



Affiliated with
New England Clinic of Reproductive Medicine, Inc.

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December 21, 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

To Whom It May Concern:

In my opinion the FDA proposed regulation that would require the quarantining of embryos resulting from donor egg IVF is unfortunately not based on good understanding of the process of egg donation and it is not supported by any scientific data.

Since there is no evidence that oocytes, embryos or isolated sperm cells used with IVF-ET are vectors of the diseases listed in the FDA proposal. HIV or other infectious diseases are not passed by IVF-ET. No specific papers claiming this have been found. No HIV has been contracted from IVF in 21 years as far as anyone knows.

Quarantining embryos will significantly increase costs by tens of thousands of dollars, and will increase the numbers of cycles needed to obtain the same pregnancy rate.

Quarantining embryos will decrease the success rate for donor IVF in my estimation by 50-60%. I also feel that there will be unnecessary deaths of embryos from the proposed rules to mandate freezing. This will further increase anxiety and possible health risks in the woman delaying childbirth.

Finally, in the proposed rules, there seems to be no understanding by the FDA that using semen carries with it a much different risk for transmission of disease than the hypothetical risk associated with the use of isolated and washed sperm cells, oocytes and embryos.

Sincerely,

Vito R. S. Cardone, M.D.

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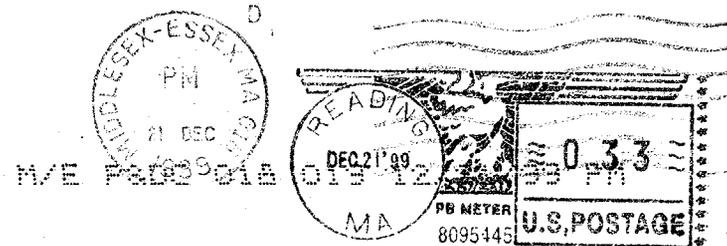
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Address Correction Requested



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