IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI WESTERN DIVISION

VITTI LABS, LLC, Plaintiff, v. U.S. FOOD AND DRUG ADMINISTRATION, et al., Defendants.	)	Case No. 4:25-CV-00011-BCW

ORDER

Before the Court are Plaintiff's motion for summary judgment (Doc. #23) and Defendants' cross motion for summary judgment (Doc. #27) requiring review of a final agency action taken by the U.S. Food and Drug Administration. The Court, being duly advised of the premises, grants Plaintiff's motion, denies Defendant's motion, and reverses the agency action.

BACKGROUND

This case is about whether the appropriate regulatory framework was applied to CORDGRAFT, a product produced by Plaintiff Vitti Labs, LLC ("Vitti Labs") from human umbilical cord. On January 7, 2025, Vitti Labs filed this action against the U.S. Food and Drug Administration ("FDA"); Marty Makary, in his official capacity as Commissioner of the FDA;[1] the U.S. Department of Health and Human Services ("HHS"); and Robert F. Kennedy, Jr.,[2] in his official capacity as Secretary of HHS. (Doc. #1). Vitti Labs alleges Defendants violated the Administrative Procedure Act ("APA"), 5 U.S.C. § 706, by misapplying regulations enacted

[1] Marty Makary, Commissioner of the U.S. Food and Drug Administration as of April 1, 2025, is substituted as defendant in this cause. Fed. R. Civ. P. 25(d).
[2] Robert F. Kennedy, Jr., Secretary of the U.S. Department of Health and Human Services as of February 13, 2025, is substituted as defendant in this cause. Fed. R. Civ. P. 25(d).

pursuant to the Public Health Service Act ("PHS Act"), 42 U.S.C. §§ 262–264, to one of Vitti Labs' products.

The parties filed cross-motions for summary judgment, the Court held a hearing on the motions on February 17, 2026, and this matter is now ripe for disposition.

ADMINISTRATIVE RECORD STATEMENT OF FACTS

Vitti Labs is a tissue bank that is registered with the FDA as a Section 361 HCT/P[3] manufacturer. (Docs. #24 at 12, #28 at 22). "Section 361" refers to Section 361 of the PHS Act, and "HCT/P" refers to a category of products regulated under Section 361 "containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient." 21 C.F.R. § 1271.3(d); (Docs. #24 at 6, #28 at 5). Section 361 HCT/P's are regulated exclusively by Section 361, are not regulated as a "biologic," and do not require FDA premarket review and approval. (Docs. #24 at 6, #28 at 13).

To qualify for regulation solely under Section 361, an HCT/P must satisfy four criteria, enumerated in 21 C.F.R. § 1271.10. Relevant here, the first of those criteria is that the "HCT/P is minimally manipulated." 21 C.F.R. § 1271.10(a)(1). Minimal manipulation means, "[f]or structural tissue, 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). The FDA's guidance, published in July 2020, expands upon the FDA's interpretation of the "minimally manipulated" requirement. (Docs. #24 at 8, #28 at 16). The guidance states:

> Original relevant characteristics of structural tissues generally include the properties of that tissue in the donor that contribute to the tissue's function or functions. . . . Processing that alters the original characteristics of the HCT/P, raises increased safety and effectiveness concerns for the HCT/P because there would be less basis on which to predict the product's function after transplantation. Thus, the determination of whether an HCT/P is minimally manipulated is based on the effect

[3] The acronym HCT/P refers to "human cells, tissues, or cellular or tissue-based products." 21 C.F.R. § 1271.3(d).

> of manufacturing on the original relevant characteristics of the HCT/P as the HCT/P exists in the donor, and not based on the intended use of the HCT/P in the recipient.

(Doc. #41 at 126).

