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December 23, 2002

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Ms. Margaret M. Dotzel  
Associate Commissioner for Policy  
The Food and Drug Administration  
Dockets Management Branch (HFA-305)  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: Docket No. 02D-0266

Dear Associate Commissioner Dotzel:

The Eye Bank Association of America (EBAA) is pleased to provide comments on the Food and Drug Administration's (FDA's) published "Draft Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jacob Disease (CJD) and Variant Creutzfeldt-Jacob Disease (vCJD)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); Availability" (67 Federal Register 122; June 25, 2002). We recognize and appreciate FDA's intent in publishing these guidelines which are directed at protecting the public from the possible risk of transmission of CJD and vCJD in this country. The EBAA shares a concomitant and parallel level of commitment to protect our transplant recipient population's health and has taken the initiative to revise our screening criteria for ocular tissue to further protect transplant recipients from possible exposure to the agents of CJD and vCJD.

**Historical Context:**

The history of EBAA actions taken to prevent disease transmission through corneal transplantation demonstrates our commitment to safety. We will not compromise public health either by allowing inadequate protections, weak enforcement of standards, or, at the opposite end of the continuum, by

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unnecessarily limiting public access to sight restoring transplantation. Standards adopted by the eye banking and corneal transplantation community are based on current scientific knowledge, as well as justified anticipation of potential areas of concern.

Thus, in 1980, the EBAA was the first transplant organization to adopt medical standards. In the mid-eighties, the EBAA became the first transplant organization to require testing for HIV, then hepatitis B, with HCV shortly following, and the first transplant organization to develop and implement an inspection and accreditation program for eye banks. In the early 1990's, when leishmaniasis was a concern with Veterans returning from the Gulf War, the EBAA advised its members to take preventive steps to defer donations from candidates likely to be carriers. There is a process in place to address emergent outbreaks that may have specific epidemiological limitations.

Throughout the 1990's and into the millennium, the EBAA has partnered with the FDA in setting appropriate standards and best practices that will assure the best outcome for our patients and will protect public health and confidence in our system. The result is a truly impressive history of success: with the adoption of the HCV requirement in the mid-eighties, there has been no systemic disease transmission through corneal transplantation.

As a further protective measure for the safety of our transplant patients, the EBAA instituted an adverse reaction reporting system in 1990. This reporting system provides " a method for the receiving surgeon to report adverse reactions from the transplantation of corneal, scleral or other ocular tissue to the source eye bank (EBAA Medical Standard G100, Quality Assurance). The EBAA developed a report form which is provided to corneal surgeons when they receive donor tissue by the providing bank or through periodic mailings from their affiliated eye bank. Surgeons are asked to complete the form and return it whenever infection or other dysfunction attributable, or potentially attributable, to the donor eye tissue occurs in a recipient. Systemic infectious disease such as HIV, hepatitis, or syphilis which develops in a recipient, whether or not it is suspected to be donor tissue related, must be reported to the EBAA. Additional data are recorded by eye bank personnel, including status of the mate cornea from the same donor. A copy of the completed form is then forwarded to the EBAA for entry into the Adverse Reaction Registry. This data is reviewed by the EBAA's Medical Review Subcommittee, which then reports the periodically updated summary data at the semiannual meeting of the EBAA's Medical Advisory Board. The Subcommittee determines if further epidemiologic investigation appears warranted, and the Board may then implement corrective and preventive actions. The process of the adverse reaction reporting system has been previously published (Archives of Ophthalmology 1995;113:1497), and the registry serves as a useful resource for monitoring the safety of eye banking in North America. In sum, surveillance of the entire community is ongoing and is predictive of emerging problems.

## **Transmission of CJD via Corneal Transplant Occurred Prior to the Adoption of EBAA's Medical Standards:**

Transmission of CJD has occurred through corneal transplantation; however, the one reported case occurred in 1974 [1], prior to the inception of EBAA medical standards, which just six years hence would have interrupted the chain of events that led to transmission. The corneal tissue was provided directly within the hospital to the waiting recipient and was not processed through an eye bank. That loophole has been closed and would not occur today.

