April 9, 2025

Marty Makary, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Dr. Makary,

We, the undersigned organizations, write to congratulate you on being confirmed and sworn in as the 27th Commissioner of Food and Drugs. We look forward to working with you. You undoubtedly have a long list of priorities, but we write today to encourage you to immediately rescind two guidance documents issued as final for immediate implementation by the previous 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* by HCT/Ps** (Mtb guidance)

The implementation date for the guidance documents has since been delayed from February 3, 2025, to May 4, 2025, but we remain concerned that no revisions have been made, and the documents remain final. Our organizations have raised numerous concerns with these documents in previous correspondence to the agency (and Trump transition team), including operational challenges, unclear directives, and the potential for a significant reduction in the availability of musculoskeletal and ocular tissue products.[1,2,3] 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.

[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
[3] https://www.aatb.org/sites/default/files/Government%20Advocacy%20Correspondence/AATB%20Sepsis%20Mtb%20Letter%203.27.25.pdf

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

Even if the expectations in the guidance documents were clear, affected stakeholders would need weeks, if not months, to implement the changes. Therefore, it is critical that the agency rescinds – or revises and clarifies – the guidance documents as soon as possible. Already, the industry has been working under significant uncertainty since these documents were published, and we are confident you understand the importance of operating in a controlled and predictable regulatory environment given your experience as a scientist and islet transplant surgeon. The longer this issue remains unresolved, the more difficult it becomes for tissue banks, eye banks, and organ procurement organizations to operate efficiently, as significant resources need to be dedicated to planning and implementing substantially problematic and flawed guidance documents.

The stakes are high, as while we agree with the FDA that transmission of Mtb or disease agents associated with sepsis through transplanted HCT/Ps is tragic, the guidance documents as written will have a devastating effect on the availability of musculoskeletal and ocular tissue products and will adversely impact the availability of life transformative tissue products for patients. This is unfortunate considering the extensive and robust policies already in place in the form of FDA regulations and guidance, as well as AATB and EBAA standards, to ensure the safety of recovered tissue. There are more than 2.5 million tissue transplants and grafts performed each year to restore Americans' eyesight, improve their mobility, or heal their wounds, but these guidance documents risk making otherwise safe tissue unavailable to patients in need.

We appreciate that the FDA previously revised the implementation date from February 3, 2025, to May 4, 2025, but the new implementation date is rapidly approaching, and the guidance documents have not been revised, rescinded, or reissued in a modified form. **We therefore urgently request that you rescind or further delay the implementation of these guidance documents until the previously stated concerns have been addressed.**

Thank you for considering this request, and please let us know if our organizations can be of assistance in your new role.

Sincerely,

Marc Pearce, MBA
President and CEO
American Association of Tissue Banks

Dorrie Dils
President
Association of Organ Procurement Organizations

Kevin Corcoran, CAE
President and CEO
Eye Bank Association of America