



American Association of Tissue Banks®

February 21, 2024

LCDR Cicely Reese, Pharm.D.
Marie DeGregorio
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave.
Bldg. 71, Rm. 1232
Silver Spring, MD 20993-0002

In Re: Docket No. FDA-2024-N-0008

Submitted electronically to Cicely Reese and Marie DeGregorio at CBERCTGTAC@fda.hhs.gov.

Dear Dr. Reese and Ms. DeGregorio:

The American Association of Tissue Banks (AATB or Association) write to nominate Dr. Melissa Greenwald, AATB Chief Medical Officer for the Food and Drug Administration's (FDA's or Agency's) Cellular, Tissue, and Gene Therapies Advisory Committee (CTGTAC). Dr. Greenwald is aware of this nomination and is willing to serve, if selected. Additionally, AATB is interested in participating in the selection of a nonvoting industry representative to serve on the CTGTAC.

For nearly 50 years, AATB has been dedicated to improving and saving lives by promoting the safety, quality, and availability of donated human tissue. To fulfill that mission, AATB publishes standards, accredits tissue banks, and certifies personnel. Given the CTGTAC's mission to review and evaluate "available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies, and xenotransplantation products..." we believe it is important that the CTGTAC include a nonvoting industry representative with expertise in human tissue products (thus, our nomination of Dr. Greenwald), and that AATB would be an appropriate organization to include in the selection process for a nonvoting industry representative.

In addition to the credentials described above, 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.

Melissa Greenwald, M.D., is the Chief Medical Officer for AATB and a retired Captain of the U.S. Public Health Service (USPHS). In her 25 years as an active-duty member with the USPHS, Melissa served in several high-profile roles, including as the Director of the Division of Transplantation within the Healthcare Systems Bureau of the Health Resources and Services Administration; Chief of the Human

Tissue and Reproduction Branch of the Division of Human Tissues within the FDA's Center for Biologics Evaluation and Research (CBER); Associate Public Health Advisor for Blood, Organ and Tissue Safety within the Office of the Assistant Secretary for Health; and Medical Officer within the Office of Blood Research and Review within CBER. As a result of these experiences, she is a highly sought-after national and internationally recognized expert in matters related to human cells and tissues, organs, blood, devices, and biologics.

Most recently, Dr. Greenwald spearheaded AATB's work related to the risk of *Mycobacterium tuberculosis* (MTB) transmission in the tissue donor population. These efforts resulted in multiple AATB Bulletins, including AATB Bulletin 23-6, which set forth new compliance expectations for AATB accredited establishments and their Medical Directors. More specifically, Bulletin 23-6 requires accredited establishments and their Medical Directors to rule certain potential donors of tissues or tissues containing viable cells ineligible if they have a history of certain conditions, such as tuberculosis disease. Following AATB's publication of AATB Bulletin 23-6, FDA issued a Tissue Safety and Availability Communication regarding "tuberculosis outbreaks linked to a bone matrix product." Notably, the FDA communication described risk mitigation strategies – which included many of the same requirements as AATB's Bulletin 23-6 – and listed the AATB Bulletin as an additional resource, all of which is a credit to the work of Dr. Greenwald and her colleagues in developing scientifically-sound requirements for AATB Bulletin 23-6.

Dr. Greenwald's additional qualifications include serving as a consultant to multiple companies as Principal of MA Greenwald Consulting, LLC, and in various other industry, nonprofit, and governmental roles. Those roles include positions on the Board of Directors for Donate Life America, on the Board of Directors for the Organ Procurement and Transplantation Network, with the AATB Standards Committee, and with the CBER Tissue Safety Team.

Dr. Greenwald holds an Associate of Science in Environmental Health from Roane State Community College; a Bachelor of Science in Environmental Health from East Tennessee State University; and a Medical Doctorate from the Uniformed Services University of the Health Sciences. She completed her Internal Medicine Internship at the Naval Medical Center Portsmouth, and her Internal Medicine Residency at the National Naval Medical Center.

As noted in the Federal Register, the CTGTAC is responsible for reviewing data related "to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies, and xenotransplantation products, which are intended for transplantation, implantation, infusion, and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair, or replacement of tissues for various conditions." Dr. Greenwald's experience in the government and various industry and nonprofit roles make her the ideal candidate for this role.

For these reasons, the AATB strongly supports the nomination of Dr. Greenwald to the CTGTAC. If you have any questions, please contact Kip Hanks, AATB Regulatory and Governmental Affairs Director (hanksk@aatb.org). Thank you as well for considering AATB as a potential organization to include in the selection of a nonvoting industry representative to serve on the CTGTAC.

Respectfully,

Marc Pearce

Marc Pearce
President & CEO
American Association of Tissue Banks