



Advanced Fertility
Center of Chicago

1419 '00 JAN -3 AM:16

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

December 20, 1999

To Whom It May Concern:

We are writing to express our concern regarding the proposed rules concerning donor egg IVF. Several issues need to be addressed, including:

1. There is no evidence that eggs, sperm, or embryos used with IVF-ET transmit the diseases listed in the FDA proposal. No documented HIV infection has ever occurred from IVF-ET.
2. Because of issues related to freezing and thawing, quarantine of embryos will decrease the success rate for donor IVF. At our institution, we estimate that 35% of embryos would be adversely affected.
3. Costs to the couple will increase by about 30% per cycle and about 250-300% per live birth.
4. The delay involved in quarantine will be a very significant issue for some women needing egg donation that are in their mid-to-late 40's.

We feel that this is an inappropriate mandate and the issue needs to be reevaluated with input from reproductive endocrinologists and embryologists before any further action is taken.

Sincerely,

Richard Sherbahn, M.D.
Advanced Fertility Center of Chicago

RS/lk

97N 484S

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Reproductive Endocrinology and Infertility

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