FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA, *Plaintiff-Appellant*, v. CALIFORNIA STEM CELL TREATMENT CENTER, INC., a California corporation; CELL SURGICAL NETWORK CORPORATION, a California corporation; ELLIOTT B. LANDER, M.D., individual; MARK BERMAN, M.D., individual, *Defendants-Appellees*.	No.22-56014 D.C. No. 5:18-cv-01005-JGB-KK OPINION

Appeal from the United States District Court
for the Central District of California
Jesus G. Bernal, District Judge, Presiding

Argued and Submitted February 7, 2024
Pasadena, California

Filed September 27, 2024

Before: Kim McLane Wardlaw, Michelle T. Friedland, and Jennifer Sung, Circuit Judges.

Judge Friedland delivered the opinion of the Court as to Parts I, II, III.A, and III.B, in which Judge Wardlaw and Judge Sung joined. Judge Sung delivered the opinion of the Court as to Part III.C, in which Judge Wardlaw joined. Judge Friedland filed a concurring opinion in the result as to Part III.C.

SUMMARY*

Food, Drug, and Cosmetic Act

The panel reversed the district court's judgment following a bench trial in favor of Defendants, doctors who create and administer a stem cell mixture called stromal vascular fraction ("SVF"), in the Food and Drug Administration's action alleging that Defendants were violating the Food, Drug, and Cosmetic Act ("FDCA") by improperly manufacturing and labeling SVF.

Under the FDCA, 21 U.S.C. § 301 *et seq*., the FDA is tasked with ensuring that "drugs" are safe and effective. Under the FDCA and the Public Health Service Act, 42 U.S.C. § 201 *et seq.*, the FDA also regulates human cells, tissues, and cellular and tissue-based products, abbreviated as "HCT/Ps."

In Part III.B of the opinion, the panel held that Defendants' SVF constitutes a "drug" under the FDCA based on the plain text of the statute.

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

In Part III.C of the opinion, the panel rejected Defendants' argument that even if SVF is a "drug," their same-day SVF treatment for patients is completely exempt from FDA regulation under the "same surgical procedure" exception ("SSP exception"), which applies to "an establishment that removes HCT/P's from an individual and implants such HCT/P's into the same individual during the same surgical procedure." 21 C.F.R. § 1271.15(b). Because the text of the HCT/P regulations does not provide a clear answer to the meaning of the SSP exception, the panel examined the SSP exception's context and structure and resolved the seeming textual ambiguity in the FDA's favor. The SSP exception applies to a procedure only if the removed HCT/P and the implanted HCT/P are the same. For Defendants' SVF procedure, the removed HCT/P is the fat tissue, not the cells targeted for implantation. Because the SVF procedure removes fat tissue but implants SVF, the procedure is not exempt from regulation under the SSP exception.

Concurring in the result of Part III.C, Judge Friedland agreed with the majority's conclusion that Defendants' same-day version of the SVF treatment did not fall under the SSP exception, but she would arrive at this conclusion for a different reason. After examining the HCT/P regulations' text, structure, purpose, and history, she would hold that the SSP exception is genuinely ambiguous, and that the court owes *Auer* deference to the FDA's reasonable interpretation of the SSP exception such that Defendants' treatments do not fall under the SSP exception.

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OPINION

FRIEDLAND, Circuit Judge:

This case requires us to decide whether the Food and Drug Administration can regulate certain stem cell mixtures advertised as treatments for a host of medical conditions. Defendants are doctors who create such a mixture by removing fat tissue from a patient and breaking it down to concentrate the portion containing stem cells. The result is a mixture of stem cells, other types of cells, and cell debris called stromal vascular fraction ("SVF"), which they then administer to the patient. For example, Defendants inject SVF directly into a patient's knee to treat osteoarthritis. In recent years, clinics offering similar stem cell mixtures have proliferated despite concerns over whether such treatments are safe and effective.

After inspecting Defendants' two clinics, the FDA brought this lawsuit, claiming various violations of the Federal Food, Drug, and Cosmetic Act. Defendants argue that their SVF is not a "drug" within the meaning of the Act and that, even if it is, some of their uses of SVF fall under an exception from FDA regulation for certain surgical procedures. We reject both arguments. Accordingly, we reverse the district court's entry of judgment in favor of Defendants.

I.

A.

