



LIONS EYE BANK OF TEXAS
DEPARTMENT OF OPHTHALMOLOGY
BAYLOR COLLEGE OF MEDICINE



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January 21, 2000

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

Re: 21 CFR, Parts 210.211, 820 and 1271
Docket No. 97N-484S

I am writing in reference to HCFA's proposed rule published on September 30, 1999, entitled "Suitability Determination for Donors of Human Cellular and Tissue Based Products." Ms. Patricia Aiken-O'Neill, President and CEO, Eye Bank Association of America, has previously submitted a comment on behalf of United States member eye banks. Ms. O'Neill's letter is dated December 26, 1999, and eloquently speaks for the eye banking community on the FDA's proposed rule. I support the position of the Eye Bank Association of America.

The Lions Eye Bank of Texas at Baylor College of Medicine is particularly concerned about the additional requirements for prion screening that would eliminate legislative consent tissue through medical examiners and coroners laws. The EBAA has appointed a Prion Subcommittee to study this as stated in Ms. O'Neill's letter. The FDA should not change the wording in the July, 1997 Final Rule to require a medical history interview for every donor until such time there is scientific evidence to support a public health need.

In particular, I also support the EBAA's proposal on page five of Ms. O'Neill's letter. This is the last paragraph in bold type "The EBAA respectfully requests relief from the imposition of additional broad regulatory requirements established under this proposed rule for human eye tissue until a public health threat is founded." Evidence points to the effectiveness of the EBAA Medical Standards in preventing disease transmission since these standards were established in 1980.

97N 484S

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I appreciate the opportunity to comment on this rule.

Sincerely,

A handwritten signature in black ink that reads "Mary Beth Danneffel". The signature is written in a cursive style with a large, looping "D" at the end.

Mary Beth Danneffel, R.N.
Executive Director

Rlb

Cc: Dan B. Jones, M.D.
Kirk R. Wilhelmus, M.D.
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