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December 21, 1999

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Suitable Determination for Donors of Human Cellular and Tissue-Based products  
Docket No. 97N-484S

To whom it may concern:

As a Reproductive Endocrinologist involved in the practice of assisted reproductive technologies, I have serious concerns about the proposed regulations regarding screening and quarantine of donated oocytes. I do understand that all regulations of this type are intended to protect the public, but I believe unfounded concerns regarding disease transmission may serve to harm the very patients the regulations seek to protect.

I am unaware of any data to suggest an isolated egg, retrieved during the process of in vitro fertilization, has been shown to transmit the diseases listed in the screening requirements. Secondly, the diagnosis of some of these infections (e.g. HTLV), in the absence of a clear consensus as to prognosis and/or treatment, would lead to serious, deleterious consequences for those individuals who test positive. The finding of a positive test, in the absence of any knowledge regarding the consequence of this finding, is quite distressing to patients. I believe the relevance of specific testing, for specific disease entities, to oocyte donation should be considered before regulations are put into place.

The most critical concern I have about the proposed regulations is the requirement for quarantine of the oocytes (embryos) before use. This has not been a problem for donated sperm as "retrieval" costs are minimal and the survival and function retained after cryopreservation and thaw are adequate. The case for donated oocytes is quite different. The process of screening, retrieval, fertilization (as unfertilized oocytes do not survive the

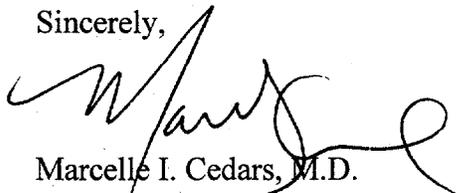
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cryopreservation process well), cryopreservation and thaw will exceed \$15,000. The data from the CDC are quite clear that frozen embryo transfer is approximately 50% as effective as fresh transfer (16% vs. 27.9% - 1996 CDC-SART data). Thus, these regulations would require patients to pay large "upfront" costs (the cost for the fresh cycle PLUS costs for cryopreservation and thaw), delay a chance for conception (the quarantine period plus lower likelihood for success with each transfer) and then lessen their overall chance for conception (as only 70% of embryos will survive freezing and thawing and those that do implant at a lower rate). Thus, the out-of-pocket costs for per healthy pregnancy (born largely by the patients themselves) would increase without the evidence to suggest such restrictions are required or will lead to improved patient safety. Lastly, most recipients of donated oocytes are over the age of 40 and thus this delay in transfer and ultimate pregnancy would also increase obstetrical risks should a pregnancy occur.

I do understand you have the interests, and protection, of the individual consumer as your focus. However, the focus on infectious disease risk (not well documented for oocyte donation) has occurred in a vacuum regarding other relevant issues to our patients. The increased testing and it's associated costs and risks, the requirement for quarantine which will delay transfer and further increase cost with the possibility of no embryos surviving the cryopreservation process, and the lowered ultimate success are real concerns for our patients. I would ask that you regard all these issues together and that the real risk of disease transmission be evaluated for oocyte donation. No regulations should be enacted until a scientific investigation of risk has been conducted and until other relevant issues to the consumer may be included in the analysis.

Sincerely,

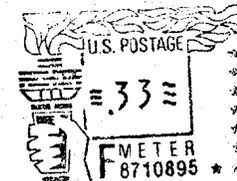
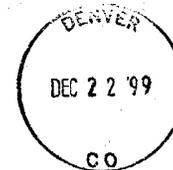


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