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DIPLOMATE OF THE AMERICAN BOARD OF
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Dockets Management Branch "HFA-305"
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
January 11, 2000

RE: Docket NO. 97N-484S

To Whom It May Concern:

I have recently read the proposed rules for "Suitability Determination for Donors of Human Cellular and Tissue Based Products." I am a Reproductive Endocrinologist in private practice in Dallas, Texas. I have conducted over 100 cycles of oocyte donation in the past 5 years and feel I am qualified to comment on these proposed rules. I intend only to summarize these comments, as lengthy detail could be obtained in other documentation.

Requiring a quarantine-period for donated oocytes is simply unacceptable, and creates an undo burden on clinics offering oocyte donation and patients receiving these services. While sperm can be quarantined on an economical basis without significant reduction in success, the same principles do not hold for oocyte donation. Oocytes, unlike sperm, are not easily cryopreserved, and oocyte cryopreservation in fact is still considered an experimental procedure. Furthermore, embryo cryopreservation, while shown to have reasonable success, results in pregnancy rates far below current oocyte donation practice and the expectations of our patients. Furthermore, embryo cryopreservation pregnancy rates vary dramatically among ART clinics. From the viewpoint of our patients, requiring donated oocytes, or embryos created from donated oocytes to undergo cryopreservation and a quarantine period would greatly reduce the chance of success, probably by 50%. Success rates from many IVF clinics using donated oocytes are 50% or better, while pregnancy rates from cryopreserved embryos remain low by comparison.

Would a quarantine-period for oocytes reduce the transmission of disease? Although sperm donation has resulted in transmission of HIV, I personally do not know of any case (reported or otherwise) where oocyte donation has resulted in the transmission of HIV. The proposed rules also regulate additional testing to be conducted on oocyte donors. While additional testing would indeed add a little to the cost, the additional cost of \$160.40 per donor is grossly underestimated. Additionally, there are many good scientific and medical reasons why some of the tests, specifically CMV, may not need to be conducted amongst oocyte donors based on the fact that the CMV virus does not appear to infect oocytes or surrounding cells.

Requiring a quarantine period would also escalate costs. Your report does not indicate the real costs of a quarantine period, which would include additional cost of cryopreservation, thawing and facility fees associated to this treatment.

Overall, these proposed regulations are simply an attempt to assure appropriate screening tests are conducted, of which I am in favor. The quarantine of donated oocytes or embryos created from donated oocytes, however, creates a great undo burden on clinics physicians and patients. I strongly encourage you to reverse your opinion on this matter or make exception for donated oocytes, so that our patients are indeed better served. The guidelines currently stated are not in the best interest of patients receiving donated oocytes.

Respectfully submitted,



Samuel J. Chantilis, MD
Director, Oocyte Donation
Presbyterian Hospital ARTS Program

97N 484S

cc: Sean Tipton
Public Affairs Director, ASRM

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