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Certified Member:
EYE BANK ASSOCIATION of AMERICA
And member of the
Eye Bank Association of Texas

5 May 2001

Jane Henney, MD
Commissioner
Food and Drug Administration
5630 Fishers Lane
Rockville, Maryland 20852

Dear Dr. Henney:

We are writing to comment on your proposed rule for current good tissue practices. Our first FDA inspection in 1999 was without violation. We are currently undergoing a second FDA inspection.

Our eye bank is a 501(c)3 non-profit organization that has served central Texas for more than 26 years. The Lions Club members that comprise our board of directors are committed to sight restoration and sight conservation. Their record of providing donor tissues gratis and at reduced fees (all tissues were gratis for the first 17 years of our eye bank's service) speaks volumes for their dedication to this mission.

Also, we are extremely proud of our eye bank's excellent record of donor tissues of the highest quality being provided for transplantation. Not one adverse reaction has been related to donor tissue. During the year 2000, our eye bank was fortunate to distribute 1018 donor corneas to Texans, to U. S. citizens, and individuals throughout the world for sight restoration

Since 1993, Food and Drug Administration has worked to regulate eye banking with little or no knowledge of this unique program and its processes. The proposed rule for current good tissue practices further illustrates that little has changed in eight years.

Review of the proposed Current Good Tissue Practices for Manufacturers of Human Cellular and Tissue-Based Products shows that the least financial impact this rule will have on our organization will be an additional $180,000/year. This cost estimate does not include many areas that currently are written so broadly or in a non-specific manner as to render the costs of implementation as incalculable. Additional expenses of this magnitude are not conducive to keeping down medical costs; and, could signal the end to many small non-profit organizations such as our eye bank.

The terminology used in this proposed rule is simply not applicable to eye banking or tissue banking. We do not manufacture human corneas. These precious anatomical gifts are recovered at the request of the donor and/or donor's family. May we suggest "Donor Program" or "Tissue Service Organization" as being more appropriate than "manufacturer"? These human tissues are gifts and not "products". May we suggest "Anatomical Gift" or "material" as being more appropriate than "product"?

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With these things being said, I now set forth to address problems and concerns regarding this proposed rule, section-by-section.

Section §1271.150 Current Good Tissue Practice: General

We believe the regulatory language in section 1271.150 is too broad and open to multiple interpretations. One reading, for example, would make us responsible for ensuring entities such as couriers, medical examiner's offices, and laboratories were meeting requirements of the rule applicable to the subcontracted function. And, to require "validation" of a subcontractor's work on each tissue is unrealistic. Not only would our eye bank need to hire a staff several hundred percent larger than we now have, finding staff with specific expertise to review each type subcontractor is nearly impossible and would be financially prohibitive.

Section 1271.160 Establishment and Maintenance of a Quality Program

The "quality program" referred to in this section applies to a set of activities, including management review, training, audits and corrective and preventative actions. A portion of this program will require investigation and documentation of "all product deviations. . . (that) may adversely affect the function or integrity of the product". To comply with this section, our Eye Bank will be required to hire a "quality control" officer. Not only will this employment be expensive; it will be time consuming to advertise and interview for this position.

Section 1271.190 Facilities

This section is vague regarding suitable size, construction, location, etc. We can only urge a standard of reasonableness.

Section 1271.195 Environment Control and Monitoring

The introduction of a comprehensive major environmental control system is not necessary to ensure safe corneas suitable for transplant. Most donor corneas are recovered *in situ*; otherwise, donor corneas are excised from recovered whole globes under a laminar flow hood and using aseptic technique. Purchasing and having installed a major environmental control system is also cost prohibitive. Our investigation has revealed the initial cost to be approximately $31,000; plus, an additional $6,000 each six months for monitoring and maintenance of the system.

Section 1271.200 Equipment

This section stipulates that any automated, mechanical, electronic, computer or other equipment used for inspection, measuring and testing shall be capable of producing valid results. We believe the manufacturers of this equipment and those who regularly service the equipment are best qualified to analyze the equipment's function. Therefore, we ask that this rule be amended to accept vendor validation and maintenance records for compliance.

