



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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MAY 23 2000

**TO:** Kathryn Zoon, Ph.D.  
Director, CBER, FDA

**FROM:** Acting Director, NIH

**SUBJECT:** Clarification of the NIH Position on the Proposed Medical History Interview Requirement for Creutzfeldt-Jakob Disease (CJD) Screening for Corneal Donation

This is in response to your April 19 memorandum requesting clarification of the NIH position on the medical history interview set forth in the FDA's proposed rule, "Suitability Determination for Donors of Human Cellular and Tissue-Based Products," published in the *Federal Register*, September 30, 1999.

In March 1999, NIH reviewed a draft of the proposed rule and, based primarily on the expert scientific advice of Dr. Paul Brown, provided the Department with a nonconcur response. We nonconcurred because the proposed rule failed to impose appropriate donor screening requirements, especially in light of the legislative consent provision that permits corneal tissue to be harvested in some States without the consent of the donor's next of kin. NIH recommended that corneal tissue be subject to the same screening history as dura mater; i.e., mandatory medical history at a minimum, and if such screening could not be conducted in a timely manner, then the corneal tissue should be determined to be unsuitable for donation.

Subsequently, FDA modified the proposed rule to reflect NIH's position. That is, FDA revised the proposed rule to require a donor medical history interview for all corneal donations. NIH reviewed FDA's modifications and concurred with these changes in April 1999.

In a letter dated January 27, 2000, the FDA received comments on CJD risk in corneal transplantation and donor screening under all circumstances from a committee commissioned by the Eye Bank Association of America (EBAA). The committee recommended against such screening because it "would likely lead to minimal additional improvement in safety" considering the "remarkably low" risk of developing CJD following corneal transplantation with use of the current practices for screening potential donors, but would reduce the overall supply of donor corneas and result in many patients not receiving treatment. Dr. Paul Brown, as a member of the committee, signed the January 27 letter, thereby raising questions with regard to the actual NIH position on this aspect of the FDA proposed rule.

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Dr. Brown's position as reflected in the January 27 letter from the EBAA committee was based on a newly completed risk-benefit analysis of the impact of donor medical history interviews for all corneal donations. The analysis provides convincing evidence that the revised proposed screening requirement would, at most, prevent about one death due to CJD per million corneal donors, over a period of ten years, with an accompanying loss of tens of thousands of unnecessarily excluded donors. Consequently, Dr. Brown has concluded that the language in the original proposed rule, the same as that currently set forth at 21 CFR 1270.21(g), permitting corneal donation under legislative consent without a donor medical history interview, would be preferable. Officials in other reviewing offices at NIH, including the National Eye Institute, concur with Dr. Brown's position, noting the newly proposed requirements would be highly unlikely to reduce the already extremely small chance of transmission of CJD via donor corneal tissue.

Therefore, NIH recommends the proposed rule be revised to reflect the language in the original proposed rule, permitting corneal donation under legislative consent without a donor medical history interview.

I apologize for any confusion or inconvenience that this change in our position has caused. However, as with all issues based on the best and most current science, new data can, and when warranted should, lead to new conclusions. Such is the case with NIH's position on this issue. We're grateful for the opportunity to revise our position.

Please direct any questions concerning this matter to Mr. Jerry Moore, NIH Regulations Officer, telephone 301-496-4607.

  
Ruth L. Kirschstein, M.D.