

SOUTHWESTERN
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SOUTHWESTERN MEDICAL CENTER
AT DALLAS

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

RE: Docket #02D-0266

Dear Sir or Madam:

I would like to support strongly the significant objections of the entire corneal transplant community in the United States as sent to the FDA in a recent guideline document from the American Academy of Ophthalmology providing comment in response to the FDA's draft "*Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)*". As currently stated, the proposed guidance document will essentially eliminate the possibility of patients receiving corneal transplants in the United States on a timely basis. This conclusion is supported by both a sound cost-benefit analysis and a risk-avoidance analysis, which are not theoretical but have actually been published in the scientific, peer-reviewed literature. The reason for this unfortunate state of events is that the guidance document as currently provided by the FDA is based on a blood-based blood-banking analysis. Corneas are not blood. Careful attention to the details in the American Academy of Ophthalmology position paper will reveal both the factual basis for my comments, as well as the appropriate measures needed to resolve them. In the case of corneal transplantation and eye-banking, we can have continued safety and preserve the benefit for patients. I urge responsible officials at the Agency to review these documents. They will rapidly conclude that eye-banking is a separate case from blood-banking and that separate guidance documents are required. If they go further, they will realize that the eye-banking community is already concerned about these issues, and has successively addressed them. The proof is that there has been no case of transmission of CJD in the United States since 1974, which was before eye-banking started.

Thank you for your consideration.

Sincerely,



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