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CAHP Building, 121 Washington Avenue
Lexington, Kentucky 40536-0003
FAX (606) 257-1816 (606) 323-1100 ext. 262
Divisions of:
Clinical Laboratory Sciences (606) 323-1100 ext. 260
Clinical Nutrition (606) 323-1100 ext. 246
Communication Disorders (606) 257-7918
Physical Therapy (606) 323-1100 ext. 240
Radiation Sciences (606) 323-1100 ext. 248

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20852

As a group of concerned professionals, with a special interest in reproductive policy and ethics, we have formed a committee to address risks associated with the practice of gamete and embryo donation and developing regulation in this area. Members of the committee have been working on these issues for the past several years, and this special interest group, now referred to as the "Donor Registry Committee" has been convening since early 1998.

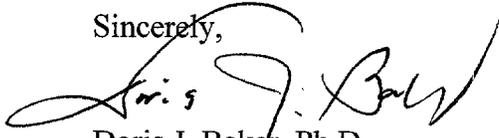
Although members of the Donor Registry Committee have concerns regarding certain aspects of the FDA's proposed regulation on reproductive tissue, this committee supports both the FDA proposal that would require reproductive tissue banks to register with the agency and guidelines for testing and use of donated reproductive tissue. The requirement for tissue banks to register with the FDA is a strong positive step toward protecting all individuals involved, but we promote a stronger alternative which is the establishment of a **CENTRAL REGISTRY** for tracking all reproductive tissue donors. Since there is the potential for donors, especially sperm donors, to provide samples to various tissue banks across the United States and since these "donors" may not always provide accurate information about the numbers of past donations, it would be difficult to track a given individual should a serious problem arise. If all donors, donations and recipients are recorded in a central data file, both the donor and all recipients could be rapidly located in an emergency situation. We are proposing a registry that would have a unique identifier for each donor and a system designed to protect donor confidentiality absent a serious problem. Since the registry is being proposed as strictly as a safety mechanism, and is not intended to erode donor anonymity/confidentiality, the committee has addressed certain concerns associated with the proposed central registry, including development of a unique identifier system for donors and who should have access to the registry.

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We would like to ask that our recommendation for a central registry be considered as the FDA continues to develop regulation in this area. Members of the Donor Registry Committee would gladly serve the agency in an advisory capacity.

Sincerely,



Doris J. Baker, Ph.D.
Committee Chair
e-mail: Dbake0@pop.uky.edu

Committee Members:

Doris J. Baker, Ph.D.

Associate Professor and Education Coordinator for Reproductive Laboratory Science, University of Kentucky, Lexington, KY

Andrea Braverman, Ph.D.

Director of Psychological Services, Pennsylvania Reproductive Associates, Plymouth Meeting, PA

Stephen L. Corson, M.D.*

Program Director, Pennsylvania Reproductive Associates, Philadelphia, PA

Susan Crockin, J.D.*

Attorney at Law, Newton, MA

Armand Karow, Ph.D.

Xytex Corporation, Augusta, GA

Jeanne V. Linden, M.D., M.P.H.

Blood and Tissue Resources, Wadsworth Center, New York State Department of Health, Albany, NY

Loren Marshall, M.D.

Center for Fertility & Reproductive Endocrinology, Virginia Mason Medical Center, Seattle, Washington

Martha McKinney, Ph.D.

Community Health Solutions, Inc., Richmond, KY

Julie A. Ribes, M.D., Ph.D.

Director of Clinical Microbiology, Dept. of Pathology, University of Kentucky, Lexington, KY

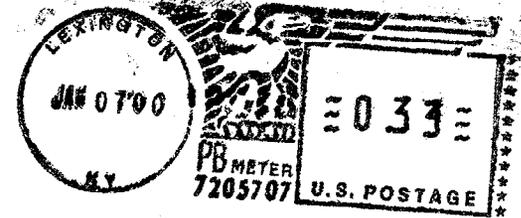
Jeannine Witmyer, Ph.D.

Supervisor, Embryo and Gamete Cryopreservation, Boston IVF, Boston, MA Doris J. Baker, Ph.D.

*did not provide input for this letter

UK UNIVERSITY
OF KENTUCKY

Department of Clinical Sciences
210 CAHP Building
121 Washington Avenue
Lexington, KY 40536-0003



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