis in fact.

1. There is no evidence that oocytes, embryos or isolated sperm cells used with IVF-ET are vectors of the diseases listed in the FDA proposal. HIV or other infectious diseases are not passed by IVF-ET. No specific papers claiming this have been found. No HIV has been contracted from IVF in 21 years as far as anyone knows.
2. Quarantining embryos will significantly increase costs and will increase the numbers of cycles needed to obtain the same pregnancy rate. (If you can estimate what that increased cost would be at your institute, please do so.)
3. Quarantining embryos will decrease the success rate for donor IVF. (If you can estimate the approximate decrease at your institute, please do so. The national average is about half).
4. There will be unnecessary deaths of embryos from the proposed rules to mandate freezing. (We estimate that possibly 9,000 embryos will be lost per year, representing a terrible loss of biological material and potential human lives.)
5. Increased delay causes anxiety and possible increased health risk in the woman delaying childbirth.

Summary: The FDA is interfering with the practice of medicine by attempting to require the quarantining of embryos resulting from donor egg IVF. There is no scientific justification (any transmission of HIV or other infectious disease) from IVF. Quarantining would increase costs, decrease success rate (pregnancy rate), and cause the unnecessary death of embryos and a delay in childbirth in an already older patient.

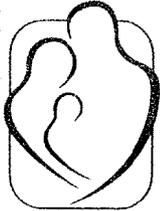
Finally, in the proposed rules, there seems to be no understanding by the FDA that using semen carries with it a much different risk for transmission of disease than the hypothetical risk (so far no risk) associated with the use of isolated and washed sperm cells, oocytes and embryos.

I hope you will reconsider these guidelines prior to December 29, 1999.

  
Cristina Bastias, M.D.  
The Center for Reproductive Health  
326 21<sup>st</sup> Ave North, Nashville, TN 37203  
Fax: (615) 321-8877

97N 484S

C 319



the CENTER for REPRODUCTIVE HEALTH  
P.O. Box 24007 • Nashville, TN 37202



ALWAYS

USE

ZIP CODE

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

Jaime Vasquez, MD • Medical Director  
Diplomate American Board Obstetrics & Gynecology  
Subspecialty in Reproductive Endocrinology & Infertility

20852/9999

