

September 17, 2019

Jeffrey Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health (CDRH)
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Peter Marks, M.D., Ph.D.
Director
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration
10903 New Hampshire Avenue
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Dear Dr. Shuren and Dr. Marks:

The undersigned organizations, representing patient advocacy groups, surgeons, and tissue banks, request that the Food and Drug Administration (FDA or Agency) hold a joint CDRH/CBER public workshop on the use of human ADMs in breast reconstruction with recipients, stakeholders from industry, health care professionals, and other interested parties.

Human acellular dermal matrixes (ADMs) were first described for use in breast surgery in 2001.¹ Since this initial report, ADMs have become an increasingly common component of implant-based breast reconstruction procedures.² According to the American Society of Plastic Surgeons, of the approximately 101,657 breast reconstruction procedures performed by member surgeons in 2018, about 83,200 (roughly 82%) utilized tissue expanders and/or breast implants. Of these procedures, approximately 74% (61,713) utilized ADMs.

During the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee Meeting on March 25 and 26, 2019, FDA officials seemed to indicate that ADMs for breast reconstruction would soon be regulated as class III medical devices.³ Prior to the Panel meeting, licensed tissue banks marketed human ADMs for breast reconstruction as 361 HCT/Ps. Therefore, this potential policy shift could result in loss of access to these ADMs for breast reconstruction.

To avoid any disruption in patient access to key components of reconstructive surgery, we look forward to working with the Agency to plan such a public workshop, prior to implementation of any regulatory change by the Agency.

Sincerely,

American Association of Tissue Banks
American Society of Breast Surgeons
American Society of Plastic Surgeons
Living Beyond Breast Cancer
The American College of Surgeons Commission on Cancer
Tiger Lily Foundation

¹ Margulies I, Salzberg C. The use of acellular dermal matrix in breast reconstruction: evolution of technique over 2 decades. *Gland Surgery* 2019; 8(1):3-10.

² Sheina A Macadam, MD MHS and Peter A Lennox, MD. Acellular dermal matrices: Use in reconstructive and aesthetic breast surgery. *Can J Plast Surg.* 2012 Summer; 20(2): 75–89.

³ <https://www.fda.gov/media/122962/download>, slide #11.