American Association of Tissue Banks®

March 27, 2025

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Dr. Marks,

The American Association of Tissue Banks (AATB) writes today to reiterate our continuing concerns with the two guidance documents issued as final for immediate implementation by the Food and Drug Administration on January 6, 2025:

- **Recommendations to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by HCT/Ps** (Sepsis guidance)
- **Recommendations to Reduce the Risk of Transmission of *Mycobacterium tuberculosis* (Mtb) by HCT/Ps** (Mtb guidance)

As you know, AATB raised numerous concerns with these documents in our letter to you[1] on January 15 and a subsequent letter on January 16 to the Trump transition team.[2] The AATB letters described many issues that need to be addressed, including operational challenges, unclear directives, and the potential for a significant reduction in the availability of musculoskeletal and ocular tissue products. For example:

- Both documents appear to require extensive consultation with the donor's "primary treating physician," raising practicality, liability, and other concerns – with an unclear benefit, as the tissue establishment medical director is best positioned to accurately assess the donor's risk for infectious disease transmission.
- The sepsis guidance requires tissue establishments to "determine to be ineligible" any donor with a risk factor for sepsis, which includes individuals "known to have a medical diagnosis of sepsis or suspicion of sepsis." However, it is unclear what constitutes a "suspicion" of sepsis or who should be responsible for determining a suspicion of sepsis.
- The Mtb guidance directs tissue establishments to collect information about two potential Mtb exposure risks, occupational exposure risk and current residence in a nursing home, as part of

[1] https://www.aatb.org/sites/default/files/2023/Federal%20Advocacy%20Letters/AATB%20Comments%20-%20Mtb%20and%20Sepsis%2C%20January%202025.pdf
[2] https://www.aatb.org/sites/default/files/2023/Federal%20Advocacy%20Letters/Joint%20Trump%20transition%20letter%20on%20Mtb%20and%20Sepsis%20guidance%20documents%201.16.25.pdf

the Donor Risk Assessment Interview (DRAI) process. Adding these criteria to the DRAI is a process that would require months of planning and execution.

Following AATB's outreach on January 31, 2025, the FDA revised the implementation date from February 3, 2025, to May 4, 2025. While we appreciate the FDA's decision to delay implementation, we are hopeful that the delay reflects a willingness to review industry concerns further and seek additional comments. However, the implementation deadline is rapidly approaching, and the guidance documents have not been revised, rescinded, or reissued in a modified form. **We therefore urgently request a meeting to learn more about the FDA's thinking on this topic, and in the meantime, ask you to rescind or further delay the implementation of the guidance documents as you consider the next steps.**

If the FDA does not rescind, revise, or delay the guidance documents in the coming weeks, we will likely pursue additional options, up to and including litigation.

Thank you for considering this request, and we look forward to your response.

Respectfully,

Marc Pearce
President & CEO
American Association of Tissue Banks