EYE BANK ASSOCIATION of AMERICA

11 February 2010

Blood and Tissues Unit
Standards and Code of GMP
Office of Devices Blood and Tissues
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
biologicals_consultation@tga.gov.au

Dear Sir/Madam:

On behalf of the 85 U.S. and 14 international eye bank members, the Eye Bank Association of America (EBAA) appreciates the opportunity to comment on the Australian Therapeutic Goods Administration's (TGA) Draft *Standards for minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapies*.

EBAA Background

The 85 U.S. and 14 international eye bank members of the EBAA are proud of their history. The first corneal transplant was performed in 1905 and the first eye bank opened in New York in 1944, marking the first organized attempt to facilitate the transfer of tissue from donor to patient. This eye banking model was successfully replicated in other communities across the United States. Following the development of the eye banking system, the EBAA was founded in 1961 by the American Academy of Ophthalmology.

All eye bank members of the EBAA are not for profit organizations whose mission is to recover and provide donated human eye tissue for sight restoring transplantation procedures, education, and research. Significant gains in ophthalmology are, in part, due to donated ocular

tissue provided by these eye banks. The EBAA strives to ensure the superior quality of banked human eyes through the adoption and implementation of stringent medical standards.

U.S. eye banks lead the transplantation field with an accreditation program and medical standards that provide a model of success in the transplant community. The present system works extremely well, as demonstrated by our ability to provide sufficient amounts of tissue to those in need of sight restoring transplants and by the history of providing tissue safe for transplantation.

All EBAA member eye banks are not for profit organizations, operating on limited and carefully planned budgets that are supplemented in many communities by philanthropic organizations like the Lions Club and other charity organizations. Securing these precious human gifts of donation is a labor intensive process.

Balance must be achieved in drafting regulations with significant differences between the processing of eye tissue and the processing of other types of cellular and tissue-based products. In addition, about 20% of corneal tissue is distributed outside the U.S. which makes harmonization of international standards crucial to the global distribution of these tissues. To this end, EBAA believes the comments on the following pages complement and achieve TGA's safety objectives as well as harmonize with international standards.

Schedule 1, Table 1, page 6

Corneas preserved at less than or equal to 10 degrees Celsius – Compliance with requirements set out in Schedule 2 (All requirements except clause 4). Clause 4: "The manufacturer must have policies in place for the acceptance and release of each human blood and blood component, human tissue or human cellular therapy product based on the microbial specifications."

Recommendation: Remove requirement for culturing of all ocular tissue to harmonize with EBAA standards, as cited below:

(EBAA Medical Standards) G1.210 Microbiologic Culturing

Culturing of eye bank donor eyes may be performed despite the recognition by many that bacteriologic contamination of donor eyes does not necessarily lead to infection and that presurgical or surgical cultures may not correlate with postoperative infection if it should occur. Cultures may be performed either before and/or at the time of surgery.

a. Presurgical Cultures

Eye banks may elect to perform corneal-scleral rim cultures at the time of corneal preservation in tissue culture medium. Positive culture reports shall be reported to the receiving surgeon or recipient eye bank.

b. Surgical Culturing

Each eye bank shall indicate on the information sheet accompanying the tissue for transplantation whether corneo-scleral cultures were performed prior to distribution. Positive results in cases of postoperative infection shall be reported to the eye bank that recovered the tissue as well as to the eye bank that distributed the tissue.

Schedule 2, Clause 4, page 9

Clause 4 seems to contradict the requirement to look at the bioburden of these corneas in 8 (4) of the draft standard for banked ocular tissue.

Recommendation: Revise 8 (4) of the draft standard for banked ocular tissue to remove the requirement for culturing of all ocular tissue (see comment above).

Table 2, page 10

Under “Period of Ineligibility Prior to Donation for Allogeneic use”:

(a) Tattoo or body piercing

Recommendation: Use similar language for acupuncture – "6 months unless the tattoo or body piercing in that period was performed by a licensed practitioner using sterile, non-reused needles or equipment". Utilizing non-sterile practice is identified as the risk factor

(h) Ever injected any drug for a non-medical reason - Permanent

Recommendation: Change permanent to 5 years to harmonize with the U.S. Food and Drug Administration and EBAA timeframe.

(EBAA Medical Standard) D1.120 Contraindications, A – Penetrating Keratoplasty, 26 - HIV

b. Persons who have injected drugs for a nonmedical reason in the preceding 5 years including intravenous, intramuscular, or subcutaneous injection of drugs.

(i) A recipient of human derived clotting factors – Permanent

Recommendation: Change permanent to 5 years to harmonize with the U.S. Food and Drug Administration and EBAA timeframe.

(EBAA Medical Standard) D1.120 Contraindications, A – Penetrating Keratoplasty, 26 - HIV

c. Persons with hemophilia or related clotting disorders who have received human-derived clotting factor concentrates in the preceding 5 years. A donor who received clotting factors once to treat an acute bleeding event more than 12 months ago may be eligible to donate.

(s) Being a recipient of allogeneic organ(s) or cells, or deceased donor tissue allograft - Permanent

Recommendation: Remove (s) to harmonize with the U.S. Food and Drug Administration and EBAA standards where this is not a contraindication.

Schedule 5 (1)(c), page 16

Recommendation: Allow for an ante-mortem exam, or a limited autopsy, to harmonize with the U.S. Food and Drug Administration.

The Eye Bank Association of America appreciates this opportunity to provide public comments on the Australian Therapeutic Goods Administration's draft regulations.

Sincerely,

Patricia Aiken-O'Neill, Esq.
President & CEO
Eye Bank Association of America (EBAA)