



# THE EYE-BANK FOR SIGHT RESTORATION, INC.

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Serving Metropolitan New York, Nassau, Suffolk, Westchester, Rockland, Putnam and Orange Counties.

December 18, 2002

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

Re: Docket # 02D-0266

Dear Sir or Madam:

This is in response to the FDA's draft "Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)". As the executive director/CEO of the world's first eye bank, I am concerned that the preventive measures the FDA is recommending in the above named guidance document go far beyond what is reasonable to keep the public safe from CJD transmission after cornea transplantation, and as a result pose unnecessary costs to not-for-profit eye bank organizations.

It would be reasonable and appropriate to exclude a donor who

- has been diagnosed with vCJD or any other form of CJD;
- is at increased risk for CJD; (Donors are considered to have an increased risk for CJD if they have received a dura mater transplant, human pituitary-derived growth hormone, or have one or more blood relatives diagnosed with CJD)

However, I am concerned that excluding donors based on the length of time the individual has lived or traveled in the U.K. and/or Europe will be difficult to ascertain with certainty and would needlessly eliminate donors that pose no risk of transmitting CJD to the public.

It would be inappropriate to apply the guidelines used to screen living blood donors to screen cadaver eye/cornea donors. In the case of blood donors, the information about past medical and social history is obtained directly from the source – the blood donor. There is time to verify the information and obtain follow-up without incurring extraordinary expenses or rendering the donation useless. That is simply not the case with a cadaveric donor.

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Reviewing donors that have been transplanted at The Eye-Bank for Sight Restoration in the past two years reveals multiple scenarios in which the medical histories under the proposed guidelines would eliminate those donations from the pool of transplantable tissue. In particular, the requirement to exclude donors who have been diagnosed with dementia or any degenerative or demyelinating disease of the central nervous system unless microscopic examination of the brain rules out the possibility of any form of CJD will eliminate thousands of deaths from the pool of suitable donors. Additional expenses for this examination, an estimated \$3,000 in the New York metropolitan area, would in turn increase the processing fee for each donor. Never mind that the results of this examination wouldn't be known until well after the time frame that donor corneas are considered viable for most transplant procedures (which is within seven days after death). The requirement of a microscopic examination of the brain for these donors would apply to deaths such as cerebral vascular accident, trauma and most cancers, thereby eliminating at least 42% of the donor tissue currently considered suitable and provided by our eye bank.

**Therefore we oppose the exclusion of any donor who:**

- has been diagnosed with dementia or any degenerative or demyelinating disease of the central nervous system (CNS) or other neurological disease of unknown etiology; (HCT/Ps from donors with dementia confirmed by gross and microscopic examination of the brain to be caused by cerebrovascular accident, brain tumor, head trauma, or toxic/metabolic dementia and who are confirmed not to have evidence of TSE on microscopic examination of the brain may be acceptable based on an evaluation by the Medical Director.)

**Suggested change:** Instead, it is recommended that the diagnosis of dementia due to cerebrovascular accident, brain tumor, head trauma, or toxic and metabolic dementia be determined on clinical grounds with supporting documentation. The eye bank Medical Director should be charged with final review of such donor evaluation to determine suitability for transplant on a case-by-case basis.

Additionally, the requirement that donors be excluded from transplantation if insulin injection was received unless the manufacturing origins of the insulin was known and acceptable will be next to impossible to obtain. While some family members are familiar with the current drugs their loved one had been taking, it is completely unreasonable to

Food and Drug Administration  
Docket #02D-0266  
Page 3.

expect them to recall the product names of a drug that was taken within the past twenty years. This requirement would eliminate another significant portion of donors from the suitability pool. Based on our data another 16% of donors that were previously suitability for donation would be excluded from transplantation.

**Therefore, we oppose the exclusion of any donor who:**

- *has injected bovine insulin since 1980, unless you can confirm that the product was not manufactured after 1980 from cattle in the U.K.*

**Suggested change:** Omit this exclusion based on a lack of scientific correlation linking CJD with bovine manufactured insulin.

With respect to deferring donors who received blood transfusions while in the U.K. or Europe since 1980, it is only theoretical at this point that CJD could be transmitted by blood transfusion. Without scientific evidence that correlates blood transfusions and the transmission of CJD, it would be unreasonable to implement a deferral of a donor who had received a blood transfusion while in the U.K. or Europe.

Should these proposed guidelines become requirements, the result would mean increased costs associated with processing donor tissue and even more importantly, longer waiting time for patients needing the sight-saving cornea transplant surgery because of a significantly reduced supply of donations. This would impact the youngest recipients the most because corneas from trauma and cerebral vascular accident donors are often used on young recipients. Each of the proposed guidelines should have sound scientific evidence supporting the rationale for its implementation. Many of the proposed guidelines suggest theoretical risks. It would be inappropriate to implement drastic restrictions based on theoretical risks.

I appreciate the opportunity to comment on these proposed guidelines.

Sincerely,



Patricia Dahl  
Executive Director/CEO