In all the cases the FDA cites as possible examples of CJD transmission through corneal transplantation, the donation would have been contraindicated under current EBAA Medical Standards as all the donors exhibited signs and symptoms suggestive of prion disease. There are no documented cases that suggest the transmission of CJD or vCJD through an ocular transplant from a donor completely absent signs and symptoms suggestive of prion disease.

Only one eye bank in the United States does not belong to the EBAA. This eye bank is in a state which has incorporated the EBAA standards into their state health requirements. The EBAA has worked collaboratively with the American Academy of Ophthalmology for years to educate its members regarding the necessity of procuring tissue through a certified eye bank; there is no other option, to our knowledge.

## **Current EBAA Exclusionary Criteria for CJD and vCJD:**

Nevertheless, it took only one case 30 years ago to increase our vigilance, adding strict medical standards which have pre-empted the possibility of another transmission in the U.S. We do not hesitate to adopt and implement new criteria as an integral component of our standards for safety. Current EBAA Medical Standard D1.120, Contraindications, identifies as a contraindication for transplant donors that have history suggestive of a potential for increased risk of CJD or transmissible encephalitis. These exclusionary criteria include the following, with the recent requirement of "dementia":

- o Death of unknown cause
- o Death with neurological disease of unestablished diagnosis
- o Dementia, unless due to cerebrovascular disease, brain tumor, or head trauma. Donors with toxic- or metabolic-induced dementia may be acceptable only if approved on a case by case basis by the eye bank's Medical Director after consultation.
- o Subacute sclerosing panencephalitis
- o Progressive multifocal leukoencephalopathy
- o Congenital rubella
- o Reyes syndrome
- o Active viral encephalitis or encephalitis of unknown origin or progressive encephalopathy
- o Rabies

- o Recipients of human pituitary-derived growth hormone (pit-hGH) during the years from 1963-1985
- o Recipients of non-synthetic dura mater grafts

Any donor with an established diagnosis of CJD or dementia due to prion disease would be excluded from donation by the above criteria.

### **Other Models for Guidance:**

The EBAA has opened and maintained an ongoing dialogue with the foremost experts in CJD in other countries in order to learn from their experience and application.

Andrew Tullo, M.D., Chair of the Ocular Tissue Standards and Audit Group of the Royal College of Ophthalmologists, in England, opines "...it is felt that the bulk of the British population was exposed to contaminated food stuffs during the 1980's," and, further, "I would express the view that it is not assumed that the agent of vCJD is any more likely to be present at any time in the human cornea than in classical CJD and that none of the actual or possible incidents involving corneal transplantation and CJD would have occurred if the currently agreed to international criteria had been adhered to." Through this statement, Dr. Tullo indicates that compliance with accepted standards already in place would have prevented transmission.

When weighing these proposed safety measures, it may be reassuring to note Dr. Tullo's opinion; if this were the 1980's, there would be work to do, but an examination of eye banking medical standards demonstrates that something has been done, that the community has acted in a proactive and expeditious manner and that adequate safeguards are in place.

### **Blood Model:**

The application of FDA's draft screening criteria based on a blood model is troubling and inappropriate. The application of a blood model cannot be easily or successfully extrapolated for ocular tissue donation. The primary difference, of course, is that blood donors are alive, and almost all tissue donors are deceased (the exceptions are reproductive tissue, autologous donation, and unusual cases). In donating blood, information on the donor is provided directly by the donor; there is opportunity for follow-up and verification of information. In ocular tissue donation, by contrast, information is provided by the donor's family or someone with an "affinity" relationship to the deceased. Therefore, the information is interpretive in nature and legally considered "hearsay." Often the family cannot provide complete information, which results in a deferred donation, disposal of tissue or placement of tissue for research or training (R/T) purposes.

