



INFERTILITY & IVF CENTER

ADVANCED REPRODUCTIVE TECHNOLOGIES

A Division of Infertility & Gynecologic Med, Inc

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December 28, 1999

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

Dear Dockets Management Branch:

The proposed rules in Docket #97N-484S have caused me great concern. The concern is over the concept of only transferring quarantined embryos after freezing the embryos for a period of six months then going through infectious disease screening in the interim. I had tried this technique five years ago and the results were disastrous. First of all, the embryos do not freeze and thaw well and you lose a number of embryos, therefore, prospective children. Also, you markedly lower the pregnancy rate. Further, I am unaware of any reports of the transmission of HIV or other infectious diseases in fresh cycles of in vitro fertilization with embryo transfer. The additional freezing and need for a second embryo transfer cycle will also increase the cost, taking this technology out of the realm of many individuals because of expense. I feel this is a governmental intrusion on medical decision making, which appears good on the surface but is of great harm under the surface. There is nothing broken, so there is no need to fix it. I strongly urge you to remove this quarantine rule.

Sincerely,

Ronald P. Wilbois, M.D.

RPW/csm

97N 484S

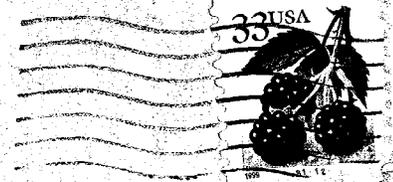
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