



# LIONS EYE BANK OF OREGON



with laboratories in Portland and Medford

An official project of the Lions Clubs of Multiple District 36 (Oregon) and a division of the Oregon Lions Sight & Hearing Foundation

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December 18, 2002

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

RE: Docket No. 02D-0266

Dear Sir or Madam,

Having reviewed the FDA's published "Draft Guidance for Industry: Preventative Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jacob Disease (CJD) and Variant Creutzfeldt-Jacob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-based Products (HCT/Ps)", I offer the following comments. As an accredited member of the Eye Bank Association of America (EBAA), the Lions Eye Bank of Oregon (LEBO) has a long history of service to the people of Oregon and Southwest Washington. We have accepted the responsibility for the provision of safe, quality eye tissue to those individuals who suffer from corneal blindness.

I appreciate the FDA's position regarding potential transmission of CJD and vCJD by transplantation of HCT/P's, however, I wish to emphasize that the EBAA has already initiated additional, required donor screening measures to protect the transplant recipients from this disease. Eye Banks are diligent stewards of potentially transplantable tissue. We are non-profit organizations and do not send transplant tissue to any for-profit entities, eliminating even a hint of risk-taking during donor screening. Our only incentive is to provide safe, quality eye tissue for transplant. EBAA medical standards were formulated and constantly reviewed/revised by knowledgeable experts using the most current, known medical science information.

A retrospective review of LEBO donor records from 1/1/02 through the present revealed that the proposed regulations would have an adverse effect on the number of corneas available for transplantation. 6.4% of total donor families in 2002 reported insulin dependence; under the proposed regulations, this would have represented a loss of 100 donors in 2002. In the period from 1/1/02 through 3/31/02 (3 months), a total of 52 prospective donors presented with CVA as the cause of death. Even if brain biopsy could be performed in a timely manner on these prospective donors, obtaining consent for this additional procedure from donor families could result in additional loss of viable donor tissue. Families in grief are reluctant to consent to additional procedures performed on their loved one, and hence further loss of vital transplant tissue would result.

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In sum the EBAA has historically been pro-active in strengthening medical standards to effectively screen for CJD and vCJD. While over 40,000 cornea transplants are performed annually, there has been only one reported case of transmission of CJD, and that case occurred in 1974, prior to the institution of EBAA medical standards in 1980. No cases have been reported since that time. For these reasons, FDA's adoption of the proposed Preventive Measures to Reduce the Possible Risk of Transmission of CJD and vCJD by HCT/Ps" must be revisited. Thank you.

Sincerely,

A handwritten signature in cursive script that reads "Barbara L. Crow". The signature is fluid and elegant, with a prominent initial 'B' and a long, sweeping tail on the 'w'.

Barbara L. Crow, CEBT  
Executive Director  
EBAA Immediate Past Chairman