



ALABAMA EYE BANK®
A NON-PROFIT EYE BANKING NETWORK

483121

2 August 2004

Marcia Newton
Senior Policy Analyst/Technical Advisor
Office of Clinical Standards & Quality
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore MD 21244

Dear Ms Newton:

Alabama Eye Bank Executive Director Doyce Williams was recently in San Francisco at the NATCO meeting. Upon returning he reported that he had had the opportunity to talk with Doctor Moritsugu, Deputy Surgeon General, regarding our concerns with a provision of the new cGTPs (donor eligibility): the listing of syphilis serology again being required for potential donors of corneas for transplantation. In our opinion, this is but the latest example demonstrating why eye banking should be considered separate from the general transplantation community as far as FDA regulations such as the cGTPs are concerned.

The Medical Advisory Board for the Eye Bank Association of America (MAB) had instituted syphilis serology as a requirement in the early days of HIV infections, basing it on the merely supposed possible usefulness thereof as a marker for a social history suggesting a greater likelihood for the presence of HIV infection. When HIV serology became available, the MAB removed syphilis serology as a requirement, since there is no scientific data suggesting danger or even possibility of transmitting Treponema via corneal transplantation, nor has a fifty plus year experience with Treponema and corneal transplantation indicated a need for Treponema serology.

In the 1 July 2004 CDC Telebriefing following the recent rabies transmission cases, as reported in the CDC Media Advisory, Doctor Daniel Hayes was quoted as saying "there have been hundreds of thousands of corneas and organ transplants with only -- prior to this, only one documented case of transmission, so I don't think that such a rare event should trigger any kind of widespread panic or reaction to do testing on a disease that is so infrequent." Not to mention that in the rarest event, considering the remoteness of possibility, of transmission of Treponema via keratoplasty, the condition is treatable. To require syphilis serology is simply not cost effective. -- and will be required in eye

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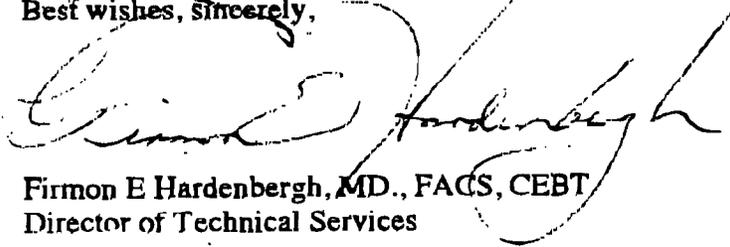
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banking only because the FDA has insisted on generalizing; i.e., applying all transplantation regulations to eye banks, to organ centers (distributing viable organs for transplantation) and tissue centers (distributing cadavaric skin, tendons, bone, cardiovascular tissue, e.g., heart valves and cadavaric organs) indiscriminately.

It is our position that eye tissue for transplantation is a distinctly different animal than are the other entities and logically should be regulated less generically and within reason rather than simply convenience. We would greatly appreciate your consideration of this issue to offer us guidance. If you wish, we could easily come to your office for discussion in person.

Best wishes, Sincerely,



Firmon E Hardenbergh, MD., FACS, CEFT
Director of Technical Services

cc: Kenneth P Moritsugu, MD, Deputy Surgeon of the US
Patricia Aiken-O'Neil, Esq, President/CEO, Eye Bank Association of America

FEH:ss