1440 '00 JAN -3 A11:23

THE SAN FRANCISCO CENTER
FOR REPRODUCTIVE MEDICINE

Philip E. Chenette, M.D.
Carl M. Herbert, M.D.

December 22, 1999

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

RE: Docket No. 97N-484S
Suitability Determination for Donors of Human Cellular and Tissue-Based Products

Dear FDA:

I am concerned about this Docket No. 97N-484S, Suitability Determination for Donors of Human Cellular and Tissue-Based Products. I am a practitioner of *in vitro* fertilization and assisted reproduction techniques with a busy practice in San Francisco. Our patient group consists of women in the ages of 35 to 45, who are experiencing age-related infertility. They commonly resort to oocyte donation as the best means of achieving a pregnancy.

Among the issues within the docket is a requirement to freeze embryos which result from an *in vitro* fertilization cycle and quarantine them for six months prior to transfer. There is no evidence that oocytes or embryos obtained from donors are vectors of any of the diseases listed in the docket. No case of HIV has been contracted from *in vitro* fertilization anywhere according to any current records. In addition, freezing and quarantining of these embryos is likely to substantially reduce pregnancy rates.

There is no scientific justification for quarantining embryos after oocyte donation. We think this would be an unnecessary intrusion into clinical care.

I am happy to discuss this with you further if you have any questions or concerns. Please don't hesitate to contact me at the address below.

Sincerely,

Philip E. Chenette, M.D.

PEC:mjp

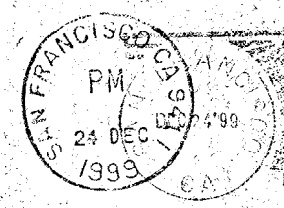
97N 484S

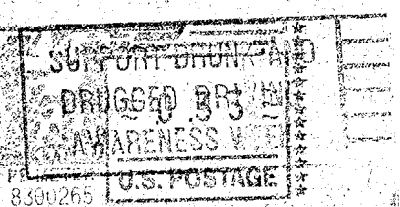
390 Laurel St., Suite 205
San Francisco, CA 94118
(415) 771-1483
Fax (415) 771-6974

C371

390 Laurel Street
San Francisco, CA 94118

THE SAN FRANCISCO
CENTER
FOR REPRODUCTIVE MEDICINE





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

20852/9999