

July 10, 2019

Robert Walsh
Designated Federal Official (DFO)
Healthcare Systems Bureau
Division of Transplantation
HRSA
5600 Fishers Lane, 8W60
Rockville, MD 20857

Re: Comments to the Advisory Council on Blood Stem Cell Transplantation (ACBSCT) on Operational Challenges Resulting from Implementing FDA's Zika Screening Guidance

Dear Mr. Walsh,

The undersigned organizations appreciate the opportunity to submit comments to the ACBSCT. Collectively, our organizations represent cord blood banks and individuals in the cord blood community, such as physicians and other healthcare providers, researchers and professionals in cord blood banking and transplantation. We are submitting this letter with a request to be added to the next ACBSCT meeting agenda to discuss the issue detailed below.

Cord blood banks are experiencing significant operational challenges as a result of implementing the Food and Drug Administration's guidance entitled "Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products."¹ The guidance specifies that:

Living donors of HCT/Ps should be considered ineligible if they have any of the following risk factors:

1. Medical diagnosis of ZIKV in the past 6 months.
2. Residence in, or travel to, an area with an increased risk for ZIKV transmission within the past 6 months.
3. Sex within the past 6 months with a person who has either of the risk factors listed in items 1 or 2, above.

Additionally, donors of umbilical cord blood, placenta, or other gestational tissues should be considered ineligible if the birth mother who seeks to donate gestational tissues has any of the following risk factors:

4. Medical diagnosis of ZIKV infection at any point during that pregnancy.

¹ FDA Guidance for Industry: Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products, *available at* <https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM488582.pdf> (last visited April 3, 2019).

5. Residence in, or travel to, an area with an increased risk for ZIKV transmission at any point during that pregnancy.

6. Sex at any point during that pregnancy with a person who has either of the risk factors listed in items 1 or 2, above.

As a result of these requirements, several licensed cord blood banks have reported that approximately 25 percent of their cord blood units banked each month are ineligible.

The FDA's guidance relies on the Centers for Disease Control and Prevention's surveillance to identify areas of "increased risk for ZIKV." According to the CDC's website, as of February 28, 2019 there are currently no areas in the United States at increased risk of ZIKV transmission through blood or tissue donation. While there are no areas in the world having an outbreak at this time, there are many areas throughout the world classified as "Current or Past Transmission but No Current Outbreak." Notably, CDC indicates that "these counties have a potential risk of Zika, but we do not have accurate information on the current level of risk."²

Our collective organizations support the respective roles of the FDA and the CDC in protecting the public's health. We share the FDA's goal of ensuring that cord blood and other biological products are safe, effective and available to patients who need them. In addition, we appreciate CDC's significant surveillance effort, which is intended to inform prospective travelers on ZIKV risks throughout the world. Our organizations understand that ZIKV demonstrates a unique etiology and a potential preference to reside in gestational tissues and stem cell reservoirs and believe that infectious disease experts are essential partners to evolving our shared understanding of vertical transmission. It is imperative for public and private stakeholders to work together to ensure that the nation's cord blood inventory remains adequate and available to treat both the patients of today as well as the patients of tomorrow.

Currently, all public cord blood banks screen potential donors for travel to ZIKV risk areas. Additional practices vary. Despite the absence of an FDA approved test, some cord blood banks test maternal donors for ZIKV NAT as part of routine donor screening. In addition, some cord blood banks have implemented a 1 year follow up for babies born to parents who traveled to 'risk areas' within 15 – 18 months of delivery as an additional check on the health of the baby donor. While neither testing maternal donors for ZIKV NAT nor the 1-year follow up changes the eligibility of the cord blood units, these practices may provide additional clinical information.

We are concerned that the FDA's guidance is having an unintended negative effect on the availability and use of a significant number of unrelated cord blood units. The assignment of "ineligible donor" discourages physicians from using them (only under "Urgent Medical Need"). Additionally, these cord blood units cannot be licensed by the FDA or included in the National Cord Blood Inventory and be funded.

We respectfully request that the ACBSCT work with the Food and Drug Administration, the Centers for Disease Control and Prevention, the Health Resources & Services

² CDC, Blood & Tissue Safety: Geographic areas at increased risk for Zika virus transmission through blood or tissue donation, available at <https://www.cdc.gov/zika/areasatrisk.html> (last visited April 3, 2019).

Administration, our organizations and infectious disease experts to get a more accurate estimate of the risk of ZIKV transmission in the various countries, identify research or data needed to support policy changes, and identify potential ways to test HCT/P donors (in blood or tissue), or possibly, clear donors retrospectively by following up on their health status, and therefore continue to ensure the safety and availability of cord blood units.

If you have any questions or need additional information, please contact Leah Stone at lmstone@aabb.org or 301-215-6554.

Sincerely,

AABB (formerly known as the American Association of Blood Banks)

America's Blood Centers

American Society for Transplantation and Cellular Therapy

Bloodworks Cord Blood Program

Carolinas Cord Blood Bank at Duke

Cleveland Cord Blood Center

Cord Blood Association

Cryo-Cell International

Foundation for the Accreditation of Cellular Therapy

GenCure

ISCT International Society for Cell & Gene Therapy

National Cord Blood Program of the New York Blood Center

NMDP/Be the Match

StemCyte, A Global Regenerative Therapeutics Company

University of Colorado and St. Louis Cord Blood Banks