



DELAWARE VALLEY INSTITUTE OF FERTILITY & GENETICS

449200 JAN 12 10 43

Eytan R. Barnea, M.D., FACOG

George S. Taliadouros, M.D., FACOG

Chung H. Wu, M.D., FACOG

Geoffrey D. Nusbaum, Ph.D.

Teresa Wiesak, Ph.D.

Jennifer Fries, BSN, R.N.

December 27, 1999

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

2001-F Greentree Executive Campus
Route 73 & Lincoln Drive West
Marlton, NJ 08053
Phone: 856/988-0072
Fax: 856/988-0056
E-mail: gstusa@ivfconsultants.com

Re: Docket #97N-484S, Suitability Determination for Donors of
Human Cellular and Tissue-Based Products

2848 Delsea Drive, Building 2
Vineland, NJ 08360
Phone: 856/794-8080
Fax: 856/794-3058

Dear Sir or Madam:

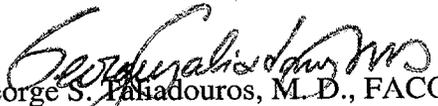
Mastori's Professional Plaza
163 Route 130, Building 2
Bordentown, NJ 08505
Phone: 609/324-0800
Fax: 609/324-9057

I am writing to protest the unnecessary intrusion of the Food and Drug Administration in the management of patient care with donor oocytes. The rules published by the FDA in the website are acceptable with the exception of the unnecessary requirements to test the egg donor six month after the harvest of the eggs, before the eggs are donated to the recipient. A six-month quarantine requirement will increase the number of cycles needed, the number of oocytes needed, and the number of embryos lost through this process. This will affect the cost of the treatment for the patient.

There is no adequate documentation to indicate that HIV or other infectious diseases are transmitted through the IVF-ET procedure. The concern about such a transmission must be balanced against the cost and the emotional expenditure of the patients under treatment.

Therefore, I would like to register my complaint and objection to these rules.

Sincerely,


George S. Taliadouros, M.D., FACOG

GST/sa

FDA122799-2

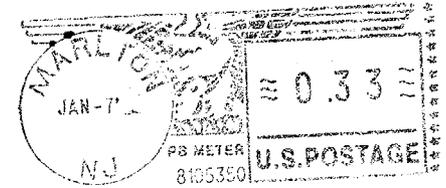
97N 484S

C434



**DELAWARE VALLEY INSTITUTE
OF FERTILITY & GENETICS**

Greentree Executive Campus
2001-F Route 73, Lincoln Drive, West
Marlton, NJ 08053



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