February 5, 2025

Division of Dockets Management (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,** Recommendations to Reduce the Risk of Transmission of Human Immunodeficiency Virus (HIV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry

Dear Dockets Manager:

The Association for the Advancement of Blood and Biotherapies (AABB), America's Blood Centers (ABC), and the American Red Cross (ARC) are pleased to submit joint comments to the U. S. Food and Drug Administration (FDA) in response to the recently released, Recommendations to Reduce the Risk of Transmission of Human Immunodeficiency Virus (HIV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry.

**COMMENT 1 – Support for draft guidance recommendations**

Our organizations would like to take this opportunity to express our support for the FDA's commitment to evolving policies which result in new, evidence-based recommendations using the same risk-based questions regardless of sex or gender to determine HCT/P donor eligibility and remove unnecessary deferrals. These updated recommendations are critical to ensuring these lifesaving products are safe and available to meet the critical needs of patients.

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**COMMENT 2 – Support for updated guidance format**

We support FDA's updated guidance format which incorporates separate guidance documents with recommendations for reducing the risk of transmission of specific communicable disease agents or diseases.

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**COMMENT 3 - 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…*
6. *Persons who have had sexual contact in the preceding 3 months with any individual who has engaged in non-prescription injection drug use…*

The risk assessment timeframe for the secondary sexual partner is not provided. 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. For example:

- An individual who "exchanged sex for money" 12 months ago, would themselves be determined to be eligible. Their sexual partner (with whom they had sex one month ago) would be determined to be ineligible based on "sexual contact with an individual who has exchanged sex for money."
- An individual who "engaged in non-prescription injection drug" use 12 months ago, would themselves be determined to be eligible. Their sexual partner (with whom they had sex one month ago) would be determined to be ineligible based on "sexual contact with an individual who engaged in non-prescription injection drug"

**Request:**

Please provide a timebound recommendation for the secondary sexual partner similar to the recommendations for blood donors in the May 2023 Guidance, Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products, page 7. 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…

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**COMMENT 4 – Request for alignment of blood donor recommendations**

We support the alignment of the HCT/P recommendations with similar blood donor eligibility criteria. We note that the HCT/P recommendations [Section IV.A.13, page 10] outline a 3-month period of consideration for the following:

> *"Persons who have been in lock up, jail, prison, or a juvenile correctional facility for more than 72 consecutive hours in the preceding 3 months"*

We recognize that this update from 12 months to 3 months was possible because this HCT/P recommendation is not tied to regulation as is the case for blood donor screening (21 CFR 630.10(e)(1)(iv)). We recognize that CBER/OBRR plans to pursue this change via the rulemaking process and look forward to further alignment in policies.

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**COMMENT 5 – Request for an extended implementation period**

**Request:**

Our organizations request an extended implementation period of at least one year. 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 computer system, HCT/P Donor History Questionnaires, Flowcharts, policies and procedures, and extensive staff training and education.

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AABB (Association for the Advancement of Blood & Biotherapies) is an international, not-for-profit organization representing individuals and institutions involved in the fields of transfusion medicine and biotherapies. The Association works collaboratively to advance the field through the development and delivery of standards, accreditation and education programs. AABB is dedicated to its mission of improving lives by making transfusion medicine and biotherapies safe, available and effective worldwide.

Founded in 1962, America's Blood Centers is North America's largest network of community-based, independent blood programs. The network operates more than 600 blood donor centers providing over half of the U.S., and a quarter of the Canadian blood supply. These blood centers serve more than 150 million people and provide blood products and services to more than 3,500 hospitals and healthcare facilities across North America. America's Blood Centers' U.S. members are licensed and regulated by the U.S. Food and Drug Administration. Canadian members are regulated by Health Canada.

The American Red Cross shelters, feeds and provides emotional support to victims of disasters; supplies about 40 percent of the nation's blood; teaches skills that save lives; provides international humanitarian aid; and supports military members and their families. The Red Cross is a not-for-profit organization that depends on volunteers and the generosity of the American public to perform its mission. About 5.6 million units of whole blood are collected from roughly 3.3 million Red Cross volunteer donors, separated into 8 million transfusable blood products and supplied to approximately 2,700 hospitals and transfusion centers across the country for patients in need.

Thank you for the opportunity to offer these comments.

Sincerely,

[*signatures on file*]

Sharon Carayiannis
Vice President Science and Practice
AABB

Kate Fry
Chief Executive Officer
America's Blood Centers

J. Chris Hrouda
President, Biomedical Services
American Red Cross