



Boston IVF

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2099 '00 JAN -5 P2:33

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Hospital Partnerships

Beverly Hospital, Beverly, MA
MetroWest Medical Center,
Framingham, MA
Mount Auburn Hospital,
Cambridge, MA
Portsmouth Regional Hospital,
Portsmouth, NH

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 Sirs,

I was so dismayed when informed of the proposed rules described
above since the proposed rule to freeze and quarantine the embryos
is so outrageous.

Firstly, there is no evidence that any diseases can be transmitted by
embryos, and freezing them will significantly decrease the success
rates and therefore the cost and human anguish when donor eggs
are used for IVF.

It appears that the FDA does not understand that there is a huge
difference between the actual risks from using semen with
hypothetical risks (none) that have been associated with the use of
oocytes and embryos. It is my opinion that the FDA should not
interfere with the practice of medicine by attempting to require the
quarantining of embryos resulting from the donor egg IVF.

Sincerely,

Merle J. Berger MD
Associate Clinical Professor of Obstetrics of Gynecology at
Harvard Medical School

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97N 484S

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