

Reproductive Partners

MEDICAL GROUP, INC.



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December 23, 1999

Dockets Management Branch (HFA-305)
Food and 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 Sir:

As previous commissioner of the ASRM-CAP Reproductive Laboratory Accreditation Program, I would like to vigorously object to the FDA proposal to require freezing of embryos resulting from oocyte donation on the basis that the risk of transmission of HIV or other diseases is extremely small if not virtually 0, and that the patients (the infertile recipients) have the right to make this decision when balancing this extremely remote risk against the two-fold higher success rate and consequently lower cost of fresh-embryo transfer.

With oocyte donation the donor is chosen as a low risk individual without high risk behaviors and with a stable sex partner. Data on blood transfusion would put the risk of HIV with a negative HIV test in such an individual at an extremely low level. Further, as a female without high risk behaviors any transmission would come from the male sexual partner and it is well known that the rate of sexual transmission is low.

With IVF the oocytes are washed after being retrieved. They are moved through multiple changes of culture medium before being transferred. This dilution and washing process would result in exposure of the recipient to an extremely small amount of serum from the donor probably analogous to a needle stick or less, which is known to carry a very low risk of transmission from a known HIV positive individual. There has in fact been no instance of HIV transmission with IVF in over 21 years of practice. If one multiplies the chance of an HIV negative female having HIV times the risk of contracting HIV with a needle stick from an HIV positive person the resulting risk would be of the order of 1 in 1 million or less. The recipient undertakes risks greater than this when travelling in airplanes or

97N 484S

Orange County

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South Bay/Los Angeles

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Redondo Beach, CA 90277
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San Diego County

9850 Genesee Ave. #800
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automobiles for the benefit of transportation. Surely it must be the individuals' right to undertake a risk of lesser magnitude for the benefit of resolving their infertility.

In summary, the infertile woman must be allowed, with informed consent, to undertake such a remote risk (if not 0) for the benefit of a much higher success in achieving a pregnancy. Patients assume greater medical risk with other infertility treatments and in their daily lives. To deny them their right to choose would be an unwarranted intrusion of government into their individual freedom.

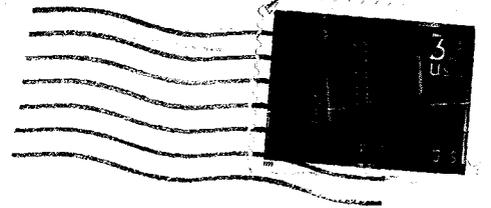
Sincerely,

A handwritten signature in black ink, appearing to read "Meldrum", written over a horizontal line.

David R. Meldrum, M.D.
Scientific Director

DM:dr

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