



September 21, 2026

Karim Mikhail, B. Pharm, MSc
Director
Center for Biologics Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Director Mikhail:

On behalf of the Association for Advancing Tissue and Biologics (AATB), congratulations on being selected to serve as Director of the Center for Biologics Evaluation and Research (CBER) in a permanent capacity. We look forward to working with you.

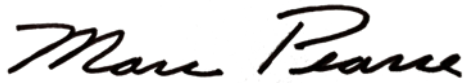
AATB is a non-profit organization dedicated to advancing the safety, quality, availability, and benefits of donated human tissue for transplantation worldwide. AATB achieves this through standards development, accreditation, education, and collaboration with regulatory partners to ensure donated tissue has the greatest impact on patient care.

Over the years, AATB has developed a close working relationship with CBER staff, and we hope to continue that partnership under your leadership. AATB recently submitted a request for a formal liaison meeting and hope to meet before the end of the year. We will plan to discuss our current work more during the meeting, but our top priorities are patient safety and the prevention of infectious disease transmission via tissue products.

As you may know, following two rare but tragic *Mycobacterium tuberculosis* (MTB) transmission events in 2021 and 2023, AATB acted to strengthen donor screening and tissue product safety by publishing the *AATB Standards for Tissue Banking*, 15th Edition (Standards). This document, which includes new requirements for tissue donor screening, was developed by a multidisciplinary working group, including infectious disease experts. The requirements took effect on January 31, 2025, and are designed to provide robust, evidence-based criteria for donor screening and evaluation to prevent disease transmission in all tissue donors. We know the FDA also acted following the MTB transmission events, and AATB submitted comments on CBER's draft donor eligibility guidance documents. We hope you will work with us to mitigate our concerns (especially with regards to the sepsis guidance document) prior to finalizing these proposed policies.

Congratulations again on your new role. In addition to the formal liaison meeting, we are happy to meet in a small group on an ad-hoc basis as new issues arise. Please feel free to contact me if AATB can be of assistance to CBER in the future.

Respectfully,

A handwritten signature in black ink that reads "Marc Pearce". The signature is written in a cursive, flowing style with a large initial 'M' and 'P'.

Marc Pearce
President & CEO
Association for Advancing Tissue and Biologics