Additionally, and most importantly, in eye and tissue donation, the donor's actual medical record is examined. A physical examination of the body is required and testing and review of donor specimens and donated tissue for possible disease transmission is standard.

Unlike eye donation, blood donors can be deferred with the possibility of donating at a later date and appeals can be issued to the public for emergency donation. Ocular tissue donors are one-time cadaveric donors; while appeals can be issued for increased donation, the finite number of deceased individuals will not increase. Unlike a commercial product, the cornea supply cannot be ordered or assured.

When developing screening criteria for donation, the differences of the blood donor community and the tissue donor community must be taken into account. The tissue community has the benefit of access to a patient's medical record and physical review of the body, in addition to testing results and an interview with the family. The overall process provides a much more comprehensive health account at the time donation occurs.

In all the cases the FDA cited as potential examples of CJD transmission through corneal transplantation as a justification for its exclusionary criteria, the donation would have been contraindicated under current EBAA Medical Standards as all the donors exhibited signs and symptoms suggestive of prion disease. The blood industry does not have access to an individual donor's health record, nor do they have the opportunity to physically examine the donor's body and therefore, cannot ascertain health related information with the certainty that the tissue community can.

### **Overview of Supply of Corneal Tissue:**

EBAA's membership is comprised of 92 U.S. member eye banks, a participation rate of 99% of the eye banks in this country. Our member banks provide approximately 97% of all corneal tissue for transplantation. All eye banks are 501(c)(3) organizations whose sole mission is to procure and provide donated human eye tissue for sight restoring transplantation procedures. The EBAA takes pride in ensuring the highest standards of safety for our member eye banks to practice and has established strict Medical Standards that are reviewed and revised annually. To be accredited, EBAA members are subject to an inspection and certification program to demonstrate adherence to such standards and other requirements.

EBAA member banks provided 46,532 corneas for transplantation in 2001 [2]. A total of 83,075 were actually procured, with the difference deemed unsuitable for transplantation. These corneas did not meet strict eye bank standards, and based on exclusionary criteria, were not used for transplant, but were instead provided for research, education, or destroyed.

Corneas are a gift of human eye tissue made by the donor prior to death, or by the donor's family following the donor's death. As a gift from a human donor, a supply can not be ordered or assured. Further, a supply can not be maintained, because a cornea loses its viability within days of procurement. To meet the need of approximately 46,000 corneas each year, it is necessary to procure approximately twice the amount of tissue.

The future availability of corneas for transplant procedures is uncertain, given the increasing use of LASIK and other surgical procedures which modify the cornea. Currently, individuals who have undergone these procedures are not considered suitable donors for corneal transplantation. In the past five years alone, there has been a sharp increase in LASIK procedures, doubling from 1997 to 450,000 in 1998. The number of procedures in a five year period totals 5,415,000. This is cumulative and increasing and could well adversely affect the supply of corneas for transplantation.

The future demand for transplantable corneas and ocular research tissue is likely to increase. The National Eye Institute and Prevent Blindness America released a report in March of this year, concluding that more Americans than ever are facing the threat of blindness from age related eye disease. "Over one million Americans aged 40 and over are currently blind and an additional 2.4 million are visually impaired. These numbers are expected to double over the next 30 years as the Baby Boomer generation ages" [3].

In sum, in order to ensure a sufficient supply of corneal tissue for transplantation, necessary for the restoration of sight, eye banks must collect and distribute corneal tissue within strict time parameters and in volume sufficient to meet the need.

#### **FDA Donor Deferral Criteria/EBAA Response:**

**FDA Donor Deferral Criteria 1:** "has been diagnosed with vCJD or any other form of CJD"

**EBAA Response:** We support this donor deferral criteria as our standards already require that such tissue be ineligible. We will, however, modify our standards to directly state this deferral requirement as the FDA has suggested.

