

Sujatha Gunnala, M.D.,  
Fellow, A.C.O.G.,  
Diplomate, A.B.O.G.,  
Medical Director  
Reproductive  
Endocrinology & Infertility



Max Wynberg, M.S.,  
Embryologist  
Supervisor-Andrology Lab

Leslie Owen, R.N.,  
C.O.G.N.P.  
Certified OB/GYN Nurse  
Practitioner  
Reproductive Endocrinology  
and Infertility

Heather Pisarski, R.N.,  
O.G.N.P.  
OB/GYN Nurse Practitioner  
Reproductive Endocrinology  
and Infertility

Lana Schlotthauer, R.N.C.  
Infertility Nurse  
IVF Coordinator

## SOUTHWEST FERTILITY CENTER

ARIZONA CENTER FOR ENDOMETRIOSIS AND RECONSTRUCTIVE SURGERY

Specializing in Infertility, Reproductive Endocrinology & Complex Gynecology

3125 North 32<sup>nd</sup> Street, Suite 200, Phoenix, Arizona 85018

(602) 956-7481 Fax (602) 956-7591

Home Page: <http://www.primenet.com/~swfertil>

July 11, 2000

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville MD 20852

RE: Suitability Determination for Donors of Human Cellular and Tissue Based Products

We are writing to advise we have serious objections to the proposed quarantine and re-testing of egg donors prior to embryo transfers. The proposed testing actually needs to be performed prior to introduction of the recipient couple's sperm. However, by current medical standards, we have not yet achieved the ability to freeze ova without first fertilizing. In addition the couple's chances to achieve pregnancy with frozen embryos is considerably diminished over fresh embryo transfers. If we can provide any additional information, feel free to contact us.

Sincerely yours,

  
Sujatha Gunnala M.D.  
SG/dw

cc: SART

97N-4845

C 487

**OUTWEST FERTILITY CENTER**

15 North 32<sup>nd</sup> Street  
Suite 200  
Phoenix, Arizona 85018



Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane Rm 1061  
Rockville, MD 20852

