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May 3, 2001

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

RE: Proposed New Good Tissue Practice Rules

Dear Sirs:

I appreciate the concerns of the Food and Drug Administration in attempting to assure the highest quality of tissue practices in eye banking. The issue of primary cornea graft failure and other adverse reactions from keratoplasty is of great concern to eye bankers and is an appropriate concern of the Food and Drug Administration. The implication however from the Good Tissue Practice proposals is that greater regulation will decrease the frequency of untoward events.

The present self-regulatory process of the Eye Bank Association of America, which includes reporting to the EBAA all adverse events, has documented the impressively low frequency of adverse events. A review of this process by Wilhelmus, et al (Arch Ophthalmol 1995;113:1497-1502) concluded that "no clearly defined donor or eye banking factor accounted for most cases of primary graft failures..." Certainly the adverse event reporting system of the Eye Bank Association of America has not demonstrated any systematic eye banking source of adverse events.

In estimating the cost impact of primary corneal graft failures, the implication is that cost savings will be substantial by eliminating adverse events. The frequency of primary graft failures in 1999, as reported the Eye Bank Association of America, was only 42 cases out of approximately 40,000 keratoplasties. Intraocular infections (endophthalmitis) were reported in only 14 cases out of the same total number of transplants. These rates are impressively low and it is unlikely that additional regulations will have a significant impact on these. The use of the data from the Wilhelmus paper is

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misleading since it is based on a combination of reports from the literature with no standard or centralized reporting methods. The discussion in that paper suggests that the "current incidence (of primary graft failure) is believed to be about 1%..." In reality the incident is probably substantially lower. For our eye bank (MEBTC) for fiscal year 2000 there were five primary donor failures in 2,795 grafts or 0.18%.

In summary it appears that increased regulation through the proposed new GTP regulation will substantially increase the cost of providing sight-restoring tissue to patients but unlikely to significantly alter the safety of such tissue.

Thank you for the opportunity to make these comments.

Sincerely,

Joel Sugar, MD
Medical Director
Illinois Eye Bank

JS/rj

cc: Patricia Aiken-O'Neill
EBAA

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