**FDA Donor Deferral Criteria 2:** "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)."

**EBAA Response:** We support this donor deferral criteria with the following modification: "has been diagnosed with dementia or any degenerative or demyelinating disease of the central nervous system (CNS) or other neurological disease of unknown etiology **with the exception of** ~~(HCT/Ps from donors with dementia confirmed by gross and microscopic examination of the brain~~ **clinical, laboratory, and/or neuroimaging criteria** 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~~ **and determined** acceptable ~~based on an evaluation by the Medical Director~~ **upon evaluation**)." The EBAA will modify its standards to include this language.

The FDA requirement for gross and microscopic examination of the brain to confirm one of the noted diagnoses and to rule out evidence of TSE would eliminate a large percentage of the donor pool without significantly reducing the risk of transmission of disease. The time necessary to conduct an appropriate brain biopsy to detect prion disease would exceed the time frame for the viability of the corneal tissue, essentially rendering all potential ocular tissue donors in this category unacceptable. The impact of this criteria as drafted could eliminate, just in the numbers of donors over the age of 60, 27% of the current donor pool as well as an undetermined number of potential donors below the age of 60.

Instead, the EBAA recommends 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 clinical laboratory and neuroimaging data. The Medical Director is further charged with final review of the tissue and supporting data for its suitability for transplant on a case by case basis. These diagnoses can be made with a high degree of specificity and sensitivity. Thus possible donors will be ruled eligible on scientific grounds, rather than ineligible due to a testing requirement that is not timely.

**FDA Donor Deferral Criteria 3:** “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”

**EBAA Response:** We support this donor deferral criteria with the following modification: “is at increased risk for CJD; (Donors are considered to have an increased risk for CJD if they have received a **non-synthetic** dura mater graft, human pituitary-derived growth hormone during the years of 1963-1985, or family history of blood relatives diagnosed with CJD” The specific exclusionary criterion of family history of a blood relative with CJ disease was approved at the Fall 2000 Medical Advisory Board and appeared in the November 2000 edition of the EBAA Medical Standards. It was inadvertently omitted from current EBAA Medical Standards and will be corrected immediately. This was the result of a printing error, not a policy change.

Medical records for those that have received dura mater transplants may indicate whether the dura mater was synthetic or non-synthetic. Synthetic material has not been shown to transmit disease.

**FDA Donor Deferral Criteria 4-6:**

(4) “spent three months or more cumulatively in the U.K. (see Appendix) from the beginning of 1980 through the end of 1996;”

(5) “is a current or former U.S. military member, civilian military employee, or dependent of a military member of civilian employee who resided at U.S. military bases in Northern Europe (Germany, U.K., Belgium, and the Netherlands) for six months or more from

1980 through 1990, or elsewhere in Europe (Greece, Turkey, Spain, Portugal, and Italy) for 6 months or more from 1980 through 1996;”

(6) “lived cumulatively for 5 years or more in Europe from 1980 until the present (note this criterion includes the time spent in the U.K. from 1980 through 1996)”

**EBAA Response:** We do not support donor deferral criteria 4-6, all relating to travel or residence in Europe for various periods of time, during certain years. We would instead support the soliciting of this donor information for inclusion in the donor profile as part of a controlled investigation to determine the impact of such information as a factor to reduce the risk of CJD and vCJD transmission (discussed below). As drafted, this exclusionary criteria will disqualify a great number of donors without any scientific basis to demonstrate that risk would be reduced. Unlike blood donors, tissue donors are all cadaveric. A medical and social history must be obtained from family members or significant others rather than directly from the donor. Accordingly, a documentable travel history is difficult to obtain. If the family or significant other can not answer these questions with certainty, the donor would have to be deferred. Incomplete travel histories, coupled with positive travel histories that are only a theoretical risk, would devastate our donor pool.

