



Central Florida Lions Eye & Tissue Bank, Inc.

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June 29, 2000

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

Re: Docket No. 97N-484S; Suitability Determination for Donors of Cellular and Tissue-Based Products; 64 Federal Register 189; September 30 1999.

To whom it may concern:

This letter is written in response to 21 CFR Parts 210, 211, 820 and 1271 Suitability determination for donors of Cellular & Tissue-Based Products. I have read the new proposed rule with much concern in regard to recipient safety. As the Executive Director of the one the largest eye banks in the world, I feel this new rule presents a high potential risk for recipients and exemplifies a double standard for tissue recovery.

In 1993 when the FDA proposed a new rule regulating eye tissue procurement the eye banking community was concerned over the amount of eye tissue that could be lost by such a rule. In a short amount of time the eye banks realized the important issues addressed in this proposed rule and commended the FDA for such a positive approach to tissue safety. I know that during such time the FDA received multiple letters from eye banks that used "legislative consent procedures" stating this would be harmful to donation. Since the implementation, no donors have been lost and eye donation is higher than it has ever been before. In reviewing current data available, there is less than 2500 corneas procured under legislative consent compared to over 45,000 procured without it. I think the issue of "legislative consent" is again addressed in this new rule allowing a double standard to exist. I feel that the only way to accurately obtain the information the FDA request for recipient safety is through a thorough next-of kin interview.

The issues of the double standard process are relevant in items 1-14 listed below. The following donor screening questions required by the FDA and in no way possible can be determined by autopsy alone:

1. Men who have had sex with another man within the preceding five years.
Impossible to be assessed without donor screening.
2. Persons who have injected drugs for a non-medical reason in the preceding 5 years, including intravenous, intramuscular and subcutaneous injections.
Impossible to be assessed without donor screening.

97N-484S



5523 W. Cypress St. • Suite 100 • Tampa, FL 33607

Tel. (813) 289-1200 • Fax (813) 289-1800

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3. Persons with hemophilia or related clotting disorders who have received human-derived clotting factor concentrates.
Impossible to be assessed without donor screening.
4. Persons who have had sex in exchange for money or drugs in the preceding 5 years.
Impossible to be assessed without donor screening.
5. Persons who have had sex in the preceding 12 months with any person described in the 4 items above or with any person suspected of having HIV, hepatitis B virus, or hepatitis C virus infection.
Impossible to be assessed without donor screening.
6. Persons who have been exposed within the last 12 months to known or suspected HIV, HBV and/or HCV infected blood through percutaneous inoculation (needle stick) or through contact with an open wound, non-intact skin or mucous membrane.
Impossible to be assessed without donor screening.
7. Children 18 months of age or less born to mothers HIV-infected or at risk for HIV infection and who have been breast fed within the preceding 12 months, regardless of HIV status.
Impossible to be assessed without donor screening.
8. Current inmates of correctional systems (including jails and prisons) and individuals who have been incarcerated for more than 72 consecutive hours during the previous 12 months.
Impossible to be assessed without donor screening.
9. Persons who have had close contact with another person having viral hepatitis within 12 months preceding donation.
Impossible to be assessed without donor screening.
10. Persons who have had or have been treated for syphilis or gonorrhea during the preceding 12 months.
Impossible to be assessed without donor screening.
11. Persons who within 12 months of donation have undergone tattooing, acupuncture, ear or body piercing in which shared instruments are known to have been used.
Impossible to be assessed without donor screening.
12. Persons with diagnosis of Creutzfeldt-Jakob Disease or known family history (blood relative) of a person with non-iatrogenic Creutzfeldt-Jakob Disease.
Impossible to detect by autopsy alone without donor screening.





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13. Person who have received injections of human pituitary-derived growth hormone (pit-hGH).

Impossible to be assessed without donor screening.

14. Persons who are known to have received transplants of dura mater.

Impossible to be assessed without donor screening.

All 14 mandatory question listed above cannot be answered through autopsy unless a family or social screening is conducted.

Our eye bank has ruled out over 40 donors within the past year with the criteria listed above which was solely obtained by the interview of the next-of-kin. In perspective there are close to 100 eye banks across the nation. This could potentially equal 3,000-5,000 donors or 6,000-10,000 corneas for transplant. Is the medical community to believe that not a single of these cases would come through a "legislative consent" eye bank? In regard to the questions listed above, not a single one can be answered through an autopsy. Are we ruling out quality tissue without cause or is this a double standard within the rule? I also find it hard to believe that these same donor screening questions are mandatory for anyone donating blood, bone, or other tissues. At what point do jeopardize the safety of our recipients just to satisfy those few that refuse to change?

In closing, I would hope the FDA keeps the final rule as-is making a next-of-kin interview mandatory for all eye donations. The little affect if any it has on less than a handful of eye banks surely is outweighed by the risk we pose to the recipients.

Please feel free to contact me with any questions you may have.

Sincerely,

Jason K. Woody
Executive Director/CEO
Central Florida Lions Eye and Tissue Bank





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