New Jersey

Michael C. Darder, M.D.

Susan L. Treiser, M.D., Ph.D.

Annette Lee, M.D.

2006 '00 JAN -5 P2:01

December 24, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5360 Fisher's 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:

It has come under our attention that the proposed rules published in the Federal Register regarding the above would require that an egg donor be tested for infectious diseases prior to her egg retrieval and that the resultant embryos would be frozen and quarantined for six months at which time the donor would be re-tested. I am writing to strongly object to such a measure on scientific grounds and also because this would be a severe set-back to egg recipients in the United States.

From a scientific standpoint, it is well known by the scientific community that HIV and other infectious diseases are not passed on by in vitro fertilization. This comes from twenty-one years of experience in performing in vitro fertilization around the world. Specifically, to date there is no report of a case of HIV being passed from an egg donor to an egg recipient. There is, therefore, no scientific evidence that quarantining embryos is necessary. Furthermore, quarantining of embryos will result in many harsh impacts on women who are planning to be egg recipients. The chance of them conceiving will drop significantly if they are unable to use fresh embryos which are of better quality then frozen embryos. Many of these embryos will die because of the freezing and thawing process and therefore thousands of potential lives will be destroyed because of this. Because there have not been any lost lives with the transfer of fresh embryos from egg donors, it seems totally unreasonable to sacrifice thousands of potential lives by following the proposed rule.

Many other negative impacts will be felt by egg recipients because of these measures. We cannot be assured that an egg donor will be available for re-testing six months later. Therefore, an egg donation cycle costing a recipient

Fertility & Gynecology Center, P.A.
1527 Highway 27
Somerset, NJ 08873
Phone: 732.220.9060
Fax: 732.220.1122

193 Route 9 South • Suite 2A
Manalapan, NJ 07726
Phone: 732.577.6500
Fax: 732.577.6510
800.IVF.NJ44 • www.ivfnj.com

97N 484S

C397

over $20,000.00 may be wasted. If we try to avert this by compensating egg donors after re-testing, many, if not the majority of egg donors will elect to not undergo the arduous task of egg donation. Already egg donors are in scarce supply and this will certainly increase the time that women have to wait to undergo the egg donation procedure and will increase the cost of the procedure. Please realize that a delay in conception is of great concern to many of these women who have been trying for years to conceive and are in their forties. They really don't have the luxury of time to undergo the egg donation process. In addition, the cost of this procedure is already very high and increasing the cost adds a tremendous burden to these patients.

All in all, I cannot imagine that the women who you are trying to protect would agree with such an action that would be of no discernable benefit to them and yet only cause undue hardship, anxiety and ultimately may cost them the ability to have a family. We implore you to reconsider these actions and to apply good science and consideration for the effect that this will have on the people that you serve. IVF with egg donation does not cause the transmission of HIV from egg donors to egg recipients. This proposal, however, will cause the loss of potential human lives and cause many women who would otherwise have children to go childless.

Sincerely,

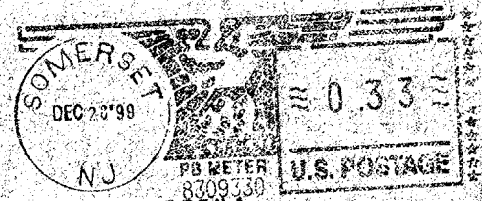
Susan L. Treiser, M.D., Ph.D.

Michael C. Darder, M.D.

Annette Lee, M.D.

New Jersey

Fertility & Gynecology Center, P.A.
1527 Highway 27
Somerset, NJ 08873



KILMER P&DC 12/28/99 18:53 MLB/ISS#4

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

20852/3333