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FDA Classification Setback Bodes Well For Wound Care Cos.

By **Steven Gonzalez, Peter Dickos and Adrienne Lenz** (November 3, 2026, 2:15 PM EST)



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In MiMedx Group Inc. v. U.S. Food and Drug Administration,[1] the U.S. District Court for the Northern District of Georgia on Sept. 21 **handed** the regenerative medicine industry a significant win, vacating and remanding the FDA's designation of MiMedx's wound care product Axiofill as a biological product, instead of a medical device or a human cell, tissue, and cellular and tissue-based product, or HCT/P, regulated under Section 361 of the Public Health Service Act.

The ruling carries broad implications for HCT/P manufacturers, as it constrains the analytical framework the FDA has used to classify certain HCT/Ps as biological products subject to significantly higher regulatory standards than alternative classifications.

The decision comes on the heels of the FDA's loss in a similar case, Vitti Labs LLC v. FDA, in which the U.S. District Court for the Western District of Missouri vacated on similar grounds the FDA's classification of Vitti Labs' umbilical cord-derived product as a biological product rather than a Section 361 HCT/P.[2]

FDA Regulation of HCT/Ps

Depending on the extent and manner of processing and the intended use of an HCT/P, different regulatory frameworks will apply to the product.

An HCT/P that meets the four criteria set forth in Title 21 of the Code of Federal Regulations, Section 1271.10(a), including that it is minimally manipulated and intended for homologous use, is exempt from the FDA's premarket licensure, approval or clearance requirements, and subject to a more narrowly tailored set of requirements set forth in Section 361 of the Public Health Service Act, and Title 21 of the Code of Federal Regulations, Part 1271.

In contrast, HCT/Ps that do not satisfy these criteria are subject to more extensive regulation by the FDA. Depending on the characteristics of the specific HCT/P, it may be regulated and require premarket licensure, approval or clearance as a biological product, drug or medical device.

The FDA's Axiofill Classification

Axiofill is a dry powder made from extracellular matrix isolated from donated human placental tissue, processed through soaking, rinsing, cutting and grinding, and applied to wounds as a structural scaffold to support new cell growth. MiMedx submitted a request for designation to the FDA requesting that Axiofill be classified as a Section 361 HCT/P.

In response, the FDA found that Axiofill failed the minimal manipulation criterion for a Section 361 HCT/P, and then classified Axiofill as a biological product rather than a device.

The FDA regulation defines minimal manipulation in this context as "processing that does not alter

the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement."[3]

In guidance and in the Axiofill request for designation, the FDA has analyzed whether an HCT/P is minimally manipulated based on the effect of manufacturing on the original relevant characteristics of the HCT/P as it exists in the donor, and not based on the intended use of the HCT/P in the recipient.[4]

On that basis, the FDA determined that processing the placental tissue into a particulate product constituted more than minimal manipulation because the processing eliminated the characteristics the placental tissue exhibits in a donor — i.e., acting as a selective barrier that provides a transport function between fetal and maternal circulatory systems.

Although MiMedx did not propose a classification for Axiofill other than a Section 361 HCT/P, the FDA concluded that Axiofill was a biological product rather than a device because it is intended to treat injured skin through chemical action.

MiMedx challenged the FDA's determinations under the Administrative Procedure Act.

The MiMedx Case

The court sided with MiMedx on both the minimal manipulation and medical device issues. It rejected the FDA's interpretive approach to minimal manipulation, finding that the FDA's regulation requires it to consider the original characteristics of the tissue that relate to its utility for reconstruction, repair or replacement in a recipient, rather than limiting the analysis to characteristics associated with the tissue's function in the donor.

In doing so, the court expressly followed Vitti Labs, which also found the FDA had interpreted "minimal manipulation" too narrowly by focusing solely on how the umbilical cord tissue's processing affected its ability to perform the function it originally performed in a donor (i.e., as a conduit for blood flow between a mother and fetus), rather than functions the tissue could perform in a recipient.

