Medical Advisory Board Alert

February 2, 2016

The Medical Advisory Board met by conference call in an urgent session on February 1, 2016 to discuss a potentially life threatening adverse event. A recipient of a keratolimbal allograft developed a malignant melanoma in the operative eye within two months of surgery. The donor tissue came from a patient with a history of malignant melanoma. While formal testing to confirm that the melanoma is donor derived is pending, all clinical evidence suggests it is. During the conference call, the MAB discussed the specifics of this case and several published articles on the behavior of malignant melanoma identified from a cursory review of current literature.

Following the discussion, the unanimous consensus of the MAB was that until a more formal analysis could be performed:

1. Ocular tissue from donors with any history of melanoma may not be released *for any surgical use*.

2. Ocular tissue from donors with any history of metastatic solid tumors may not be released for surgical use of vascular components, such as conjunctiva or keratolimbal tissue. Cornea and scleral distribution is acceptable.

These restrictions take effect immediately and will remain in effect until the EBAA Fall Meeting on October 13, 2016, when it is expected more targeted updates to the Medical Standards will be made to minimize the risk of tumor transmission from ocular tissues. This moratorium creates additional restrictions on ocular tissue donor eligibility determination and does not alter the current EBAA Medical Standards (November 2015).

To more thoroughly analyze the risks of tumor transmission and propose appropriate medical standard changes to the MAB at the Fall Meeting, a special subcommittee was created. Members of the subcommittee are:

- Jennifer Li, MD (Chair)
- Brian Philippy
- Jason Brosious
- Alan Sugar, MD
- Mary Gatien
- Michael Nalesnik, MD (Professor of Pathology, Medical Director, Histology and Immunocytochemistry Laboratories Division of Transplantation and Hepatic Pathology, UPMC Montefiore)

Questions regarding these changes can be directed to Michael Nordlund, MD, PhD, Chair of the Medical Advisory Board (mnordlund@cincinnatieye.com).