



February 09, 2024

Office of Procurement, Acquisition and Logistics
Strategic Acquisition Center (SAC)-Division 4D
Department of Veteran Affairs
10300 Spotsylvania Ave, Suite 400
Fredericksburg, VA 22408

In Re: Request that tissue banks submit RFD/TRG letters for 361 tissue products

Sent via email to vacovaoffa@va.gov and vacosac-f@va.gov.

Dear Madams and Sirs:

The American Association of Tissue Banks (AATB or Association) and the American Association of Tissue Bank's Tissue Policy Group (AATB TPG or TPG) send these comments to inform your deliberations regarding a recent request from your office that several of our accredited tissue banks submit to you "their FDA Designation letter" for review. While we appreciate the goal of the Department of Veterans Affairs (VA) having appropriate documentation for tissue products, we are concerned with requiring documentation related to all 361 human cells, tissues, and cellular and tissue-based products (HCT/Ps), as further detailed below.

The American Association of Tissue Banks (AATB) is a professional, non-profit, scientific, and educational organization. AATB is the only national tissue banking organization in the United States, and its membership totals more than 120 accredited tissue banks and over 7,000 individual members. These banks recover tissue from more than 70,000 donors and distribute in excess of 3.3 million allografts for more than 2.5 million tissue transplants performed annually in the US. The overwhelming majority of the human tissue distributed for these transplants comes from AATB-accredited tissue banks.

The AATB TPG includes Chief Executive Officers and senior regulatory personnel from U.S. tissue banks that process donated human tissue. The purpose of the TPG is to drive policy in furtherance of the adoption of laws, regulations, and standards that foster the safety, quality, and availability of donated tissue. The TPG's membership is responsible for the vast majority of tissue available for transplantation within the U.S.

First, we encourage you to discuss this issue directly with the Food and Drug Administration (FDA), as we believe the development of an FDA list of well-established 361 HCT/P tissue products would both eliminate much of the confusion and also clarify which tissue products the VA should request TRG letters for and/or conduct an internal review. Additionally, we are concerned that your request of tissue banks to submit an FDA designation letter (1) is contrary to the regulations detailed by the Food and Drug Administration (FDA or Agency), (2) will likely put an undue burden on the FDA, and (3) may result in loss of key health care resources for veterans.

Contrary to FDA regulations. When the FDA established the regulatory framework for tissue products, the process dictated that the responsibility of each tissue bank was to register and list its products with the Agency. The FDA would then ascertain compliance with the regulations, including the appropriateness of the product's classification as a Section 361 HCT/P, during routine inspections. There was not a separate requirement that tissue banks receive a Tissue Reference Group (TRG) letter or submit a Request for Designation (RFD) for each tissue product to seek confirmation or approval from the Agency regarding the product's classification. While payers may opt to add requirements as part of their oversight, it is important to understand that this is not simply a document request but a request for both tissue banks and the Agency to engage in additional and substantial submission and review activities neither contemplated nor intended by the regulations. In [our experience](#), it may take up to a year for a tissue bank to receive a TRG letter. We anticipate that an increase in TRG or RFD requests will increase the turnaround time for a response, and in the interim, patients may not be able to receive needed tissue grafts. In light of this, we urge you to revise your proposed deadline of February 9, 2024, to ensure that there is appropriate time to provide such information to the FDA and receive its response.

It is also important to note that while the VA email alluded to "new efforts and guidance from the Food and Drug Administration to **crack down** (emphasis added) on products regulated under FDA Section 361....," we are not aware of a meaningful effort by the Agency to change how 361 HCT/Ps are regulated. FDA periodically issues or updates enforcement actions, guidance documents, and regulations, but the fundamental regulatory framework related to product classification remains the same: tissue banks register and list products with the Agency, and the Agency ascertains compliance with the regulations, including the appropriateness of the product's classification as a Section 361 HCT/P, during routine inspections. We do not think it is appropriate for the VA's PSAS Technical Team to "re-review... effected (sic) biological products" to determine the appropriateness of the product's classification as a Section 361 HCT/P.

Undue burden on FDA. Given that you are requesting new documentation, we note that the broad scope of this request will likely put an undue burden on the FDA. As noted above, it already takes nearly a year in some cases for tissue banks to receive a TRG letter, and an influx of requests may further slow down the process. As a result, we request that you discuss this issue directly with the FDA to determine their ability to accommodate an influx of TRG submissions. It is important to note that many 361 HCT/Ps, in particular certain wound-related products regulated as 361 HCT/Ps, have a well-established history of use. Again, the AATB and TPG encourage you to discuss this issue directly with the FDA to identify categories of products that have a well-established history of use and regulation as 361 HCT/Ps and therefore should not require a TRG or RFD letter from the FDA.

May result in loss of key healthcare resources for the military. Our key concern is that, if you continue with the current request and do not ensure that there is adequate time to submit and receive information from the FDA, the VA will unnecessarily limit access to these critical healthcare resources. Donations of connective tissues such as ligaments, tendons, and cartilage can be used to repair, replace, and reconstruct joints and resurface cartilage surfaces. Patients injured in military activities, by trauma or through arthritis or other diseases, can benefit from restored mobility and can regain independence in daily activities.

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Finally, we note that patient access to skin substitutes is particularly important given the disproportionate impact of diabetic foot ulcers and venous leg ulcers on racial and ethnic minority populations. Latinos, African Americans, and Native Americans in particular, have the highest incidence of foot ulcers in the United States, and limiting access to these important wound care products may lead to greater disparities and worse outcomes for patients.

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We hope that you will find this information useful in your deliberations. We would welcome the opportunity to discuss this matter, including the impetus for the request, at your convenience. The AATB and the TPG stand ready and willing to assist the VA in any way that you deem appropriate.

Respectfully,



Marc Pearce
President & CEO
American Association of Tissue Banks



Doug Wilson
Chair
Tissue Policy Group

CC: Peter Marks, M.D., Ph.D., Director, FDA Center for Biologics Evaluation and Research