The MiMedx court applied the U.S. Supreme Court's Kisor v. Wilkie/Auer framework for evaluating agencies' interpretations of their own regulations, set forth in 2019. Under that framework, agencies receive deference from the courts, but only if the regulation is genuinely ambiguous — and according to the court, this one wasn't.[5]

The court also found that the FDA classified Axiofill differently than similar wound products that had been classified as devices rather than biological products, without sufficient explanation or evidence to justify the disparate treatment, rendering that determination arbitrary and capricious. On remand, the FDA must reconsider both issues consistent with the court's order.

Industry Impact

The FDA has not yet indicated whether it will appeal the MiMedx decision; it has until late November to decide. The agency did not appeal the Vitti Labs decision.

If left undisturbed, the MiMedx and Vitti Labs decisions mark a meaningful check on the FDA's discretion in classifying HCT/Ps. By requiring the agency to evaluate minimal manipulation in terms of its impact on a tissue's utility in the recipient rather than its original function in the donor, these decisions potentially expand the scope of products that can be classified as Section 361 HCT/Ps and sold without FDA licensure, approval or clearance.

In just the last two years, the FDA has issued at least a dozen warning letters to companies marketing Section 361 HCT/Ps challenging the regulatory classification of their products. In most of these letters, the FDA concludes that the HCT/P is not minimally manipulated using the analytical framework rejected by the courts in MiMedx and Vitti Labs. The FDA has likely rejected far more requests from companies for designation of Section 361 HCT/Ps on similar grounds.

We expect that companies looking to market Section 361 HCT/Ps will begin to cite MiMedx and Vitti Labs in future requests for designation, or ask the FDA to revisit prior ones.

The cases do not, however, establish binding precedent, so even if the FDA does not appeal MiMedx, the agency will have to decide whether and how it will apply the new criteria in future cases — i.e., whether it will comply with the orders on remand of the specific requests for designation at issue, but not apply them more broadly.

If the FDA continues to use the minimal manipulation analysis rejected in these cases, HCT/P companies may prefer to market their products without seeking formal classification from the FDA, as requests for designation are voluntary and there may be no value in seeking the FDA's likely adverse determination on minimal manipulation.

The practical impact of MiMedx and Vitti Labs may be dampened if the FDA shifts its arguments against the Section 361 HCT/P classification of these products to focus on the homologous use criterion.

Neither of these cases directly addressed this criterion. In MiMedx, the court found that a footnote in the FDA's request for designation response suggesting that Axiofill also may not be intended for homologous use was not final agency action that it could review. The homologous use analysis — which requires that an HCT/P perform the same basic function in the recipient as in the donor — frequently overlaps with minimal manipulation.

The court's finding in MiMedx that the FDA needs to justify disparate classification of similar products will also be encouraging for manufacturers of extracellular matrices and other HCT/P products that may not qualify as Section 361 HCT/Ps.

The FDA has long classified certain HCT/P products as devices, which will make it difficult for the FDA to justify classifying similar HCT/P products as biological products. Device regulations are significantly less stringent and costly than those applicable to biological products.

Companies that receive adverse Section 361 HCT/P determinations from the FDA may view a device classification as a reasonable path forward and a biological product classification as a death knell for the product.

The MiMedx case also illustrates the limits of Auer deference after Kisor. Unlike the new Loper Bright standard that does not permit any deference beyond "respectful consideration" to an agency's view of the meaning of a statute, Kisor still allows for deference to an agency's interpretation of a regulation — but it has to be genuinely ambiguous first. Here, the court found the regulation unambiguous.

The MiMedx and Vitti Labs decisions provide an opportunity for HCT/P manufacturers to revisit the classification of their own products and weigh the risks and benefits of seeking formal FDA designation. In the meantime, they should watch closely for the FDA's next moves in reaction to both cases, including whether the agency appeals MiMedx, how it might apply their holdings on remand, and whether it applies them to future products.

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[1] Order, MiMedx Group, Inc. v. FDA, No. 1:24-cv-01287, ECF No. 79 (N.D. Ga. Sept. 21, 2026).

[2] Vitti Labs, LLC v. FDA, No. 25-cv-011 (W.D. Mo. Mar. 18, 2026), motion to alter or amend judgment denied (Aug. 28, 2026).

[3] 21 C.F.R. § 1271.3(f)(1).

[4] FDA, Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based

Products: Minimal Manipulation and Homologous Use at 7 (July 2020).

[5] Kisor v. Wilkie , 588 U.S. 558, 573 (2019).

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