Summary of FDA Response to Citizen Petition from the American Association of Tissue Banks

On August 25, 2022, the U.S. Food and Drug Administration (FDA) issued a response[1] to the citizen petition submitted by the American Association of Tissue Banks (AATB) on December 30, 2019.[2] AATB's citizen petition was submitted to obtain clarification of FDA's position on human-derived acellular dermal matrix (human ADM) allografts intended for use in post-mastectomy breast reconstruction. Specifically, starting in 2019, FDA appeared to take the position that this intended use is non-homologous and that these products are Class III medical devices rather than human cellular and tissue-based products regulated exclusively under section 361 of the Public Health Service Act and 21 C.F.R. Part 1271 ("361 HCT/Ps").

In the citizen petition, AATB requested that FDA "confirm . . . that human ADM allografts that otherwise meet the requirements for regulation solely under Section 361 of the PHSA shall not be considered non-homologous or otherwise ineligible for classification as '361 HCT/Ps' solely because they are labeled and/or advertised for use in post-mastectomy breast reconstruction." AATB further requested that FDA revise its final guidance document titled "Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use" (2017) to present human ADM allografts for post-mastectomy breast reconstruction as an example of a homologous use.

FDA granted AATB's first request to confirm that human ADM allografts that otherwise meet the requirements for regulation as 361 HCT/Ps shall not be considered non-homologous solely because they are labeled and/or advertised for use in post-mastectomy breast reconstruction. FDA denied AATB's second request to revise the 2017 final guidance document on minimal manipulation and homologous use.

In granting the first request, FDA confirmed that it does "not view use in post-mastectomy breast reconstruction, in and of itself, as determinative of whether a use is homologous." Rather, FDA acknowledged that some uses of human ADM in breast reconstruction are homologous. For instance, FDA acknowledged that, if a human ADM allograft is intended to perform a covering function (like skin) in connection with such procedures, that is a homologous use. The only example FDA provided of a non-homologous use is where the human ADM allograft is intended to form an extension of the submuscular pocket for placement of a breast implant.

Based on FDA's citizen petition response, companies now know that simply labeling and promoting a human ADM allograft for use in breast reconstruction procedures is not sufficient, in and of itself, for FDA to assert that the human ADM allograft is non-homologous and therefore not a 361 HCT/P.

---

[1] FDA, Response to Citizen Petition, FDA-2019-P-6100-0036 (Aug. 25, 2022), https://www.regulations.gov/document/FDA-2019-P-6100-0036.

[2] AATB, Citizen Petition, FDA-2019-P-6100-0001 (Dec. 30, 2019), https://www.regulations.gov/document/FDA-2019-P-6100-0001.