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**Male Infertility
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Embryology

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2004 '00 JAN -5 P2:00

December 20, 1999

Dockets Management Branch (HFA-305)
Food & 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**

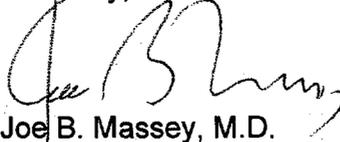
Dear Madam/Sir:

Currently egg donor procedures for in vitro fertilization offer the best hope for many couples. The success rates are in the 40% range. The proposed quarantining of donor embryos would reduce this success to 15%. The current cost for live born baby in our center is approximately \$20,000 to \$25,000. This cost would triple if only cryopreserved embryos were used. This would virtually eliminate this therapy as a rational option for approximately 20% of the in vitro fertilization candidates in this country.

As physicians we all are taught to first do no harm. The proposal to quarantine donor embryos would do great harm to patients who are generally in an older age group. Please examine the scientific literature, which provides no support for quarantining procedures as a public health measure. There have been no cases of HIV contracted from IVF. The risk that an oocyte could be a vector of infectious disease is infinitesimally small.

Thank you very much for your attention to this matter. We all share the same concern for our patients' welfare.

Sincerely,



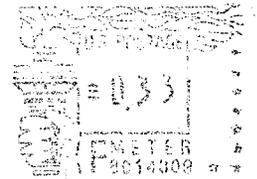
Joe B. Massey, M.D.

JBM:dwb
cc: Philip McNamee, M.D.

97N 484S

C386

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