EYE BANK ASSOCIATION OF AMERICA

February 6, 2025

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Submitted via http://www.regulations.gov

Re: Docket No FDA-2022-D-0467.

Dear Dockets Manager:

The Eye Bank Association of America (EBAA) appreciates the opportunity to provide comments in response to the Food and Drug Administration's draft guidance entitled "*Recommendations to Reduce the Risk of Transmission of Human Immunodeficiency Virus (HIV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)"* [Docket No. FDA-2022-D-0467].

The EBAA is the world's oldest transplantation association, established in 1961 by the American Academy of Ophthalmology (AAO) and is the nationally recognized accrediting and standards setting body for eye banks.

The association strives to ensure the superior quality of banked human eye tissue through the adoption and implementation of stringent medical standards, which are scientifically based, and specific to ocular tissue. The association is committed to "the restoration of sight worldwide," and works toward this vision by developing and delivering standards, accreditation, and educational programs that optimize patient and donor care and safety.

EBAA eye banks are non-profit organizations that recover, medically evaluate, process, and distribute ocular tissue for transplant, research, and education. In 2023, U.S. EBAA eye banks provided tissue for 86,986 sight-restoring corneal transplant surgeries.[1]

The EBAA appreciates this opportunity to provide public comments on proposed Center for Biologics Evaluation and Research (CBER) regulatory requirements. On behalf of our member banks, we would like to offer these general comments for consideration.

COMMENT 1 – Support for draft guidance recommendations

EBAA commends the FDA for their extensive work to support this landmark policy change resulting in new, evidence-based recommendations for donor eligibility criteria while maintaining appropriate safeguards to protect patients receiving tissue transplants.

We applaud the elimination of the donor screening questions specific to men who have sex with men (MSM) and women who have sex with MSM and, instead recommending that establishments assess HCT/P donor eligibility using the same individual risk-based questions for every donor regardless of sex or gender.

The risk for HIV (and HBV and HCV) is assessed through sexual practices and not through sexual orientation, so that individuals who report having a new sexual partner and anal sex in the past three months or multiple sexual partners and anal sex in the three last months would be deferred. Similarly, physical evidence of perianal lesions in all donors (male and female) would be considered high-risk behavior for HIV.

The uniform use of HIV NAT testing for all HCT/P donors with NAT window periods estimated to be an average of 11–15 days for HIV donor screening tests, supports the reduction of certain time-based deferrals for HIV risk factors and conditions to a 3-month deferral period.

COMMENT 2 – Recommendations to address donor use of PrEP/PEP/ART

EBAA agrees with the addition of screening measures to identify the use of antiretroviral drugs to prevent or treat HIV infection. FDA-approved antiretroviral drugs (ART) can reduce the HIV viral load to undetectable levels, but do not fully eliminate the virus from the body. The use of PrEP and PEP may delay detection of HIV by licensed screening tests for HCT/P donors, potentially resulting in false negative results.

The ADVANCE (Assessing Donor Variability and New Concepts in Eligibility)[2] Study's data indicated that about half of HIV-negative participants (50.4%) reported they did not use pre-exposure prophylaxis (PrEP) in the past three months. Among this group, 66.2% reported one sexual partner or no anal sex in the past three months, and 69% reported no new sexual partners or no anal sex with a new partner in the past three months.

Although this recommendation will require the addition of new screening questions and deferral periods for potential donors, these data indicate that the recommendations for individual risk assessment can be implemented safely and effectively and will expand donor eligibility to some groups that had previously been deferred unnecessarily.

COMMENT 3 –Request for clarification as to the definition of a "new sexual partner".

Our members are requesting that FDA provide a definition of "new partner".

The guidance includes the following examples which would be considered having sex with a new partner: having sex with someone for the first time; or having had sex with someone in a relationship that ended in the past and having sex again with that person in the last 3 months.

This could be problematic at the operational level. For example, would a military spouse deployed for a year be considered a "new partner" upon return?

COMMENT 4 - Clarification of the risk assessment timeframe for the secondary sexual partner

Section IV. Recommendations, page 8:

A. Screening a Donor for Risk Factors and Conditions of HIV Infection

The following conditions or behaviors should be considered risk factors for HIV:

5. Persons who have had sexual contact in the preceding 3 months with any individual who has exchanged sex for money, drugs or other payment. If there is any uncertainty about when their sexual partner exchanged sex for money, drugs or other payment, the person is ineligible for 3 months.

6. Persons who have had sexual contact in the preceding 3 months with any individual who has engaged in non-prescription injection drug use. If there is any uncertainty about when their sexual partner engaged in non-prescription injection drug use, the person is ineligible for 3 months

The eligibility assessment should consider the timeframe for the sexual partner's injection drug use or payment for sex to be consistent with all other time-bound donor screening questions.

Without a timebound recommendation for the secondary sexual contact, the donor would be determined to be ineligible for sexual contact with anyone who has EVER "exchanged sex for money, drugs or other payment" and anyone who has EVER "engaged in non-prescription drug use." This results in an inconsistent eligibility determination of certain donors based on sexual contact with individuals who are themselves eligible to donate.

We suggest an evidence-based approach to evaluate HIV risk related to sexual contact, consistently applying the 3-month deferral period. For example:

- Persons who have had sexual contact in the preceding 3 months with any individual who has, in the past 3 months, exchanged sex for money, drugs or other payment…
- Persons who have had sexual contact in the preceding 3 months with any individual who has, in the past 3 months, engaged in non-prescription injection drug use…

COMMENT 5 – Request for an extended implementation period

EBAA requests an extended implementation period of at least six months. This period should allow facilities to focus on successful implementation of changes to highly complex systems which must be updated, tested, and validated for performance. These include changes to the establishment's computer system, Donor Risk Assessment Interview (DRAI) questionnaires, flowcharts, policies and procedures, and extensive staff training and education.

Conclusion

The EBAA thanks the FDA for this opportunity to comment on existing CBER regulations. The Association appreciates the FDA's efforts to help ensure the safety of human tissues for transplant and prevent the transmission of communicable disease by HCT/Ps.

We are committed to working with the Agency to ensure that its approach is evidence-based, risk-based, and does not inadvertently interfere with patients' access to cornea and tissue transplants.

Sincerely,

Kevin P. Corcoran, CAE
President & CEO
Eye Bank Association of America

References

1. Eye Bank Association of America (2024). "2023 Eye Banking Statistical Report".
2. Custer B, Whitaker BI, Pollack LM, Buccheri R, Bruhn RL, Crowder LA, et al. HIV risk behavior profiles among men who have sex with men interested in donating blood: Findings from the Assessing Donor Variability and New Concepts in Eligibility study. *Transfusion*. 2023; 63(10): 1872–1884. https://doi.org/10.1111/trf.17515