Improving Regulation of HCT/Ps

The Association for Advancing Tissue and Biologics (AATB) supports H.R. 1082/S. ____, the *Shandra Eisenga Human Cell and Tissue Product Safety Act*, and H.R. 340, the *HCT/P Modernization Act of 2025*.

Background: H.R. 1082/S. ____, the *Shandra Eisenga Human Cell and Tissue Product Safety Act* (sponsored by Reps. John Moolenaar (R-MI) and Debbie Dingell (D-MI) and Sen. Gary Peters (D-MI)), includes provisions from H.R. 340, the *HCT/P Modernization Act of 2025*, which was introduced by Reps. Dan Crenshaw (R-TX) and Nanette Barragán (D-CA). The *Shandra Eisenga* legislation was passed by the House of Representatives by voice vote in June 2025. The bills include several important provisions:

Streamlining Regulatory Oversight of Human Cell and Tissue Products: Both bills would require the Food and Drug Administration (FDA) to publish educational materials about the Tissue Reference Group (TRG) on their website and best practices for obtaining a timely, accurate recommendation regarding human cell and tissue products from the TRG. The legislation also requires the FDA to periodically publish information on the number and type of inquiries to the TRG and average response times.

FDA Standard Operating Policy and Procedure 8004 pertains to the TRG and states that "the TRG generally responds in writing to the inquirer within 60 days of receipt... of an inquiry that contains sufficient detail for evaluation."[1] However, when AATB conducted an analysis of response times in 2022, we found that the average response time was 140.7 days, with a range of 26 to 344 days.[2] When AATB conducted an updated analysis in 2024, including only submissions from September 1, 2022, to September 1, 2024, we found that the average response times for inquiries that had received a final response was 194.75 days, with a range of 73 to 268 days.[3] Nine inquiries had not yet received a final response, and on average those inquiries had been pending for 119.67 days.

Streamlining and increasing transparency regarding the TRG process is critical, as tissue banks are increasingly being asked by payers and regulators (including the Centers for Medicare and Medicaid Services (CMS), Department of Veterans Affairs,[4] and the State of New York) for "proof" of their status as an appropriately regulated "361 HCT/P," even though the FDA does not require premarket review or approval for such products. These bills will allow tissue banks to better plan for and navigate the FDA regulatory and CMS coverage/reimbursement paradigm for HCT/Ps.

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[1] https://www.fda.gov/media/85648/download

[2] https://www.aatb.org/sites/default/files/2023/Federal%20Advocacy%20Letters/TRGLessonsFINAL20220906withattachments.pdf

[3] https://www.aatb.org/sites/default/files/2023/Federal%20Advocacy%20Letters/AATB%20TPG%20TRG%20lessons%20learned%20update%20October%202024%20FINAL.pdf

[4] https://www.aatb.org/sites/default/files/2023/Federal%20Advocacy%20Letters/AATB%20TPG%20VA%20letter%20regarding%20361%20HCTPs%20FINAL.pdf

Other Key Provisions: The bills include other key provisions, including that the Secretary of HHS open a public docket to receive comments on modernizing the regulation of human cell and tissue products, including considerations associated with assessing minimal manipulation and homologous use. The FDA has expressed an interest in establishing an "intermediate pathway" for HCT/Ps, which would incentivize innovation and lead to new life-transformative products for patients. Establishing this docket would support those efforts.

The FDA would also be required to conduct workshops and other interactive and educational sessions for relevant stakeholders on the regulation of human cell and tissue products to help support regulatory predictability and scientific advancement. The FDA's approach to sepsis screening in human tissue donors is a good example of a topic that FDA should focus on in a workshop or educational session. AATB is increasingly concerned that a shift in the agency's approach could lead to an approximately 25 percent reduction in tissue donors. One concern is that sepsis is currently considered a "relevant communicable disease agent or disease" by the agency, even though sepsis is not actually a communicable disease. A rigid application of FDA's donor eligibility requirements with respect to sepsis could result in the exclusion of otherwise suitable donors and failure to identify donors with true potential for disease transmission. AATB believes designating *systemic infection* as an RCDAD instead would actually do a better job of preventing infectious disease transmission via tissue products, and discussing this topic at a workshop or educational session would help improve donor screening and prevent disease transmission.

Finally, the *Shandra Eisenga* bill requires the development and dissemination of educational materials to inform health care professionals and other appropriate professionals about organ, tissue, and eye donation, including evidence-based methods to approach patients and their families; the availability of any donor screening tests; and other relevant aspects of donations. We anticipate this campaign will complement work already being done by tissue banks to support awareness of issues related to donation and transplantation.

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