



THE EYE-BANK FOR SIGHT RESTORATION, INC.

120 Wall Street, New York, New York 10005-3902

9537 '99 DEC 22 P2:14

December 14, 1999

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

RE: Docket No. 97N-484S

To Whom It May Concern:

These comments are in response to the above mentioned docket number. I would like to go on record opposing the following proposed regulation for Suitability Determination for Donors of Human Cellular and Tissue-based Products for the reasons listed below.

Part **1271.85** a (5) – Syphilis testing should not be required for eye tissue. Dr. **Marian Macsai** et al documented that syphilis is not transmitted from donor to recipient by corneal transplant. Dr. Jay Pepose documented the ineffectiveness of using syphilis testing as a marker for other diseases. Additionally, unnecessary syphilis screening would result in a 7.5% increase in the cost of serology testing for eye banks. Since we already conduct a social interview with an individual who is familiar with the donor's history, we effectively screen out unsuitable donors who may have a high-risk behavior for HIV. Therefore, syphilis testing should not be required for eye tissue.

Part 1271.80 (b) – A blood specimen should be collectable up to seven (7) days prior to or within 48 hours **after** tissue recovery to test for relevant communicable disease agents specified in 1271.85 for **all** donors, living or not. The proposed rule would appear to bar the use of specimen tests that were collected from organ donors, because they are collected **after** death (albeit a brain death note) and a day or two before tissue removal. Therefore, the collected specimen would not be from a living donor. Specimen tests collected by an organ procurement organization (OPO) for organ-eye donors are routinely utilized to determine eye tissue suitability for transplantation. The eye tissue removal may take place a day or two following the collection of the blood specimen from the brain dead donor. It would be unreasonable to require that a second blood specimen be collected at the time of eye tissue removal since known tests were performed within a reasonable amount of time. Additionally, it may be impossible to obtain an adequate blood specimen **after** the removal of major organs and the severing of major blood vessels associated with those organs.

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Therefore, a blood specimen should be collected up to 7 days prior to and within 48 hours after tissue recovery for all donors, living or not.

Part **1271.75** (a) (iv) – It is unreasonable to require eye banks to screen donors for transmissible spongiform encephalopathies (TSE) including Creutzfeldt-Jakob Disease (CJD) when there has never been a documented case of such transmission from donor to recipient in the United States in which the donor tissue was provided by an eye bank. It is unfair and unreasonable to impose regulations on the U.S. eye banking community that reflect the inadequacies of organizations outside the United States. The one documented case of CJD in the U.S. occurred more than 20 years ago after tissue was recovered from a patient who died in a neurological institute. The donor tissue was never evaluated nor screened by the local eye bank.

I respectfully urge you to consider my objections to the proposed rules for Suitability Determination for Donors of Human Cellular and Tissue-based Products.

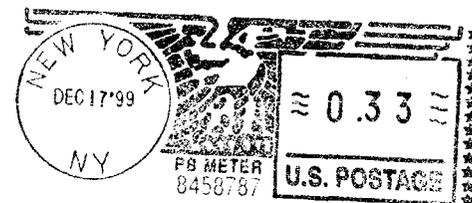
Sincerely,

A handwritten signature in black ink that reads "Patricia Dahl". The signature is written in a cursive, flowing style.

Patricia Dahl
Associate Director



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New York, New York 1000.53902



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