

Yale University

School of Medicine
Department of Obstetrics & Gynecology
333 Cedar Street
P.O. Box 208063
New Haven, Connecticut 06520-8063

Campus address:
339 Farnam Memorial Building
333 Cedar Street

0645 '99 DEC 30 10 59

December 26, 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:

This letter is in regards to the proposed rules appearing in the Federal Register on December 3, 1999 pertaining to embryos resulting from donated oocytes. The proposed rules mandate quarantine of all embryos obtained from donated eggs. I find the proposed rules extremely disturbing. Clearly, all necessary steps must be taken to protect the public from infectious and other diseases. However, sweeping regulations such as those in the proposed rules should be based on evidence rather than on unfounded presumptions of danger. In vitro fertilization has been practiced for approximately 21 years; there is no conclusive evidence the gametes serve as vectors for the HIV virus.

The proposed rules will create numerous other problems that will not serve the public well. Quarantining embryos will result in astronomical increases in costs to our patients. Not only will the cost per oocyte donation cycle increase; the number of cycles needed to obtain a pregnancy will also increase. Pregnancy rates after transfer of frozen-thawed embryos is far less than pregnancy rates achieved after transfer of fresh embryos. We estimate that cryopreserved embryos would decrease the pregnancy rate in our oocyte donation program by about 60-70%.

There will be a tremendous loss of embryos as a result of cryopreservation and quarantine of embryos. Thousands of viable human embryos will be destroyed. The thought of destroying embryos based on unfounded concerns regarding transmission of infectious diseases is very troubling.

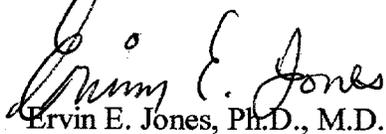
97N 484S

C342

We must also take into consideration the health and well being of our patients. A 6-month quarantine of embryos after freezing will result in unacceptable delays, perhaps even years, since the number of cycles required to achieve a pregnancy will be increased. A majority of recipients requesting egg donation are of advanced age to begin with. There are numerous obstetrical risks associated with advanced maternal age. Recipient mothers would be much older at the time of their pregnancy and many would give up or choose not to pursue child bearing. As a result, many potential recipients of donated embryos will be denied the chance to have child.

If the proposed rules go into effect, care of our patients will be severely compromised and thousands of embryos will be destroyed. Please reconsider the proposed rules with these thoughts in mind.

Sincerely,

A handwritten signature in cursive script that reads "Ervin E. Jones".

Ervin E. Jones, Ph.D., M.D.

Professor and Director

Assisted Reproduction

Division of Reproductive Endocrinology

Director of Medical Studies

Department of Obstetrics and Gynecology

EEJ/jlm

FedEx USA Airbill

FedEx Tracking Number

808474366773

Form I.D. No.

0210

Recipient's Copy

1 From
Date 12/29/99

Sender's Name Ervin E. Jones, Ph.D., M.D. Phone 203-785-3581

Company YALE UNIVERSITY

Address SI- Dept./Floor/Suite/Room

City NEW HAVEN State CT ZIP 06511

2 Your Internal Billing Reference Information VIP 1233555 68LA YALE CHG #

3 To
Recipient's Name Dockets Management Branch (HFA-305)

Company Food an dDrug Administration

Address 5360 Fishers Lane Room 1061 Dept./Floor/Suite/Room

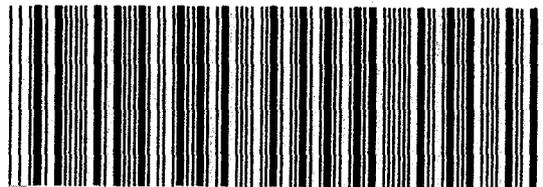
City Rockville State MD ZIP 20852

For HOLD at FedEx Location check here

Hold Weekday (Not available with FedEx First Overnight) Hold Saturday (Not available at all locations) (Available for FedEx Priority Overnight and FedEx 2Day only)

For WEEKEND Delivery check here (Extra Charge, Not available at all locations)

Saturday Delivery (Available for FedEx Priority Overnight and FedEx 2Day only) NEW Sunday Delivery (Available for FedEx Priority Overnight only)



8 0 8 4 7 4 3 6 6 7 7 3

4a Express Package Service Packages under 150 lbs.

FedEx Priority Overnight (Next business morning) FedEx Standard Overnight (Next business afternoon)
 FedEx First Overnight (Earliest next business morning delivery to select locations) (Higher rates apply)
 FedEx 2Day (Second business day) FedEx Express Saver (Third business day)
FedEx Letter Rate not available. Minimum charge: One pound rate.

4b Express Freight Service Packages over 150 lbs.

FedEx Overnight Freight (Next business day) FedEx 2Day Freight (Second business day) FedEx Express Saver Freight (Up to 3 business days)
(Call for delivery schedule. See back for detailed descriptions of freight services.)

5 Packaging FedEx Letter (Declared value limit \$500) FedEx Pak FedEx Box FedEx Tube Other Pkg.

6 Special Handling (One box must be checked)
Does this shipment contain dangerous goods? No Yes (Shipper's Declaration not required) Yes (Shipper's Declaration required)
 Dry Ice (Dry Ice, 9, UN 1845) x kg. Cargo Aircraft Only
*Dangerous Goods cannot be shipped in FedEx packaging.

7 Payment
Bill to: Sender (Account No. in Section 1 will be billed) Recipient (Enter FedEx Account No. or Credit Card No. below) Third Party Credit Card Cash/Check
 Obtain Recipient FedEx Account No.



Total Packages Total Weight Total Declared Value \$.00 Total Charges \$

*When declaring a value higher than \$100 per shipment, you pay an additional charge. See SERVICE CONDITIONS, DECLARED VALUE, AND LIMIT OF LIABILITY section for further information.

8 Release Signature

Your signature authorizes Federal Express to deliver this shipment without obtaining a signature and agrees to indemnify and hold harmless Federal Express from any resulting claims.

Questions?
Call 1-800-Go-FedEx® (800)463-3339

321

WCSL 0798
Rev. Date 3/98
Form #153023
©1994-98 FedEx
PRINTED IN U.S.A.