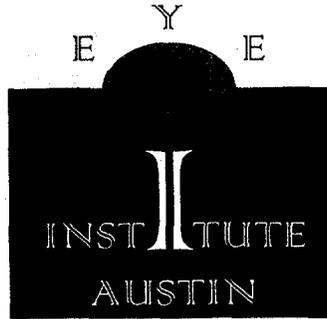


Robert L. Rock, M.D.
H. Grady Rylander, M.D.
George C. Thorne, M.D.
Gary R. Rylander, M.D.



Janet A. Lindsey, M.D.
K. Randy Pierce, M.D.
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Mark A. Plunkett, M.D.

December 17, 1999

Dockets Management Branch (HFA - 305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 97N-484S

Dear Sir or Madame:

I have been informed recently about new screening criteria for Creutzfeldt-Jakob disease scheduled to take effect in January 2000, which could dramatically limit our access to young, healthy corneal tissue for corneal transplantation. If the information is accurate and the new screening process negates the effectiveness of our current medical examiner laws I would ask that you and the Eye Bank Association of America reconsider the situation. As a corneal surgeon I would hope to be able to use the healthiest donor material with the smallest risk of disease transmittance. The risk of disease transmittance via corneal transplantation will never be zero unless such a procedure is abandoned. The risk of transmittance of Creutzfeldt-Jakob disease via corneal transplantation is theoretically small enough that I and most of my patients can live with it in order to continue a readily available supply of young donor material.

Please reconsider the impact of the new screening criteria on our future availability of healthy young corneal donor material.

Sincerely,

A handwritten signature in cursive script, appearing to read 'Gary R. Rylander'.

Gary R. Rylander, MD

97N 484S

C 350

EYE INSTITUTE OF AUSTIN, P.A.

5011 BURNET ROAD
AUSTIN, TEXAS 78756

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