American Association of Tissue Banks® AATB TPG, LLC

June 4, 2020

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

In Re: Docket No. FDA-2019-P-6100

Dear Dr. Marks:

The American Association of Tissue Banks (AATB or Association) and the American Association of Tissue Bank's Tissue Policy Group, LLC (AATB TPG) acknowledge receipt of your letter dated May 5, 2020 providing an interim response to our citizen petition (CP) related to the use of human acellular dermal matrixes allografts (ADMs) in post-mastectomy breast reconstruction. We write to request a timeframe for substantive response from FDA and to provide a point of clarification.

Specifically, your letter notes that you have "not yet reached resolution" and that you will respond as soon as you "have reached a decision." Under 21 CFR § 10.30(e)(2)(4), the tentative response "may specify when a final response may be furnished." Given that this issue is of critical importance to our membership, as well as hospitals, surgeons, and patients, we respectfully request an update on when you expect to issue a final response to the CP.

In addition, while your May 5 interim response notes instances in which FDA has gathered information on this topic, such as the March 25 and 26, 2019 Advisory Committee meeting, we would like to re-iterate our previous statement that no AATB-accredited tissue bank was invited to discuss or present on this critical topic at that meeting. For this reason, it was not a full discussion with input from all of the relevant stakeholders. Further, given that the announcement of the Advisory Committee focused on the discussion of "the use of surgical mesh in breast procedures such as breast reconstruction and mastopexy," stakeholders were not put on notice from FDA's initial announcement that the meeting would, in fact, discuss the use of *human* (non-synthetic) ADMs in breast reconstruction. Nor did the draft guidances addressed at the two-day public hearing in 2016 provide notice that FDA would be changing its regulatory approach on human ADMs. The AATB was further perplexed that notifications related to a potential change in classification of these products, which have been regulated by the Center for Biologics Evaluation and Research (CBER) for nearly two decades, were sent out to various stakeholders in 2019 by the Center for Devices and Radiological Health (CDRH) and not CBER.

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.

We look forward to receiving an updated timeline for response to our CP and hope that you will find this information useful in your continued deliberations. The AATB and the TPG stand ready and willing to assist the FDA in any way that the FDA deems appropriate.

Respectfully,

Diana Buck, M.Ed., MBA, CTBS
Chair
American Association of Tissue Banks

David M. Smith, MD
Chair
Tissue Policy Group