The travel questions are based on theoretical risk posed by those who may have been exposed to prion disease due to their residency or travel in countries identified as high risk countries. The problem with such criteria is that it is only theoretical; exposure could have occurred within an individual’s first five minutes of stepping foot in Britain. Yet, FDA’s criteria focus only on those who were there for an arbitrary length of time. This seems somewhat inconsistent. The EBAA would recommend that exclusionary criteria (4), (5), and (6) not be exclusionary criteria, but instead become questions to obtain information for the donor profile as part of a controlled investigation to determine the impact of such information as a factor to reduce risk of transmission the agents of CJD and vCJD. The EBAA would further recommend that questions be broadened for the purpose of a compiling a more comprehensive donor travel profile for any travel or residence in the United Kingdom from 1980 through 1996, or any travel or residence in Europe from 1980 through 1996. As noted earlier, this information is obtained through the donor’s family or those with an affinity relationship to the donor. A broader question is more likely to establish whether a donor ever traveled or resided in identified high risk countries. Given that the risk is only theoretical, the EBAA recommends only the collection of data at this juncture. There is no scientific basis that indicates implementation of this requirement will indeed reduce risk.

Strict medical screening criteria are in place to examine the body for signs and symptoms suggestive of prion disease, as well as information provided by the present social interview to exclude those with possible prion disease from the donor pool. In all the cases the FDA cites as possible examples of CJD transmission through corneal transplantation, the donation would have been contraindicated under current EBAA Medical Standards as all the donors exhibited signs and symptoms suggestive of prion disease.

**FDA Donor Deferral Criteria 7:** “received any transfusion of blood or blood components in the U.K. between 1980 and the present”

**EBAA Response:** We do not support donor deferral criteria 7. We would instead support the soliciting of this donor information for inclusion in the donor profile as part of a controlled investigation to determine the impact of such information as a factor to reduce the risk of CJD and vCJD transmission. The possibility of CJD or vCJD transmission through blood or blood products in humans or primates remains theoretical. Blood or blood products have not been shown to transmit the agents of CJD or vCJD [4] and there has been no transmission to date. Therefore, it is premature to exclude donors who have received blood or blood products in the U.K. The EBAA would recommend that exclusionary criteria (7) not be an exclusionary criteria, but instead become a question to obtain information for the donor profile as part of a controlled investigation to determine the impact of such information as a factor to reduce the risk of transmission of the agents of CJD and vCJD.

Given that this risk is only theoretical, and that strict screening criteria are in place to screen for signs and symptoms of prion disease in donors, we recommend only the collection of data at this time. There is no scientific basis that indicates implementation of this requirement will indeed reduce risk. In all the cases the FDA cites as possible examples of CJD transmission through corneal transplantation, the donation would have been contraindicated under current EBAA Medical Standards as all the donors exhibited signs and symptoms suggestive of prion disease.

**FDA Donor Deferral Criteria 8:** has injected bovine insulin since 1980, unless you can confirm that the product was not manufactured after 1980 from cattle in the U.K.

**EBAA Response:** We do not support donor deferral criteria 8. We would instead support the soliciting of this donor information for inclusion in the donor profile as part of a controlled investigation to determine the impact of such information as a factor to reduce the risk of CJD and vCJD transmission. There is no scientific evidence that prion disease can be transmitted through use of bovine-derived insulin. The draft guidance document even acknowledges that: “no cases of transmission of vCJD have been reported in recipients of bovine insulin or other injectable products manufactured in BSE-countries.” Donors in BSE-countries, who have used bovine-derived insulin, are not excluded from the donor pool.

Implementation of this criteria would eliminate almost all insulin users from our donor pool. Eye banks must rely on the donor’s next of kin and medical records to determine whether insulin was used and where such insulin was manufactured. The majority of donor families will not be able to answer this question with certainty. Additionally, insulin has not always required a prescription for purchase. Incomplete information would result in donor deferral.