Defendants are two California-licensed physicians and the entities they co-founded: the California Stem Cell Treatment Center and the Cell Surgical Network. The California Stem Cell Treatment Center operates two clinics in Beverly Hills and Rancho Mirage. At those clinics, as part of what they call "patient-funded investigational research," Defendants offer stem cell treatments to "[p]atients who are looking for non-surgical alternatives to their degenerative disorders." Defendants advertise that they have "technology to produce a solution rich with your own stem cells" that they say can alleviate dozens of medical conditions, including Alzheimer's, arthritis, asthma, cancer, macular degeneration, multiple sclerosis, heart problems, pulmonary problems, Crohn's, Parkinson's, and erectile dysfunction. The treatments are not covered by insurance, so patients pay out of pocket. A single treatment typically costs $8,900, and a twelve-treatment option costs $41,500. Defendants have treated thousands of patients.

Through the Cell Surgical Network, Defendants also operate a network for "physicians who want[] to bring regenerative medicine into their own practices." Affiliates agree to follow Defendants' treatment protocol and pricing guidelines; share "research data"; and purchase Defendants' equipment for isolating cells, called the "Time Machine," for about $30,000.

The substance that Defendants produce is called "stromal vascular fraction," or "SVF." SVF is "a liquified mixture of cells and cell debris" derived from fat tissue. Fat tissue, which looks a bit like honeycomb when magnified, is a connective tissue primarily made up of fat cells. Fat tissue

also comprises many other types of cells, including mesenchymal stem cells. Most of the cells are embedded in an "extracellular matrix," a structure made partly of collagen fibers that holds the cells in place. Fat tissue also contains interspersed blood vessels.

Defendants derive SVF from fat tissue using a multi-step process. First, after administering local anesthesia to a patient, Defendants use liposuction to remove fat tissue. The retrieved tissue is then centrifuged (spun at high speed) to separate and remove blood and anesthesia. The next step is called "enzymatic digestion." An enzyme blend is added to the tissue, and during a thirty-minute incubation period, the enzymes break down the extracellular matrix (the tissue's structural components). During this period, cells detach from the matrix and become free-floating. Through another round of centrifugation, the fat cells, which made up the bulk of the tissue, are removed and discarded. What is left is repeatedly flushed with a solution to wash away as much of the enzyme blend as possible and centrifuged to concentrate the remaining cells. The resulting "slurry" is pushed through a filter to remove the broken-down structural components. The end result, SVF, is a concentrated mixture of many types of cells, including stem cells, and cell debris. Defendants administer it in a variety of ways, including by injection, intravenous drip, and inhalation.

That entire process is sometimes done on one day: The patient undergoes liposuction, waits for the tissue to be processed, and receives SVF all during one visit. But in the "expanded" version, the collected tissue is not processed onsite. Instead, the tissue is sent to a cell bank for processing and the cells are replicated ("expanded") for later use in the same patient.

B.

In 2017, the FDA inspected the California Stem Cell Treatment Center clinics. The inspectors concluded that the clinics were manufacturing and administering unapproved drug products. They found violations of the FDA's manufacturing requirements and a lack of proper documentation of adverse health events related to the clinics' SVF treatments.

In 2018, the FDA filed this lawsuit and sought injunctive relief, alleging that Defendants were violating the Food, Drug, and Cosmetic Act by improperly manufacturing and labeling SVF. After a seven-day bench trial, the district court entered judgment in favor of Defendants, holding that Defendants' treatments were not subject to FDA regulation. The district court held that Defendants' SVF is not a "drug" under federal law, reasoning that "Defendants are engaged in the practice of medicine, not the manufacture of pharmaceuticals." The court also alternatively held, as to the same-day procedure, that Defendants' use of SVF falls within an exception to regulation for certain surgical procedures. That holding was based on the court's factual finding that the cells in the same-day SVF "are not altered, chemically or biologically" and that the procedure "does not create any new material or introduce any foreign article" into the body. The FDA timely appealed.

II.

We review a district court's conclusions of law de novo and its findings of fact for clear error. *Yu v. Idaho State Univ.*, 15 F.4th 1236, 1241-42 (9th Cir. 2021).

III.

A.

Under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, the FDA is tasked with ensuring that "drugs" are safe and effective, as part of its mission to protect public health. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133-34 (2000) (citing 21 U.S.C. § 393(b)(2)); *see also Wyeth v. Levine*, 555 U.S. 555, 574 (2009) ("Congress enacted the FDCA to bolster consumer protection against harmful products.").

The FDCA requires all new drugs to receive premarket approval from the FDA, which in turn requires drug manufacturers to demonstrate each drug's safety and efficacy through clinical trials. *See Wyeth*, 555 U.S. at 566; *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 196 (2005) (citing 21 U.S.C. § 355). The FDCA also prohibits any act while a drug is being "held for sale . . . after shipment in interstate commerce" that results in the drug being "adulterated or misbranded."[1] 21 U.S.C. § 331(k). As relevant here, a drug is "adulterated" if it is manufactured or handled without contaminant controls or does not conform to standards of quality, strength, and purity. *Id.* § 351. And a drug is "misbranded" if it lacks adequate directions for use or bears false or misleading labeling. *Id.* § 352.

