Central Florida Lions Eye & Tissue Bank, Inc.

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December 20, 1999

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

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 director of the one the largest eye banks in the world, I feel this new rule presents a 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. 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.
2. Persons who have injected drugs for a non-medical reason in the preceding five years, including intravenous, intramuscular and subcutaneous injections.
3. Persons with hemophilia or related clotting disorders who have received human-derived clotting factor concentrates.
4. Persons who have had sex in exchange for money or drugs in the preceding five years.
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.

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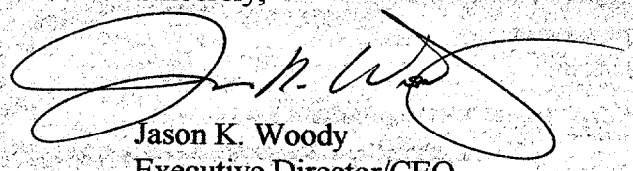
6. Persons who have been exposed within the last 12 months to known or suspected HIV, HBV and/or HCV infected blood through percutaneous inoculation (needle stick) or through contact with an open wound, non-intact skin or mucous membrane.
7. Children 18 months of age or less born to mothers HIV-infected or at risk for HIV infection and who have been breast fed within the preceding 12 months, regardless of HIV status.
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.
9. Persons who have had close contact with another person having viral hepatitis within 12 months preceding donation.
10. Persons who have had or have been treated for syphilis or gonorrhea during the preceding 12 months.
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.
12. Persons with diagnosis of Creutzfeldt-Jakob Disease or known family history (blood relative) of a person with non-iatrogenic Creutzfeldt-Jakob Disease.
13. Person who have received injections of human pituitary-derived growth hormone (pit-hGH).
14. Persons who are known to have received transplants of dura mater.

Our eye bank has ruled out over 50 donors 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,



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