One of our member eye banks, specifically reviewed its donor charts to estimate the number of deferrals that would result should criteria 8 be required. The bank determined that 11.7% of its donor pool would have been eliminated. If 11.7% of the

23,266 eye donors were ruled out due to insulin use (type unknown), then 2,722 donors or 5,444 corneas would be eliminated on an annual basis from the donor pool. Such reduction in available donors, in addition to donors ruled out based on other FDA recommendations, would have a devastating effect on the supply of corneas available for transplant and would significantly increase the population of the blind and visually impaired in this country.

Given that this risk is only theoretical, and that strict screening criteria are in place to screen for signs and symptoms of prion disease in donors, we recommend only the collection of data at this juncture. There is no scientific basis that indicates implementation of this requirement will indeed reduce risk. In all the cases the FDA cites as possible examples of CJD transmission through corneal transplantation, the donation would have been contraindicated under current EBAA Medical Standards as all the donors exhibited signs and symptoms suggestive of prion disease.

#### **Impact of the FDA's Proposed Deferral Requirements on Ocular Transplantation:**

As of the writing of this response, the EBAA does not have comprehensive data on the impact of the FDA's proposed deferral requirements on its donor pool. A reliable study would necessitate additional time. Several of the proposed deferral requirements, especially those referencing foreign travel and blood or blood product transfusions in the United Kingdom, cannot be retrospectively assessed through review of donor profiles as such requirements were not, and, are not currently, included in the donor profile. A controlled investigation would have to be established to specifically look at these proposed deferral requirements over an extended period. Based on discussions with our member banks and some preliminary information related to certain proposed deferral requirements, the Association hypothesizes that the total loss of tissue due to implementation of FDA's donor deferral criteria would devastate our donor pool and the ability to conduct sight restoring transplantation procedures. Lack of corneas would create a transplant recipient waiting list for the first time in more than a decade. Surgery would most likely return to an unscheduled, "emergency" basis. The ultimate cost of such a significant reduction in the corneal supply would be measured in patient blindness.

The EBAA, in cooperation with the FDA, has conducted a limited preliminary investigation to assess information on CJD risk provided through the medical and social history interview. When results are available, they may be used as a model to design a more extensive study with the goal of identifying adequate parameters to assess such risk. The EBAA will share these results with the FDA and looks forward to participating in a larger and broader assessment of knowledge of donor history gained through the medical and social interview.

#### **Support for a New Diagnostic Tool:**

The EBAA supports providing incentives to the research community, perhaps based on the orphan drug model, to encourage the development of a diagnostic test which can be used to further screen potential donors for the infective agents associated with CJD and

vCJD. This tool would benefit the entire donation community, but in order to be useful, must be cost effective and timely for eye banks.

We appeal to the FDA to hasten the development of a diagnostic test that will decisively determine the presence of prion disease. Such diagnostic test should not require surgical invasion of the donor, exceeding current, routine practices of eye recovery, and not delay procurement or transplantation.

### **Summary**

The EBAA supports the implementation of the FDA's deferral criteria that are scientifically determined to reduce risk for CJD and vCJD exposure for transplant recipients, whose benefit can be measured to produce the desired outcome and whose application would not adversely affect the supply of corneal tissue available to those in need. In all possible cornea transmission cases cited by the FDA in support of FDA's exclusionary criteria, the cornea donors exhibited signs and symptoms suggestive of prion disease. Strict screening for signs and symptoms suggestive of prion disease are now employed by EBAA member banks and would have rendered such problematic donors ineligible. The EBAA commits to further strengthen its screening criteria, now and in the future, when criteria have a scientific basis for reducing risk and warrant implementation.

Thank you for allowing our participation in the comment process. We look forward to an ongoing dialogue on this important matter.

Sincerely,



Patricia Aiken-O'Neill  
President

Enclosure

## **References**

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3. U.S. Department of Health and Human Services, Press Release: "More Americans Facing Blindness Than Ever Before". March 20, 2002.
4. Weber DJ, et. a. Managing the risk of nosocomial transmission of prion diseases. *Curr Opin of Infectious Diseases* 5(4):421-5, 2002.