



TEL 612 520 2600 / 800 508 9763 FAX 612 520 2606

THE MIDWEST CENTER FOR REPRODUCTIVE HEALTH, P.A.  
OAKDALE MEDICAL BUILDING, SUITE 550  
3366 OAKDALE AVE N, MINNEAPOLIS, MN 55422

0619 '99 DEC 29 A9:53

December 20, 1999

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5360 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: Docket #97N-484S

To Whom It May Concern:

Please accept this letter of concern regarding a proposal for quarantining donor embryos. Several facts need to be brought to light.

First, there is no evidence that oocytes, embryos, or isolated sperm cells used with in vitro fertilization are vectors of diseases as listed in the FDA proposal. There is absolutely no documentation that I am aware of that HIV or other infectious diseases can be transmitted as outlined.

We also feel strongly that we are working in our industry to control cost with regard to couples achieving pregnancy. Quarantining embryos will significantly increase cost and will increase the number of cycles needed to obtain the same pregnancy rate, since cryopreserved embryos do not work as well as fresh embryos.

We also feel that the overall decrease in success rates with donor in vitro fertilization will occur. We would estimate that there would be approximately a 20% decrease in the pregnancy rates in our in vitro fertilization clinic if we had to cryopreserve embryos in a donor oocyte cycle. We also feel that there will be an unnecessary loss of embryos as a result of the proposed ruling.

Last but not least, there would be, an increase, in anxiety because of the delay that would be incurred with using cryopreserved embryos.

97N 484S

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December 20, 1999

Page 2

In summary, we feel that the FDA is proposing an interference with the practice of medicine by requiring the quarantining of embryos resulting from donor egg in vitro fertilization. There is no scientific justification of this concern.

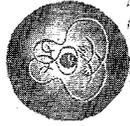
If there are other questions that might arise, please don't hesitate to let me know.

Sincerely,

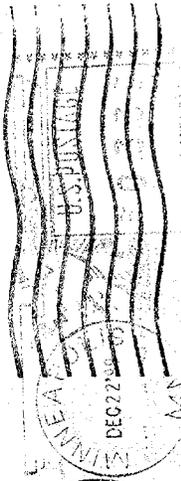
Handwritten signature of Randle S. Corfman in cursive, followed by the initials "AR" written in a separate, slightly larger cursive script.

Randle S. Corfman, Ph.D., M.D.

**Dictated, but not read**



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