Vitti Labs produces a product named CORDGRAFT from umbilical cord tissue. (Docs. #28 at 7, #34 at 4). CORDGRAFT is not presently in commercial distribution. (Docs. #24 at 12, #28 at 22). On February 28, 2023, Vitti Labs submitted a request to the FDA seeking confirmation that CORDGRAFT qualified as a Section 361 HCT/P. (Docs. #28 at 6, #34 at 4). In its request, Vitti Labs provided "step-by-step descriptions" of how CORDGRAFT is "processed, packaged, and stored," including that the umbilical cord is "cut . . . open lengthwise to expose the conduits, arteries, and veins," and "additional slits" are made "until the still-intact tissue lays flat." (Docs. #28 at 7, #34 at 4). The conduits, arteries, and veins are then removed, and the tissue is cut into small pieces. Id. The tissue that remains is composed, at least in part, of what is referred to as "Wharton's jelly." (Docs. #24 at 13, #28 at 23). Wharton's jelly exhibits cushioning and compressibility characteristics, which Vitti Labs believes to be original relevant characteristics of the umbilical cord. (Docs. #24 at 13, #41 at 115).

The FDA responded to Vitti Labs' request on June 22, 2023. (Docs. #24 at 16, #28 at 25). The FDA concluded CORDGRAFT does not satisfy the regulatory criteria to be classified as a Section 361 HCT/P. Id. Specifically, the FDA determined that the first of four criteria under Section 361—that a product cannot be more than "minimally manipulated"—was not met. Id. The FDA did not determine whether the three remaining criteria were satisfied. Id. The FDA stated in its response that if Vitti Labs disagreed with the recommendation, it could submit a Request for Designation ("RFD") to obtain a formal, binding determination on CORDGRAFT's classification (i.e., as a Section 361 product only, or as a drug or biologic). Id.

On July 16, 2024, Vitti Labs submitted a formal RFD to the FDA requesting that CORDGRAFT be designated as a Section 361 HCT/P. (Docs. #24 at 17, #28 at 25). On September 20, 2024, the FDA responded to Vitti Labs' RFD. (Docs. #24 at 21, #28 at 28). The FDA determined that the "minimally manipulated" requirement was not satisfied. Id. Having found one of the criteria was not met, the FDA declined to address the remaining criteria. Id.

The FDA concluded that the only original relevant characteristic of an umbilical cord is its function as a conduit for blood flow between a mother and fetus, and this characteristic was more than minimally manipulated to produce CORDGRAFT. (Doc. #41 at 36–38). The FDA's determination was not based on the fact that the arteries and vein are removed from the umbilical cord or that the tissue is cut into standard sized sheets. (Docs. #24 at 22, #28 at 28). The FDA's response is based solely on Vitti Labs' longitudinal slicing of the umbilical cord. Id.

The FDA determined that CORDGRAFT is an HCT/P regulated under section 351 (not 361) of the PHS Act as a biological product. (Docs. #24 at 23, #28 at 28). Under Section 351 of the PHS Act, a "biological product" means "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition in human beings." Id.

On October 4, 2024, pursuant to 21 C.F.R. § 3.8(c), Vitti Labs submitted a Request for Reconsideration ("RFR") to the FDA. (Docs. #24 at 23, #28 at 29). On October 18, 2024, the FDA responded and affirmed its decision. (Docs. #24 at 26, #28 at 30).

LEGAL STANDARD

Any person who has suffered a "legal wrong because of agency action" or who is otherwise "adversely affected or aggrieved by agency action . . . is entitled to judicial review" of that action. 5 U.S.C. § 702. "Judicial review of administrative decisions is governed by the Administrative

Procedure Act." Mandan, Hidatsa & Arikara Nation v. U.S. Dep't of the Interior, 95 F.4th 573, 579 (8th Cir. 2024). Review under the APA is "limited," and agency decisions are entitled to "a high degree of deference." Id. (quoting Sierra Club v. E.P.A., 252 F.3d 943, 947 (8th Cir. 2001)).

Under the APA, the reviewing court must "hold unlawful and set aside agency action, findings, and conclusions" found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "Not only must an agency's decreed result be within the scope of its lawful authority, but the process by which it reaches that result must be logical and rational." Michigan v. E.P.A., 576 U.S. 743, 750 (2015). "If an agency's determination is supportable on any rational basis, then a reviewing court must uphold it." Mandan, 95 F.4th at 579 (internal quotation marks omitted).

ANALYSIS

Vitti Labs contends that CORDGRAFT is properly designated as a Section 361 HCT/P. (Doc. #24). Vitti Labs argues the FDA's conclusion that CORDGRAFT is not a Section 361 HCT/P is arbitrary and capricious in two ways. First, the FDA's interpretation of "minimally manipulated" is contradictory to the regulation's plain language. Second, without adequate justification, the FDA treated CORDGRAFT differently than other similar tissues it has deemed minimally manipulated.

