



American Association of Tissue Banks® AATB TPG, LLC

September 28, 2022

Division of Dockets Management (HFA-305)
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

In Re: [FDA-2022-D-1385](#), *Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments; Draft Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders*

Submitted electronically at www.regulations.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the American Association of Tissue Bank's Tissue Policy Group, LLC (AATB TPG or TPG) submit these comments related to draft guidance released by the Food and Drug Administration (FDA or Agency) titled *Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments*.

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 6,000 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 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.

We appreciate the work of the Agency in developing this draft guidance. While we have no specific recommendations to improve the guidance, we do note the importance of developing more clinical outcome assessments (COAs), especially patient-reported outcomes (PROs), given the value of these assessments in determining clinical utility and the dearth of appropriately validated assessments. As the draft guidance recognizes, development of COAs (including PROs) is a time and labor-intensive process. As such, product manufacturers, including tissue banks, may be unlikely to develop COAs or PROs unless the Agency takes a more proactive role in helping define what specific COAs or PROs may be helpful in assessing product performance.

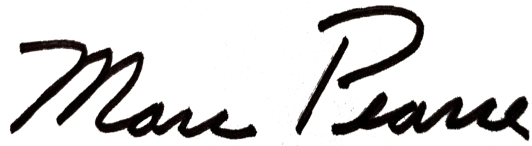
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We hope that you will find this information useful in your deliberations. The AATB and the TPG stand ready and willing to assist the FDA with its deliberations in any way that you deem appropriate.

Respectfully,

A handwritten signature in black ink that reads "Marc Pearce". The letters are cursive and fluid.

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

A handwritten signature in black ink that reads "Joe Yaccarino". The signature is stylized with a long horizontal line extending to the right.

Joe Yaccarino
Chair
Tissue Policy Group