Congress of the United States
Washington, DC 20515

May 26, 2026

Kyle A. Diamantas J.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Acting Commissioner Diamantas:

We write today regarding the Food and Drug Administration (FDA) policy on screening human tissue donors for sepsis. We share the agency's goal of reducing infectious disease transmission via contaminated human cells, tissues, and cellular or tissue-based products (HCT/Ps), as evidenced by the House of Representatives passage of H.R. 1082, the *Shandra Eisenga Human Cell and Tissue Product Safety Act* last year. As we continue to meet with experts and constituents in this field, we have heard that screening for *systemic infection* (meaning evidence of an active, disseminated infection with potential for communicable disease transmission), rather than a sepsis diagnosis, may be a more effective strategy for mitigating disease transmission. We therefore ask that the FDA consider adopting this approach prior to finalizing the draft guidance document *"Recommendations to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)"* ("sepsis guidance"). Assessment for systemic infection, rather than sepsis, aligns FDA's goal of reducing communicable disease transmission by targeting actual infection risk.

When the FDA finalized its most recent guidance on donor eligibility (DE), in 2007, it was reasonable to classify sepsis as a relevant communicable disease agent or disease (RCDAD) as a surrogate measure for infection risk. However, given the evolution of "sepsis" in clinical practice since the 2007 DE guidance, a sepsis diagnosis is not a scientifically valid surrogate for communicable disease risk in tissue donation. As detailed below, reliance on sepsis as a surrogate may both unnecessarily exclude otherwise eligible donors and potentially fail to identify donors with true potential for disease transmission.

A primary concern is that multiple sepsis definitions remain in use, and experts continue to disagree on how the term should be applied in clinical practice as it relates to the presence of an infection. A sepsis diagnosis in a potential donor's medical record may reflect an infection that warrants exclusion under donor eligibility criteria, or it may simply indicate a condition that requires additional clinical assessment. Some infections, even those that could contribute to a

sepsis diagnosis (such as a urinary tract infection), are easy to treat and should not in and of themselves be disqualifying for potential tissue donors. Absent careful, case-specific evaluation, such an approach would seem to unnecessarily disqualify otherwise eligible donors. A study conducted by the American Association of Tissue Banks suggests categorical exclusion based on a prior sepsis diagnosis could result in an approximately 25 percent reduction in tissue donors, which will most likely have an adverse effect on the availably of tissue products for patients in need.

An additional concern is that sepsis does not seem to meet the three conditions provided by FDA to qualify as an RCDAD (i.e., risk of transmission, severity of effect, and availability of appropriate screening measures or tests). In particular, sepsis is not itself a transmissible disease and may not even be the result of an infectious disease. In cases where sepsis is the result of an infection, that infection may or may not pose a risk of transmission to a tissue recipient. In short, the designation of sepsis as an RCDAD conflates clinical severity with communicable disease risk and incentivizes formulaic decision-making that is not reflective of the true risk of disease transmission. By contrast, designating systemic infection as an RCDAD—rather than relying on the presence or absence of a sepsis diagnosis—could more consistently identify potential donors who present a meaningful risk of infectious disease transmission, particularly those with objective evidence of systemic infection but that were not septic and had no mention of sepsis in their medical record.

We appreciate your continued commitment to ensuring the highest standards of safety and oversight for HCT/Ps and to minimizing the risk of infectious disease transmission. We stand ready to work with you on these issues, and we encourage you to consult with stakeholders and experts in this area as you consider an appropriate path forward.

Sincerely,

Debbie Dingell
Member of Congress

Rich McCormick, MD, MBA
Member of Congress