



CENTRAL OHIO LIONS EYE BANK, INC.

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, Maryland 20852

28 December 1999

Re: 21 CFR Parts 210, 211, 820, and 1271
[Docket No. 97N-484S]

Proposed Rule: Suitability Determination for Donors of Human Cellular and Tissue-Based Products

Dear Official:

The proposed FDA rule on the Suitability Determination for Donors of Human Cellular and Tissue-Based Products, described as the second in a three-part series of publications that lay out a comprehensive regulatory infrastructure as well as set the groundwork for future additional regulation, contains a number of provisions that are of significant concern to eye banking practitioners. It has been brought to the agency's attention during the promulgation of previous regulations affecting the eye banking community that the over-riding "one-size-fits-all" approach is detrimental to the delivery of corneal transplantation services that have historically proven both safe and beneficial for the public health. With this new proposal and the specter of the impending "good manufacturing practices" as applied to eye banking the FDA once again attempts to fix what isn't broken - and to do so without the appropriate scientific/medical justification for its series of means to that end.

Public Health Considerations It can not be overstated that the preparation of human donor corneas for transplantation is a service performed by a humanitarian community and not the "manufacturing process" of an "industry". It is perhaps the failure to accept this concept that has led to the failure to accept the reality that within the eye banking community voluntary standards *are* regulations; safety and quality *are* the only acceptable practices; and the protection of the health of corneal transplant recipients not only *is* the goal but has been achieved and diligently maintained - voluntarily - for decades.

Voluntary Eye Banking Standards The medical standards developed by the national accrediting body for eye banking - the Eye Bank Association of America (EBAA) - have not to our knowledge been called into question by the FDA; organized eye banking has been open and cooperative in its interactions with the FDA and the FDA has been an invited attendee at the regular reviews of the EBAA's medical policies. It is noteworthy that the EBAA initiated discussions of the need to assure the adequacy of required donor screening for transmissible spongiform encephalopathy well before the publication of the FDA's proposal. Equally important is the fact that the EBAA acknowledged the need for scientific validation before making its medical policy decision regarding the screening. Clearly, the EBAA has been responsible as well as diligent in its consideration of reasoned standards. Another example is the fact that the FDA-proposed requirement for syphilis testing of donors follows by years the deliberations of the EBAA over the same issue. Having become informed with published scientific data that renounced the use of syphilis as a marker for HIV and a peer-reviewed, published study concluding that the transmission of syphilis itself via corneal transplantation was not a scientifically-valid concern because *T. pallidum* does not survive standard corneal storage, the EBAA's decision *not* to require syphilis testing for eye donors was medically sound - not to mention fiscally prudent.

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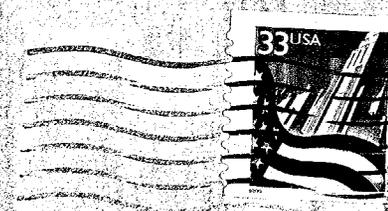
Economic Impact The work of the eye banking community is charitable by origin and ongoing nature. In a 1999 cost data study, the Lewin Group reported that the average eye bank provides corneas for transplantation at 20% below the actual cost of making them available. Eye banking is subsidized by financial contributions and volunteerism. It is incumbent on eye banks - all of which are 501(c)(3) non-profit organizations - to assure that expenses are necessary and in the best interest of the communities they serve. The economic impact data in the proposed regulation presents an average annual establishment income of \$1.23 million; many U.S. eye banks operate within budgets that are <50% of that figure. An eye bank adding the cost of testing 650 donors/year for syphilis at \$15/test, will quickly increase its annual expenses by approximately \$10,000. While the FDA argues that some of the (still considerable) costs of the proposed regulation would be one-time costs, it does not calculate some of the most significant of those costs, including staff training time. Nor is discussion presented regarding the financial burden that will doubtless accompany the third proposal in the FDA's regulatory series - "good manufacturing practices". Previously the FDA has alluded to the anticipated scope of these GMPs as far exceeding the screening of donors for preventing infectious disease transmissions; within the current proposal the reference is made to the notion that donor screening is "one step" in the manufacturing process. Again, given the track record of success held by organized eye banking in the U.S., a major overhaul of the "manufacturing process" to fit FDA-defined GMPs may wastefully and without warrant undermine standardized quality eye banking operations. Ultimately, the patients and public to whom eye banks are accountable as charitable community service organizations will rightfully require justification for the increasing cost of corneal transplant-related medical care. Excessive and unmerited government regulation will not be a well-received explanation.

Potential Conflict with HCFA's 1998 Hospital Conditions of Participation in Medicare The proposed regulation of donor suitability determination raises questions in light of the 1998 regulation in which hospitals are required to notify organ procurement organizations (OPOs) upon patients' death or imminent death. In creating this requirement, HCFA has effectively placed OPOs - which are not regulated by the FDA - in a gate-keeping position with regard to tissue and eye donations. In 42CFR Part 482 Section 482.45 (a) (1), HCFA states that "The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, *the OPO determines medical suitability for tissue and eye donation* (emphasis ours), using the definition of tissue and eye donor and the notification protocol developed *in consultation with the tissue and eye banks* (emphasis also ours) identified by the hospital for this purpose." In many parts of the country, the OPO's gate-keeping role has been interpreted as empowerment for OPO control over the donor screening process - including the generation of at least some portion of the donor records as well as the determination of eye and tissue donor suitability - potentially leaving open the question of accountability for FDA regulatory compliance. Further, although the FDA does not regulate OPOs, there are OPOs with in-house tissue procurement programs. In all of the aforementioned situations, the same OPO staff may be screening the same donors and determining donor suitability utilizing multiple (potentially conflicting) sets of criteria - some compliant with FDA regulations, and some not by virtue of the exemption of OPOs from the FDA standards for prevention of disease transmission.

Impact of HHS's Proposed Standards for Privacy of Individually Identifiable Health Information The recent publication of proposed medical privacy standards resulting from the 1996 Health Insurance Portability and Accountability Act may also present issues which the FDA will need to take into consideration related to the screening of potential donors with regard to the disclosure of individually identifiable health information that is protected under the Act. Anatomical gift procurement agencies do appear to be "covered" entities (those to which the regulations would apply) as defined providers of health care services. Eye banks are currently evaluating the possible effect of this proposal on standard donor screening practices.

As a concerned citizen of the eye banking community we respectfully request an exemption or significant reduction in the application to eye banking of the proposed all-inclusive approach to the regulation of tissue- and cellular-based products. We urge this reconsideration in the name of sound science, fiscal responsibility, and the preservation of a successful and safe system for the restoration of sight.

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