INFERTILITY AND GYNECOLOGY INSTITUTE
A SOUTHERN CALIFORNIA MEDICAL GROUP

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INFERTILITY
GYNECOLOGY
IN VITRO FERTILIZATION
LASER MICROSURGERY
GYNECOLOGIC ENDOSCOPY

December 20, 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:

I am writing this letter as an individual practitioner of in vitro fertilization. I have heard about the proposed rules regarding donor embryos. The particular rule about quarantining embryos for six months is outrageous and should never even be considered, let alone passed.

All studies have shown there is no connection between the passage of major infections, particularly HIV and donor embryos. I was one of the early practitioners of in vitro fertilization, starting in 1984, and I have never run into this problem. All the research also shows no connection. On the other hand, requiring such a quarantine would not only increase the cost but would markedly decrease the success rate of this program.

In our particular program we run at least a 70 percent success rate, yet with frozen donor embryos the success rate is less than half of that number. That would be a tragedy for the individuals involved. There is a total difference between eggs obtained for in vitro fertilization and semen used for donor insemination. There is no comparison.

Please disregard any thought of setting up a quarantine system.

Yours truly,

Paul M. Greenberg, M.D.

PMG:JC

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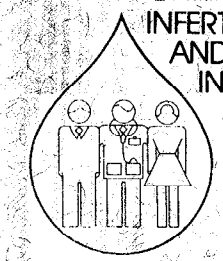

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