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DEPARTMENT OF OBSTETRICS, GYNECOLOGY  
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December 20, 1999

Docketts Management Branch (HFA-305)  
Food and Drug Administration  
5360 Fisher's Lane, Room 1061  
Rockville, MD 20852

Re: Docket #97N-484S, Suitability Determination for donors of human cellular and tissue-based products

To Whom It May Concern:

As a Reproductive Endocrinologist and an In Vitro fertilization Program Practice Director, I would like to strongly object to the proposed regulations that would require embryos derived from oocyte donors to be quarantined for six months in order to retest the donor for infectious diseases. There is no evidence that an oocyte (a single cell) is a vector for any of the diseases listed in the FDA proposal. None of us are aware of any transmission of HIV through In Vitro fertilization as long as the technique has been practiced. This regulation will cause undue hardship on the patients who we are treating. I believe that the FDA is trying to act in the best interest of the patient; therefore, I think this proposal should be rejected. By requiring a quarantine, the cost will increase significantly and success rates will also decrease significantly leading to an increased number of cycles needed to obtain the same pregnancy rates. Since one cannot guarantee that the donor will be available for follow up testing, patients would be forced to risk thousands of dollars to obtain frozen embryos, which they would lose if the donor was not available for follow up testing.

All of us adhere to the quarantine of donor sperm, however the situation with embryos is quite different. Donor sperm can be obtained quite inexpensively as opposed to donor embryos, which are attained at great cost. More importantly, it is known that the insemination of semen can transmit infectious diseases. However, millions of sperm are inseminated in a single insemination procedure, not one cell, as in the case of a donor oocyte. Semen at times is also inseminated with seminal plasma, which may also carry infectious agents.

In summary, I would like to request that the FDA take a close look at this proposed rule and reject it. This is the decision that is in the best interest of the patient.

Sincerely,

Howard D. McClamrock, M.D.  
Associate Professor and Chief  
Division of Reproductive Endocrinology and Infertility

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