Section 1271.210 Supplies and Reagents

The rules set forth in this section are costly. They require new policies and procedures; and, considerable collection and retention of receipts and records. The portion requiring the recording of each human tissue "produced" with the supply or reagent is especially unreasonable. Our eye bank only recovers human eye tissues (corneas and sclera); thus, there are considerably fewer steps where something can go wrong.

Additionally, the testing agencies (laboratories) our Eye Bank uses are regulated by the federal government (CLIA) and are therefore "validated". The validation should, then, come from the vendors (laboratories) since eye bank personnel do not have the expertise. Liability in these cases would be onerous.

Section 1271.225 Process Changes

We find this section unnecessarily broad and respectfully request that the FDA narrow this provision.

Section 1271.230 Process Validations

This section is defined as "establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications." We firmly believe the processes used in eye banking are verified through a long history of success. Additionally, validation is not appropriate for many eye banking activities; and, verification can be achieved by means of slit lamp examination and specular microscopy; plus, adverse reaction monitoring and reporting; and, when appropriate, corrective action.

Section 1271.290 Tracking

We believe the tracking requirements are too broadly defined; and, we ask the following: 1) how far is an eye bank required to go in order to demonstrate an attempt has been made to obtain from the consignee an agreement to provide tracking information, and 2) that tissue exported to other countries be exempt from this requirement. Regarding question number two: there has been demonstrated an unmet public health need for tissues in countries outside the United States and the burden of obtaining compliance from internationally-based physicians may adversely impact any eye bank's desire to provide relief.

Section 1271.320 Complaint File

We believe the proposed definition of "compliant" ["any written, oral, or electronic communication that alleges: (1) that a human cellular or tissue-based product has transmitted or may have transmitted a communicable disease to the recipient of the product; (2) that the function or integrity of a human cellular or tissue-based product may have been impaired; or (3) any other problem with a human cellular or tissue-based product that could result from the failure to comply with current good tissue practice."] is too broad. We ask that this section be revised to state specifically that the complaint be "that relating to communicable disease transmission or graft failure".

Section 1271.350 Reporting

Our experience has demonstrated that not every adverse reaction is related to donor tissue(s). Therefore, we ask that the FDA revise the definition of adverse reaction as "any communicable disease or other disease transmitted by and attributable to transplantation of donor tissue including infection and biologic dysfunction".

Also, our experience has been that more than 15 calendar days are required to thoroughly investigate reports and, to determine whether or not the reaction is directly related to transplantation of the donor cornea. Input from the transplanting surgeon is required, as well as the physician having recently seen and treated the recipient patient. Therefore, we request that reporting be required in 30 to 60 working days in order to allow for a more thorough review.

Section 1271.400 Inspections

Food and Drug Administration (FDA) inspections are extremely disruptive to the work of an eye bank. Therefore, we respectfully request notice of a pending inspection; five (5) working days for a routine inspection; and, 24 hours in a "for cause" situation. Also, we ask that this section be amended to allow an FDA inspector to call upon either the Executive Director or person serving in this capacity as opposed to the "most responsible person" at the facility. We have considerable concern regarding what material can be copied, video taped and photographed; and, ask that this section be amended to restrict the collection of information be limited to material that directly relates to possible communicable disease transmission or other disease transmitted by and attributable to transplantation of donor tissues, including infection and biologic dysfunction.

Finally, we believe that the conclusions reached by the FDA regarding the cause of primary graft failure (of donor corneas) are incorrect; and, we urge the FDA to obtain additional information from the American Academy of Ophthalmology on this subject.

Your consideration of this information will be appreciated. Thank you.

Sincerely,

Bess Beliveaux

Bess Beliveaux, CEBT
Executive Director
Lions Eye Bank of Central Texas

cc: Eye Bank Association of America
Richard E. Nieman, MD, Medical Director
The Honorable Lloyd Bentson, U.S. House of Representatives

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