



June 06, 2024

Robert Califf, M.D.  
Commissioner of Food and Drugs  
U.S. Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993-0002

**In Re: FDA’s Determination that Zika Virus is no Longer a Relevant Communicable Disease Agent or Disease (RCDAD), and Withdrawal of Guidance titled “Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products”**

Dear Commissioner Califf:

The American Association of Tissue Banks (AATB or Association) and the American Association of Tissue Bank’s Tissue Policy Group (AATB TPG or TPG) write to thank you for your determination that Zika virus (ZIKV) is no longer an RCDAD, and for withdrawing the guidance document referenced above. This decision will help increase and ensure the availability of tissue – especially placental tissue – for lifesaving wound care products, including those used in the treatment of diabetic foot ulcers and venous leg ulcers.

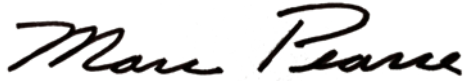
Importantly, the AATB and TPG believe that this decision will not compromise the safety of these tissue products, as we agree with FDA’s determination that “ZIKV no longer has sufficient incidence and/or prevalence to affect the potential HCT/P donor population.” As noted in the agency’s announcement, the Centers for Disease Control and Prevention “does not identify any countries or territories with current ZIKV outbreaks on their world map travel advisory,” suggesting the risk of ZIKV transmission through donor tissue is extremely low.

This decision will be especially impactful because, as you know, Americans have increasingly returned to post-pandemic life, including traveling outside of the United States. As pregnant women and their partners have increasingly traveled abroad, AATB-accredited tissue banks have seen similarly significant increases in donor deferrals due to ZIKV-related travel risk. By determining that ZIKV is no longer an RCDAD and withdrawing the donor screening guidance, FDA will help ensure recovery establishments can safely collect donor tissue from these populations for use in lifesaving tissue products.

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Thank you again for your work on this issue. The AATB and TPG look forward to continuing to collaborate with the FDA on issues affecting tissue banks and tissue availability.

Respectfully,



Marc Pearce  
President & CEO  
American Association of Tissue Banks



Doug Wilson  
Chair  
Tissue Policy Group

CC: Peter Marks, M.D., Ph.D.

**The American Association of Tissue Banks**

The American Association of Tissue Banks (AATB) is a professional, non-profit, scientific, and educational organization. AATB is the only national tissue banking organization in the United States, and its membership totals more than 120 accredited tissue banks and over 7,000 individual members. These banks recover tissue from more than 70,000 donors and distribute in excess of 3.3 million allografts for more than 2.5 million tissue transplants performed annually in the US. The overwhelming majority of the human tissue distributed for these transplants comes from AATB-accredited tissue banks.

**The AATB Tissue Policy Group**

The AATB TPG includes Chief Executive Officers and senior regulatory personnel from U.S. tissue banks that process donated human tissue. The purpose of the TPG is to drive policy in furtherance of the adoption of laws, regulations, and standards that foster the safety, quality, and availability of donated tissue. The TPG's membership is responsible for the vast majority of tissue available for transplantation within the U.S.