



9025 '99 DEC 20 P1:49

December 9, 1999

Dockets Management Branch
HFA - 305
The Food & Drug Administration
5 830 Fishers Lane
Rockville, MD 20852

RE: Docket No. 97N-484S

Dear Gentlemen:

I would like to comment on the FDA proposed rule: Suitability Determination for Donors of Human Cellular and Tissue-Based Products. Mid South Eye Bank serves the mid-south, all of western Tennessee and parts of eastern Arkansas and north Mississippi. We recover approximately 600+ corneas for transplant or whole globe eyes for research and education each year. Of those recoveries, approximately 300+ are used for transplantation, including imports from other eye banks.

Since we are not a large eye bank, the proposed regulations more profoundly impacts us fiscally and administratively since our resources and personnel are severely limited. Each new layer of regulatory burden increases the operating stresses by an order of magnitude. Like you, our primary focus has been and remains the safety and quality of the tissue we recover and distribute. In that task, we (and other eye banks) have an exemplary record. We are proud that no diseases have passed from donor to recipient in our area due to eye bank error, failure of follow protocol, neglect or improper blood testing. We will not do anything which endangers any of our recovery technicians, the lab staff, physicians who transplant tissue or the recipients of the tissue.

The Eye Bank Association of America has in place extensive quality and safety protocols which meet and, in most instances, exceed the FDA rules. We follow these rules faithfully.

We must also endeavor to run the eye bank as one would a small business. Even as a not for profit agency, we still must pay the bills, pay our technicians and be a contributing member of the Memphis community. This means that we must season our activities with a sizable dose of "real world" practicality. Herein lies the problems which we have with the proposed FDA rule.

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97N 484S

REMEMBER THE MID-SOUTH EYE BANK FOR SIGHT RESTORATION IN YOUR WILL

Most Proposed Testing: not Relevant to Corneal Transplant Tissue: Clearly, in formulating this proposed rule, the framers were thinking of blood banks, tissue banks and purveyors of other, vascularized tissue. Diseases which are easily transmissible via transplant in other tissue are not so easily transmissible by corneal transplant. Past history and current science simply does not support the regulation of corneal transplants to the extent that other tissues are regulated.

“Relevant” Testing, Unnecessary Regulations & Inappropriate Terminology: The introductory material indicates that the FDA.. .”proposes to require “manufacturers” of certain human cellular and tissue-based products to screen and test the donors of cells and tissues used in those products for risk factors for and clinical evidence of communicable disease agents and diseases.” That section further states that.. . . “FDA is also seeking to avoid unnecessary regulations.” Section II, Donor Suitability, states on page 52698 that “The proposed regulation would require.. . screening and testing for all ‘relevant’ communicable disease agents and diseases.

The terminology also is clearly directed at for-profit, Durable Medical Equipment manufacturers who must ‘manufacture’ their “product” and “market” it to the public. Eye Bankers “recover” tissue, “preserve” this precious gift until it is “provided” to physicians to restore sight. It is not marketed in the sense that FDA seems to infer.

Syphilis, HTLV-I/H, Cytomegalovirus Not Relevant to Corneal Transplants: There is currently no body of scientific evidence which supports the testing of corneal donors for Treponema pallidum (syphilis) or the other, aforementioned diseases. While there is a prevalence of the disease in the donor (that is to say, the entire) population, there exists no significant health risk to the corneal transplant recipient of contracting this disease in that procedure.

Further testing in these areas is costly and unnecessary until a tangible health threat exists. No threat has yet been shown to exist relative to corneal transplants. To regulate in this arena without clear, substantiating evidence is simply Draconian and a raw exercise of the power we already know you have.

FDA Licensed Tests: Page 52705 of the proposed regulation states that.. . “testing shall be performed using FDA-licensed, approved, or cleared screening tests in accordance with manufacturer’s instructions.” It is well-known that the majority of blood drawn for corneal donors is cadaveric. We have also previously discussed the lack of a suitable test kit for cadaveric blood.

Because the pool of eye banks is so small, it is unlikely that any commercial laboratory will take on the initiative to devise, test, and submit a cadaveric blood test to FDA. The cost relative to financial gain would simply be too great. Even if such a project were undertaken, it is likely the cost to eye banks would be prohibitively high.

Timing of Blood Collection: Many donors come to hospitals with traumatic events and require significant blood and other fluids over several days before the patient passes and the donation opportunity presents itself. The proposed regulation on blood collection (page 52704) presents practical problems for eye banks as well as for other agencies.

The present eye bank blood testing standards allow the use of an undiluted specimen recovered at a reasonable time pre-mortem. The proposed rule states” the donor specimen be collected at the

time of recovery of cells or tissue from the donor or within 48 hours after recovery:" Almost all blood collected for corneal donors is post-mortem. To require collection at the time of death would rule out any donor for whom a hemodilution algorithm must be computed, a severe blow to the donor pool (especially younger donors).

It would seem more reasonable to permit the specimen collection up to 120 hours (5 days) pre-mortem or some other reasonable time period to insure that an undiluted specimen can be obtained.

Thank you for allowing me this opportunity to express my sincere concern regarding proposed rule 97N-484S. The eye banking community is very sensitive to standards of quality and tissue safety. However, testing for the sake of disease identification serves no purpose in the absence of significant health risk. I encourage you to test these proposed rules for reasonableness and practicality before you regulate for the sake of regulation. To do differently is simply the imposition of autocratic control.

Sincerely,

A handwritten signature in cursive script that reads "Lee Williams".

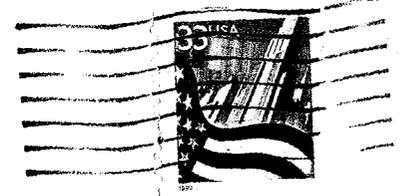
Lee Williams, Executive Director

LW;jh

cc: Pat Aiken-O'Neill, EBAA

**MIDSOUTH
EYEBANK** 
FOR SIGHT RESTORATION

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