May 09, 2025

Russell T. Vought
Director
Office of Management and Budget
725 17th Street NW
Washington, DC 20503

In Re: Request for Information: Deregulation

Dear Director Vought:

The American Association of Tissue Banks (AATB or Association) and the American Association of Tissue Banks' Tissue Policy Group (TPG) writes in response to the Office of Management and Budget's (OMB) request for information titled, "Request for Information: Deregulation." We appreciate OMB's focus on reducing regulatory burden and recommend examining tissue bank requirements related to the summary of records for 361 human cells, tissues, and cellular and tissue-based products (HCT/Ps), as detailed in 21 CFR 1271.55.

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.

For years, the AATB and TPG have sought changes to the regulatory interpretation of 21 CFR 1271.55 and the labeling requirements under §1271.370 to allow tissue banks to affix the distinct identification code (i.e., alphanumeric code that relates the HCT/P to the donor and all records pertaining to the HCT/P, likely through the use of automatic identification and data capture (AIDC), for example QR or bar code) to the HCT/P, and then provide the instructions for use (IFU) and donor eligibility and testing information electronically. We have outlined our specific request more thoroughly in a previous letter to the Food and Drug Administration, and that request is enclosed.

Adopting such a revised interpretation would improve patient safety, ensure key data are available to practitioners, and reduce the risk of certain information being detached from the HCT/P.

Thank you for taking these comments into consideration. The AATB and TPG stand ready and willing to assist in any way that you deem appropriate.

Respectfully,

Marc Pearce
President & CEO
American Association of Tissue Banks

Dean Elliott
Chair
Tissue Policy Group

American Association of Tissue Banks® AATB TPG, LLC

September 7, 2021

Manufacturers Assistance and Technical Training Branch (MATTB)
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

In Re: Electronic Summary of Records for 361 HCT/Ps

Sent via e-mail to Industry.Biologics@fda.hhs.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, LLC (AATB TPG) submit a request to you for additional clarification regarding tissue bank requirements related to the summary of records for 361 human cells, tissues, and cellular and tissue-based products (HCT/Ps), as detailed in 21 CFR 1271.55. We appreciate the work of the Manufacturers Assistance and Technical Training Branch (MATTB) in providing timely, accurate and useful information to stakeholders, and we look forward to receiving your response, hopefully within five business days.

The American Association of Tissue Banks (AATB) is a professional, non-profit, scientific and educational organization. It is the only national tissue banking organization in the United States, and its membership totals approximately 120 accredited tissue banks and 2,000 individual members. These banks recover tissue from more than 58,000 donors and distribute in excess of 3.3 million allografts for more than 2.5 million tissue transplants performed annually in the U.S. The overwhelming majority of the human tissue distributed for these transplants comes from AATB-accredited tissue banks.

The AATB's Tissue Policy Group (TPG), LLC (AATB TPG or 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 public policy in furtherance of the adoption of laws and regulations 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.

Specifically, the AATB and the TPG seek clarification as to whether a tissue bank would be in compliance with the summary of records (per 21 CFR 1271.55) and the instructions for use (IFU) requirement (per the labeling requirements contained within 21 CFR 1271.370) if the tissue bank ensures that the distinct identification code (i.e., alphanumeric code that relates the HCT/P to the donor and all records pertaining to the HCT/P, likely through the use of a QR or bar code) is affixed directly to the HCT/P, and then the instructions for use (IFU) and the donor eligibility and testing is electronically provided. **In light of the definitive patient safety benefit, the increased need for**

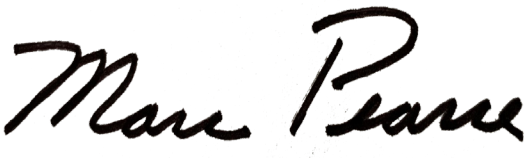
ensuring that key data are available to practitioners, and the value of an electronic exchange of information, the AATB and the AATB TPG strongly urge you to consider interpreting the regulations (e.g., clarifying the terms "accompanying records" and "accompany" in 21 CFR 1271.55 and the labeling requirements under §1271.370) to allow for an electronic summary of records and IFU.

This interpretation is consistent with current regulatory guidance. For instance, section III.G of the Guidance for Industry, Eligibility Determination for Donors of HCT/Ps states that "[e]lectronic access to accompanying records within a facility would satisfy the regulatory requirements under 1271.55(a), as long as they are in compliance with 1271.55(c) – deletion of personal information." Therefore, the Agency has already clarified that electronic access to the records is acceptable "within a facility," and it seems the concept could and should be applied for HCT/Ps being distributed from a facility. In addition, in the Guidance for Industry, CGTP and Additional Requirements for Manufacturers of HCT/Ps, Section XXIII.B states "your labeling procedures should be designed to ensure that consignees can readily link the product to all required labeling and accompanying records, such as instructions for use." This language appears to indicate that the intent of the requirements is to ensure that such linkage is possible, and electronic accesss would be consistent with that intent.

In addition, this interpretation will help ensure that the most up-to-date information (including the IFU, package insert, implant tracking cards, and summary of records) are up-to-date and readily available to both the clinician and the patient alike, while also ensuring harmony between the device and tissue regulations. In addition, this interpretation would lessen the risk of the summary of records and labeling information, including the IFU, being detached from the HCT/P (e.g., the hardcopy paper coming detached from the HCT/P) and thereby decreasing risk to the end-user. Finally, this interpretation is most consistent with the realities of tissue banking.

The AATB and the TPG stand ready and willing to assist the FDA with its deliberations in any way that the FDA deems appropriate.

Respectfully,



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