



**ROBERT WOOD JOHNSON
UNIVERSITY MEDICAL GROUP**
UMDNJ - ROBERT WOOD JOHNSON MEDICAL SCHOOL

Department of Obstetrics, Gynecology
and Reproductive Sciences

www.fertilityucref.com

Main Office

303 George Street
Suite 250
New Brunswick, NJ 08901

Patient Appointments:
732-235-7301/7302

General Number:
732-235-7300

Fax Number:
732-235-7318

Princeton Office

601 Ewing Street
Princeton, NJ 08540

Patient Appointments:
732-235-7301/7302

General Number:
609-924-8050

Fax Number:
609-924-7135

South Plainfield Office

1810 Park Avenue
South Plainfield, NJ 07080

Patient Appointments:
732-235-7301/7302

General Number:
908-222-1120

Fax Number:
908-222-1749

David B. Seifer, M.D.

*Associate Professor
Division Director*

Eckhard Kemmann, M.D.

Professor

Michael K. Bohrer, M.D.

Assistant Professor

Doreen Hock, M.D.

Assistant Professor

Rahul Sachdev, M.D.

Assistant Professor

Susan Trout, M.D.

Assistant Professor

Robert Shelden, Ph.D.

*Associate Professor
Director, Laboratory Services*

UMDNJ, New Jersey's University of the Health Sciences

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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

Dear Sir/Madam:

I just learned about a proposed ruling requesting that embryos from egg donor IVF cycles would have to be quarantined for six months, during which time the egg donors are retested for infectious diseases.

This proposed ruling is a deviation from the current standard of care. The current standard of care requires that egg donors and other recipients are tested for HIV. There are no data, that I am aware of, that indicate that the current system is inadequate.

The proposed ruling would also determine that innumerable healthy embryos will be condemned to an unnecessary procedure (namely freezing) which could lead to their demise.

In addition, the proposed changes will lead to significant cost increases, which will further exclude couples from this treatment modality, which is not covered by third party carriers.

I, therefore, request that you review the proposed ruling and adjust it to the current standard of care.

Sincerely,

Eckhard Kemmann, M.D.
Professor
Division of Reproductive
Endocrinology/Infertility

97N 484S

/cm

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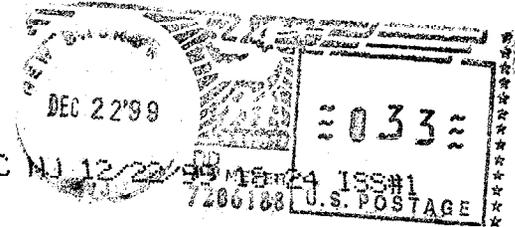
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E. Kemmann, MD

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 303 George Street, Suite 250
 New Brunswick, NJ 08901



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