Defendants also argue the language of the relevant regulation is plain, though they maintain the opposite interpretation of "minimally manipulated." (Doc. #28). Defendants argue the FDA's interpretation is reasonable and consistent with the agency's past practice.

Generally, "when evaluating competing interpretations, we defer to the agency's interpretations . . . unless we find that a regulation is contrary to unambiguous statutory language, that the agency's interpretation of its own regulation is plainly erroneous or inconsistent with the

regulation, or that application of the regulation is arbitrary or capricious." El Dorado Chem. Co. v. U.S. E.P.A., 763 F.3d 950, 958 (8th Cir. 2014) (cleaned up).

Vitti Labs argues the meaning of the regulation at issue is not ambiguous, and even if it were, the FDA's interpretation should receive no deference. The FDA does not address the issue of deference and has therefore conceded it. Satcher v. Univ. of Arkansas at Pine Bluff Bd. of Trs., 558 F.3d 731, 735 (8th Cir. 2009) ("[F]ailure to oppose a basis for summary judgment constitutes waiver of that argument."). Regardless, the Court would not defer to the FDA's interpretation in this case because "an alternative reading is compelled by the regulation's plain language." Shalala v. St. Paul-Ramsey Med. Ctr., 50 F.3d 522, 529 (8th Cir. 1995) (quoting Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994)).

In examining the meaning of a regulation, the Court's "inquiry begins with the regulation's plain language." Solis v. Summit Contractors, Inc., 558 F.3d 815, 823 (8th Cir. 2009). "The Court will avoid an interpretation of a regulation that renders some words altogether redundant" or "that would render another part of the same regulation superfluous." Id. (quoting United States v. Alaska, 521 U.S. 1, 59 (1997) and United States v. Stanko, 491 F.3d 408, 413 (8th Cir.2007)).

The regulation under consideration states that for "structural tissue" products, like CORDGRAFT, "[m]inimal manipulation means . . . processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement" ("RRR"). 21 C.F.R. § 1271.3(f)(1). The parties did not identify, nor is the Court aware of, any case where this specific subsection of § 1271 was interpreted, so no court has adopted either party's interpretation.

The parties dispute the meaning of "original relevant characteristics" and whether "utility for [RRR]" modifies the phrase to encompass functions of tissue in a donor that might aid a

recipient, as opposed to strictly referring to the functions of tissue in the donor. Vitti Labs argues the proper interpretation includes consideration of the original characteristics of tissue in a donor that might aid *a recipient* in a manner similar to how it aids the donor. (Doc. #24). The FDA argues the proper inquiry for original characteristics starts at the tissue's point of origin in the donor and focuses on the properties of the tissue that contribute to its functions in *the donor* only. (Doc. #28).

The plain language of § 1271.3(f)(1) states that the original characteristics material to the minimally manipulated analysis are those that "relat[e] to the tissue's utility for [RRR]." 21 C.F.R. § 1271.3(f)(1). Utility means "fitness for some purpose or worth to some end" or "something useful or designed for use." Utility, Merriam-Webster, https://www.merriam-webster.com/dictionary/utility (last visited Feb. 17, 2026). Moreover, Vitti Labs asserts, and the FDA does not dispute, that RRR occurs only in a recipient. Therefore, under the plain language, original relevant characteristics relating to the tissue's utility for RRR are those characteristics of the tissue in the donor that may be useful or beneficial to a recipient.

An interpretation that focuses only on the donor is inconsistent with the regulation's instruction to look to RRR. Such an interpretation would cut the definition of minimal manipulation off at "processing that does not alter the original relevant characteristics of the tissue[.]" 21 C.F.R. § 1271.3(f)(1). If the FDA had intended to focus the analysis strictly on the donor, it could have written it accordingly, but it did not. Yet, the same subsection of the regulation at issue here shows that the FDA knew how to write the regulation in that way. It can be seen in the very next sentence, following the sentence disputed by the parties:

> (f) Minimal manipulation means:
> (1) For structural tissue, processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement; and
> (2) For cells or nonstructural tissues, processing that does not alter the relevant biological characteristics of cells or tissues.

