

Alfred J. Rodriguez, M.D., P.A.

Associate Medical Director, 1441 '00 JAN -3 AM 23

Presbyterian Hospital of Plano Arts Program

Advanced Infertility, Assisted Reproductive Technologies, and Gynecology

December 21, 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:

Please accept this letter as my objection to the proposed rules titled "Suitability Determination for Donors of Human Cellular and Tissue Based Products" pertaining to donor egg IVF. Requiring 6 months quarantine on embryo created from donor eggs will add additional cost to the recipients along with decreasing the chance of pregnancy by at least one half. Since there has never been a reported case of HIV or any other infectious disease from a donor egg IVF, I do not see the reasoning for implementing these rules.

Should you need additional information you may reach me at the address below.

Sincerely,



Alfred J. Rodriguez, M.D.

6200 West Parker Road, Suite 308, Plano, Texas (972)608-8364 FAX (972)608-8362

7777 Forest Lane, Suite 236-C, Dallas, Texas 75230 (972)566-4500 FAX (972)566-6861

97N 484S

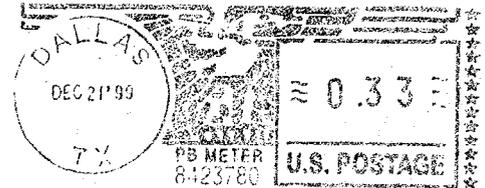
C368

NORTH DALLAS OB-GYN ASSOCIATES

OBSTETRICS, GYNECOLOGY & INFERTILITY

ALFRED J. RODRIGUEZ, M.D., P.A.
C. EDWARD WELLS, M.D., P.A.
DARRELL E. ROBINS, M.D., P.A.
JOHN PAUL ROBERTS, M.D., P.A.
STEVEN R. MACDONALD, M.D., P.A.

MEDICAL CITY DALLAS
7777 FOREST LN. BLDG. C, SUITE 236
DALLAS, TEXAS 75230



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

20852/9993

