CLIENT ALERTS & INSIGHTS

# Federal Court Hands Major Win to Tissue Product Manufacturers – FDA's HCT/P Classification Decision for Umbilical Cord-Derived Product CORDGRAFT Rejected

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Featured Practices: Healthcare, Healthcare Litigation, Litigation

**Key Takeaways**

- A federal court rejected the FDA's classification of an umbilical cord-derived product, finding the agency misapplied its own "minimal manipulation" standard and must reconsider the product's regulatory status-potentially making it easier for similar tissue products to qualify for the less burdensome Section 361 pathway.
- This is a significant check on FDA authority and could shift the regulatory landscape for tissue and regenerative medicine products. Companies may have stronger grounds to challenge FDA classifications, and more products could avoid costly biologics approval requirements-impacting market access, timelines and investment strategies.
- Stakeholders should prepare for expanded opportunities and regulatory changes as the FDA revisits its approach to structural tissue products. Companies in the tissue, regenerative medicine and biotech sectors should review their product classifications and consider challenging restrictive FDA decisions.

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On March 18, 2026, Chief Judge Brian C. Wimes of the U.S. District Court for the Western District of Missouri issued a significant decision overturning the U.S. Food and Drug Administration's ("FDA") classification of Vitti Labs' umbilical cord-derived product, CORDGRAFT. *See Vitti Labs, LLC v. U.S. Food & Drug Administration*, No. 4:25-cv-00011-BCW, slip op. (W.D. Mo. Mar. 18, 2026). The Court held that the FDA misread its own rules on "minimal manipulation" and must reconsider how the product is classified.

The ruling could materially impact tissue banks, regenerative medicine companies, HCT/P manufacturers, health systems and life sciences investors, as well as stakeholders involved in the production, manufacturing and use of skin substitute products utilizing human tissues. The Section 361 vs. Section 351[1]

classification considerations represents one of the most direct judicial repudiations of FDA's long-standing "donor-centric" approach to the minimal manipulation analysis. More importantly, the Court reaffirmed post *Loper-Bright* that FDA's interpretation of its own statutes requires no deference. *See Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244 (2024).

**Background**

Vitti Labs ("Vitti") is registered with the FDA as a Section 361 HCT/P manufacturer. At issue was whether Vitti Labs' product CORDGRAFT-derived from human umbilical cord tissue-qualifies as a Section 361 HCT/P, which would exempt the product from premarket approval requirements.

The first criterion to qualify as a Section 361 HCT/P is whether CORDGRAFT is "minimally manipulated."[2] The FDA determined in both a 2023 response and a 2024 Request for Designation ("RFD") review that CORDGRAFT did not meet the "minimal manipulation" criterion, concluding that the product's processing (specifically longitudinal slicing) altered the tissue's "original relevant characteristics." Because one criterion was deemed unmet, FDA classified the product as regulated under Section 351 (biological products), declining to evaluate the remaining criteria.

Vitti Labs then sought judicial review under the Administrative Procedure Act ("APA").

**The Court's Holding**

The Court granted Vitti Labs' motion for summary judgment, denied FDA's cross-motion, and reversed and vacated the agency's final action.

**1. The FDA's Interpretation of "Minimal Manipulation" Was Plainly Erroneous**

Under 21 C.F.R. § 1271.3(f)(1), the minimal manipulation standard for structural tissue requires examining "original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair or replacement" ("RRR") for recipients. The Court held that FDA improperly focused only on the tissue's functions in the donor, ignoring characteristics that may benefit a recipient.

Here, the Court found that the tissue's functions for a recipient, including cushioning and compressibility, were characteristics which impacted the RRR for recipients.

**2. The FDA Incorrectly Determined the Umbilical Cord Has Only One Relevant Characteristic**

The FDA concluded the only "original relevant characteristic" was the cord's function as a blood conduit between mother and fetus, and that longitudinal slicing (as is required to use the materials to make the CORDGRAFT product)necessarily altered that characteristic. The administrative record reflected additional structural and mechanical properties-such as cushioning and compressibility-that could be relevant to RRR in a recipient. The Court found the FDA's interpretation that the only original relevant characteristic as a blood conduit to be overly narrow and unsupported.

### 3. The FDA Must Consider All Functions Potentially Beneficial to a Recipient

The Court instructed the FDA to reevaluate the product recognizing that structural tissues may have multiple functional characteristics relevant to RRR, not solely their function in the donor. Importantly, the court noted that the "minimal manipulation analysis may be accomplished without reference to any specific product or intended use."

### 4. No Deference Was Owed to FDA's Interpretation

Although courts often afford deference to agency interpretations, the Court declined to do so here. Notably, the FDA **failed to argue** that deference applied, effectively waiving the issue at earlier stages of the case. However, even if this argument had been preserved by the FDA and raised here, the Court held that deference would be inappropriate because an alternative interpretation is compelled by the regulation's plain language. This aspect of the ruling follows the Supreme Court's post-*Loper Bright* framework, under which courts no longer presume agency interpretations are controlling.

### Key Insights

**For Tissue Banks and HCT/P Manufacturers:**

- Strengthens arguments for Section 361 classification.
- FDA's narrow interpretation of "minimal manipulation" may be increasingly challengeable.

**For Regenerative Medicine and Biotech Companies:**

- Products involving umbilical cord, Wharton's jelly, or structural tissues may now have a clearer path to 361 classification because minimal manipulation analysis can be accomplished without reference to any specific product or intended use and the Court's interpretation requires the FDA to consider all functions of structural tissues that may benefit a recipient, not just the tissue's original function in the donor.

**For Health Systems and Providers:**

- Potential expanded availability of certain allograft products if FDA reclassifies related products under Section 361; this is the first case to interpret this specific subsection of 21 C.F.R. § 1271.3(f)(1), so stakeholders should monitor for subsequent litigation challenging FDA classifications of other structural tissue products.
- Reinforces judicial scrutiny of FDA decisions that limit availability without clear regulatory basis.

**For Investors and Market Participants:**

- This decision creates potential regulatory tailwinds for minimally processed tissue-derived products.

**Implications for FDA and Regulatory Strategy**

- The FDA must apply an RRR-linked interpretation going forward.
- The decision highlights APA vulnerability when FDA interprets regulations contrary to their plain meaning.
- FDA must reassess CORDGRAFT without restricting analysis to donor-only characteristics.

**Conclusion**

This decision represents a noteworthy recalibration of the regulatory boundary between Section 361 HCT/Ps and Section 351 biologics. For the first time, a federal court has held that FDA's interpretation of "minimal manipulation" for structural tissues is contrary to the plain language of the regulation, requiring the FDA to consider functions beneficial to recipients-not only the donor.

FDA must now revisit its analysis on remand and reconsider CORDGRAFT-and potentially other similarly situated products-through a legally constrained lens. The broader implications for the broader HCT/P and regenerative medicine sectors could be substantial.

**The Benesch Healthcare team will continue to monitor developments and may provide additional updates as they become available. Please contact the authors of this article for additional information or if you have any questions.**

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[1] **Section 361 vs. Section 351.** HCT/Ps that meet specific criteria-such as minimal manipulation and homologous use-are regulated solely under Section 361 of the Public Health Service Act and are subject to a lighter regulatory regime and are exempt from FDA premarket approval, provided they meet four criteria set forth in 21 C.F.R. § 1271.10(a). HCT/Ps that fail to meet these criteria are regulated under Section 351 as biological products and generally require FDA premarket approval prior to marketing.

[2] For structural tissues, FDA's regulations define minimal manipulation as: "processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement." 21 C.F.R. § 1271.3(f)(1).