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December 28, 1999

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Dockets Management Branch (HFA-305)

Food & Drug Administration
5360 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket #97N-484S

Title: Suitability Determination for Donors of Human Cellular and Tissue-Based Products

To Whom It May Concern:

This letter is written in response to the proposed rules published by the FDA in the Federal Register on September 30, 1999, regarding proposed regulation for donor egg In Vitro Fertilization. The rules currently listed on the website www.fda.gov appear to be reasonable and acceptable. However, a notable exception is the requirement to freeze embryos derived from donor egg In Vitro Fertilization for a quarantine period of six months so that the egg donor can be retested for infectious diseases. This proposed rule is scientifically unjustified and ethically unacceptable. The technically advanced fields of medicine, including advanced reproductive technology, are heavily dependent upon sophisticated biological scientific findings and the application of advanced medical technology. These high-technology based fields of medicine are heavily dependent upon evidence-based medicine derived from very large data bases. Advanced reproductive science, in particular In Vitro Fertilization, has generated a huge data base of biological information since the mid-1970's, including the establishment of tens of thousands of pregnancies using these advanced techniques. Several thousand of these pregnancies were derived from donor egg In Vitro Fertilization cycles, with meticulous medical and scientific records kept of each and reported to the SART central data base.

There has never been a single report of any type of infectious disease, including hepatitis or HIV, with donor egg In Vitro Fertilization technology. Out of thousands of pregnancies established with this technique, evidence-based medicine has established that transmission of infectious diseases simply does not occur using this technology with the resolution of thousands of data points.

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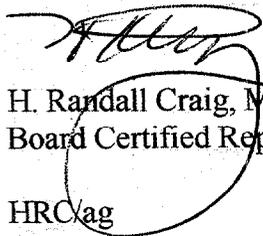
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December 28, 1999
Page 2 of 2

In addition to the complete lack of scientific evidence justifying the proposed rule for donor egg In Vitro Fertilization embryo quarantine, there is also a very strong ethical objection to the frozen embryo quarantine. The freeze/thaw efficiency for embryos derived from donor egg In Vitro Fertilization cycle has a survival ratio ranging from 30% to 60%. Thousands of embryos would be lost to the freeze/thaw cycle every year if this proposed rule was instituted. These are not simply frozen embryos expressed in a data base, but are potential human lives lost to an unnecessary and unethical regulation. Because these embryos are frozen after conception, their unnecessary loss is considered highly objectionable to a very large portion of the American population, based on religious beliefs and personal convictions. The loss of these potential human lives is totally unacceptable in light of the fact that it is based on a concept that has absolutely no scientific basis and which has been completely rejected by evidence-based medical science.

In conclusion, I find the proposed regulation for quarantine of frozen embryos derived from donor egg In Vitro Fertilization cycles medically objectionable and ethically unacceptable, and share this view with millions of other Americans. I would urge the FDA to reject this part of the proposal for suitability determination for donors of human cellular and tissue based products.

Sincerely,



H. Randall Craig, M.D.
Board Certified Reproductive Endocrinologist

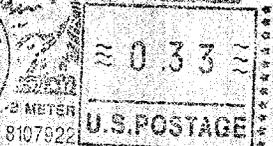
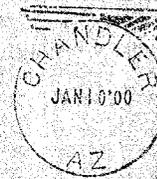
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FTC

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FORWARDING AND ADDRESS
CORRECTION REQUESTED



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