21 C.F.R. § 1271.3(f). In the definition for "cells or nonstructural tissue," there is no qualifier that states to look to RRR. If the FDA had intended for the definition with respect to structural tissue to be interpreted without reference to RRR, it could have written it that way. Yet, it did not. See United States v. California Stem Cell Treatment Ctr., Inc., 117 F.4th 1213, 1225 (9th Cir. 2024), cert. denied, 146 S. Ct. 318 (2025) (noting that "the regulations define 'minimal manipulation' differently" for structural tissue" and cells).

The Court's interpretation is also consistent with the history and purpose of the regulation, which is "to improve protection of the public health without imposing unnecessary restrictions on research, development, or the availability of new products." Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing, 66 Fed. Reg. 5447 (Jan. 19, 2001). The FDA has determined that HCT/P's "pose a potential risk of transmitting infectious disease," but not all HCT/P's raise the same level of risk. Id. at 5449. Therefore, the FDA has employed a "tiered, risk-based approach to regulating HCT/P's" that exempts from the premarket review process only those products that pose a low degree of risk. Id. at 5450–51. While the minimal manipulation requirement serves this purpose by ensuring products that have not been highly processed or altered are the only ones exempt from greater scrutiny, it nonetheless does so to facilitate bringing these products to market for patients in need of them. The entire regulatory scheme for HCT/P's revolves around sending safe products to patients, so it would not be logical to cut out consideration of recipients in the minimal manipulation analysis.

Defendants' arguments to the contrary are unpersuasive. In particular, Defendants contend that under this interpretation the FDA will be required to consider a tissue's suitability in the recipient for a different use than in the donor, which would transform the minimal manipulation analysis into an effectiveness review. The Court disagrees. The review process under Section 361

already requires the FDA to keep an eye towards functionality in the recipient (under the homologous use criterion). 21 C.F.R. § 1271.10(a)(2). This level of review is not the same as an effectiveness review. It simply requires the FDA to consider whether a tissue's functionality is transferable to recipients in a manner that is not precisely identical to the way it is in the donor. Also, § 1271.3(f)(2) does not instruct the FDA to consider only identical uses but any uses relating to RRR in a recipient. The FDA's incorrect interpretation inserts the "identical" requirement when no such words appear in the definition.

Moreover, the minimal manipulation analysis may be accomplished without reference to any specific product or intended use. Under the regulation's plain language, the FDA is required to consider all functions of the umbilical cord that may benefit a recipient. The Court is confident that the skilled staff at the FDA can analyze the umbilical cord, or another structural tissue, for all its potential beneficial functions regardless of the intended use proffered by an applicant—which the FDA may also consider, should it find it helpful to do so.

The FDA's interpretation of 21 C.F.R. § 1271.3(f)(1) is plainly erroneous and its decision with respect to CORDGRAFT is reversed and vacated. Creighton Omaha Reg'l Health Care Corp. v. Bowen, 822 F.2d 785, 789 (8th Cir. 1987) (holding that an agency interpretation that "is plainly erroneous or inconsistent with the regulation must be reversed."); see also SEC v. Chenery Corp., 318 U.S. 80, 88, 93–95 (1943) (Chenery I); SEC v. Chenery Corp., 332 U.S. 194, 196–197 (1947) (Chenery II) (describing the remand rule). The FDA concluded, based on its erroneous interpretation of § 1271.3(f)(1), that the only original relevant characteristic of an umbilical cord is its function as a conduit for blood flow between a mother and fetus. (Doc. #41 at 36–38). The FDA is instructed to reconsider its conclusion consistent with the understanding that original

relevant characteristics of structural tissue include the functions of the tissue in the donor that might aid a recipient. Accordingly, it is hereby

ORDERED Plaintiff's motion for summary judgment (Doc. #23) is GRANTED. It is further

ORDERED Defendants' cross motion for summary judgment (Doc. #27) is DENIED. It is further

ORDERED that the final agency action is REVERSED and VACATED and this matter is remanded to the FDA for further consideration consistent with this Order.

IT IS SO ORDERED.

Dated: March 18, 2026

/s/ Brian C. Wimes
BRIAN C. WIMES, CHIEF JUDGE
UNITED STATES DISTRICT COURT