# The Focal Point: Advocacy & Legislative Update
# March 5, 2019

## CDC Updates Information on Zika Transmission Risk for HCT/P Establishments

The Centers for Disease Control and Prevention (CDC) has updated the way it will report epidemiological information about Zika virus (ZIKV) to the blood and tissue collection community. For the purposes of blood and tissue safety interventions, areas at increased risk for Zika virus transmission will be identified at the county level within a state, including risk start and end dates. Defined areas of risk can be different from areas for which CDC has issued travel guidance.

The Blood and Tissue Safety webpage includes a world map of areas with risk of Zika for other countries and territories outside of U.S. states. Risk of transmission will now be conveyed by four categories shaded with a specific color:

- Country or territory with current Zika outbreak (Red)
- Country or territory with any prior or current reports of mosquito-borne Zika transmission (Purple)
- Country or territory with the vector and no reported mosquito-borne Zika transmission (Yellow)
- Country or territory with no mosquitoes that spread Zika (Green)

For the purpose of screening donors of HCT/Ps, establishments should continue to use the Food and Drug Administration (FDA), Center for Biologics Evaluation and Research's (CBER's) May 2018 Guidance for Industry titled Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products. Residence in or travel to an area with increased risk of ZIKV transmission, and sex with a male known to reside in or travel to an area with increased risk of ZIKV transmission, are considered ZIKV risk factors for the purpose of determining eligibility of living donors of HCT/Ps. Non-heart-beating (cadaveric) donors of HCT/Ps should be considered ineligible if they have a medical diagnosis of ZIKV infection in the past 6 months.

FDA considers countries and territories outside the U.S. states categorized as "Red" or "Purple" as areas with increased risk of ZIKV transmission. Currently, there are no areas at increased risk for ZIKV transmission through blood or tissue donation in the U.S. states.

Helpful links are included below:

- CDC's Blood and Tissue Safety webpage
- FDA Alert - "*Important Information for Human Cell, Tissue, and Cellular and Tissue-Based Product (HCT/P) Establishments Regarding Zika Virus Transmission Risk in the World*."

## CBER Publishes the 2019 Guidance Agenda

FDA's Center for Biologics Evaluation and Research (CBER) unveiled what guidance they plan to release in 2019. The list includes eight guidance documents related to blood products and components, including a second draft guidance that will focus on revised preventive measures to reduce the possible risk of transmission of Creutzfeldt-Jakob Disease (CJD) and variant Creutzfeldt-Jakob Disease (vCJD) by blood and blood products. In addition, other guidance is expected to be finalized, including recommendations for reducing the risk of transfusion-

transmitted Babesiosis; one on further testing of donations that are reactive on a screening test for antibodies to hepatitis C virus; and how to requalify blood donors deferred because of reactive anti-HTLV I/II test results

CBER expects to finalize the six gene therapy guidance documents which were published in July, including Human Gene Therapy for Retinal Disorders. Other guidance documents are expected to deal with standards development and their use in regulatory submissions and lot release protocol submissions to CBER in electronic format.

Interestingly, this listing does not include the guidance on "*Enforcement Policy Regarding Investigational New Drug Application Requirements for the Use of Autologous Serum Eye Drops for Lubrication for the Treatment of Dry Eye."* This was included in last year's guidance agenda but was never released.

### FDA Finalizes Regenerative Medicine Guidances

FDA has finalized two guidance documents regarding regenerative medicine therapies, first issued as drafts in November 2017.

The first guidance, Evaluation of Devices Used with Regenerative Medicine Advanced Therapies, clarifies how FDA will evaluate devices used in the recovery, isolation or delivery of regenerative medicine advanced therapies (RMATs). The guidance spells out the least burdensome principles, the available premarket pathways (510(k), De Novo, Premarket Approval Application and Humanitarian Device Exemption) and when a device and RMAT may be considered a combination product.

The second final guidance, Expedited Programs for Regenerative Medicine Therapies for Serious Conditions, describes the expedited programs that may be available to sponsors of regenerative medicine therapies for serious conditions, including the RMAT designation, Priority Review designation and Accelerated Approval.

FDA describes the therapies that could qualify for an RMAT designation, which includes cell therapies, therapeutic tissue engineering products, human cell and tissue products and combination products using such therapies.

### EuroGTP II Guide is Now Available

The European Union's Health Programme has released the EuroGTP II Guide "*Good practices for evaluating quality, safety and efficacy of novel tissue and cellular therapies and products: Guidance, Methodologies and Tools*."

The Associated and Collaborative Partners of the Good Practices for demonstrating safety and quality through recipient follow up Project (hereinafter referred to as 'EuroGTP II project') developed this guidance, to provide recommendations and to improve the quality of healthcare delivery within the field of human tissues and cells.

### Ocular Therapeutix Receives FDA Warning Letter Related to ReSure Sealant

Ocular Therapeutix received an FDA warning letter for failing to comply with post-approval study (PAS) requirements set as part of its ReSure Sealant's conditional approval.

The letter cites the company's failure to collect any data for its post-approval Device Exposure Registry study in the 4.5 years since the conditional approval. The Company is required to

provide periodic reports to the FDA on the progress of this post-approval study until it is completed.

ReSure Sealant, a hydrogel ophthalmic wound sealant, is the first and only sealant that is FDA-approved for ophthalmic use. The product is indicated for intraoperative management of clear corneal incisions (up to 3.5mm) as a viable alternative to sutures to prevent wound leakage following cataract surgery with intraocular lens placement in adults.

### ISO 13485 Transition Period Comes to an End

The three-year transition period for ISO 13485:2016 officially ended February 28, 2019, and as of Friday all ISO 13485:2003 certificates are now null and void, regardless of their original expiration date.

ISO 13485 is the global consensus standard developed by the International Organization for Standardization (ISO) that sets out the requirements for a quality management system (QMS) specific to the medical devices industry. ISO 13485:2016 is already used by Regulatory Authorities in other countries as a basis for their QMS requirements.

Compliance with 13485:2016 is not a current FDA requirement for medical device manufacturers to operate and market within the US. But the FDA has been working on a blend of the current Quality System regulation and 13485:2016 and plans to leverage Medical Device Single Audit Program (MDSAP) to reduce compliance and recordkeeping burdens on device manufacturers.

### Living Organ Donation Protection Act of 2019 Introduced in House and Senate

On February 14, Representatives Jerrold Nadler (D-NY) and Jaime Herrera Beutler (R-WA) and Senators Kirsten Gillibrand (D-NY) and Tom Cotton (R-AR) introduced the Living Donor Protection Act of 2019 (H.R. 1224/S. 511) in their respective chambers of Congress.

This legislation seeks to protect living organ donors and promote organ donation in two important ways:

1. Prohibits life, disability, and long-term care insurance companies from denying or limiting coverage and from charging higher premiums for living organ donors simply based on their status as living donors; and
2. Amends the Family and Medical Leave Act of 1993 to specifically include living organ donation as a serious health condition for private and civil service employees.

EBAA joined our Transplant Roundtable members in signing the organizational support letter for this legislation.