

December 21, 1999

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

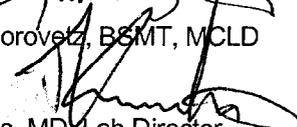
From: Joseph Karnitis, MD, LabDirector/ Fertility Center of Northwest Ohio  
Suzanne Sorovetz, BSMT, Sr. Embryologist

RE: Docket #97N-484S, Suitability Determination for Donors of Human Cellular and Tissue based Products.

On September 30, 1999, The FDA had published proposed rules regarding donor egg IVF, titled "Suitability Determination for Donors of Human Cellular and Tissue-Based Products". There is one rule that is totally unacceptable requiring all resultant embryos from donor egg IVF cases to be frozen and quarantined for six months. Pending infectious disease results, the frozen embryos would only then be suitable for a frozen embryo transfer. We all know that the potential for a positive pregnancy is significantly higher with a fresh transfer as opposed to a frozen transfer. This can be reviewed for all participating Fertility Centers in the published SART Data. The total cost to achieve a pregnancy with donor egg, will go up dramatically since one IVF cycle may not be enough. There has been no scientific justification to back this proposed rule up, no transmission of HIV or other infectious diseases have ever been linked to IVF.

Finally, it is important to note the negative impact that cryopreservation has on human embryos, therefore Representing a terrible loss of biological material and potential human lives. This will have a definite impact on the Field of Assisted Reproductive Technology, with a negative outcome for the patient, increased anxiety, increased Financial cost to achieve a pregnancy with donor IVF and unnecessary death of embryos.

  
Suzanne M. Sorovetz, BSMT, MCLD

  
Joseph Karnitis, MD, Lab Director

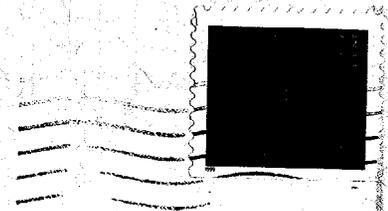
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