Under the FDCA and the Public Health Service Act ("PHSA"), 42 U.S.C. § 201 *et seq.*, the FDA also regulates

[1] The phrase "held for sale" applies to physicians "engaged in the business of providing medical services in exchange for payment." *United States v. Kaplan*, 836 F.3d 1199, 1210 (9th Cir. 2016). "[T]he 'shipment in interstate commerce' requirement is satisfied even when only an ingredient is transported interstate." *Baker v. United States*, 932 F.2d 813, 814 (9th Cir. 1991).

"human cells, tissues, and cellular and tissue-based products," abbreviated as "HCT/Ps." 21 C.F.R. § 1271.1(a); *Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing*, 66 Fed. Reg. 5447, 5449 (Jan. 19, 2001). HCT/Ps are defined as "articles 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). FDA regulations give as examples bone, ligament, skin, cornea, stem cells derived from blood, and reproductive tissue. *Id.*

The FDA has a "tiered, risk-based approach" to regulating HCT/Ps. 66 Fed. Reg. at 5448. That approach employs a hierarchy of oversight—full, limited, or no oversight—based on the FDA's assessment of the types of health risks posed by different categories of HCT/Ps. HCT/Ps at the top of the hierarchy are fully regulated as "drugs" under the FDCA, and/or as "biological products" under the PHSA, and are thus subject to premarket approval. 21 C.F.R. § 1271.20. HCT/Ps that meet certain criteria, such as being only "minimally manipulated," fall in the middle of the hierarchy and need only comply with regulations aimed at preventing the spread of infectious disease promulgated under the PHSA. *See id.* § 1271.10; 66 Fed. Reg. at 5449. Finally, HCT/Ps at the bottom of the hierarchy are not subject to any FDA oversight, even if they would otherwise be regulated as drugs under the FDCA.[2] 21 C.F.R. § 1271.15. As relevant to this case, the bottom category includes HCT/Ps that are removed from and implanted into

[2] The FDA treats HCT/Ps falling in the bottom category as excepted from *all* FDA regulation even though the text refers only to being excused from the requirements in "this part." *See* 21 C.F.R. § 1271.15(b).

the same patient during the same surgical procedure. *Id.* § 1271.15(b).

B.

The parties first dispute whether Defendants' SVF constitutes a "drug" under the FDCA. Based on the plain text of the statute, we agree with the FDA that Defendants' SVF is a drug.

"[T]he word 'drug' is a term of art for the purposes of the [FDCA]." *United States v. Article of Drug, Bacto-Unidisk*, 394 U.S. 784, 793 (1969). "Drug[s]" are defined in the Act as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," or "intended to affect the structure or any function of the body." *Id.* at 789 (quoting 21 U.S.C. § 321(g)(1)). An "article" is just a general term for "a particular thing." *Samsung Elecs. Co. v. Apple Inc.*, 580 U.S. 53, 59 (2016) (quoting J. Stormonth, A Dictionary of the English Language 53 (1885)). Defendants administer a particular thing—a liquified concentrate of cells and cell debris. And they do so with the undisputed intent, as reflected in their marketing, to treat a long list of diseases and to affect structures of the body, such as to regenerate cartilage.

Considering a similar stem cell treatment in *United States v. Regenerative Sciences, LLC*, 741 F.3d 1314 (D.C. Cir. 2014), the D.C. Circuit likewise held that the "plain language" of the FDCA compelled the conclusion that the stem cell mixture in that case was a "drug" under the FDCA. *Id.* at 1319. There, doctors extracted bone marrow or fluid from joints, isolated and cultured stem cells, combined the cells with an antibiotic to prevent bacterial contamination, and reinjected the mixture to treat orthopedic conditions. *Id.* at 1318. Although Defendants' treatment here does not

involve an antibiotic and does not always involve culturing, the D.C. Circuit's holding that the mixture in its case was a "drug" did not hinge on those aspects of the treatment. *See id.* at 1319. The court simply reasoned that the FDCA's "wide-ranging definition[] clearly appl[ied] to the Mixture, an article derived mainly from human tissue and intended to treat orthopedic diseases and to affect musculoskeletal function."[3] *Id.*

Defendants do not seem to dispute that the "admittedly capacious" language of the FDCA, read literally, encompasses their treatments. Instead, they assert that the definition should not be read literally because its breadth is intolerable. But the Supreme Court has instructed that it is error to "refuse[] to apply the [FDCA's] language as written," holding that "Congress fully intended that the Act's coverage be as broad as its literal language indicates—and equally clearly, broader than any strict medical definition might otherwise allow." *Bacto-Unidisk*, 394 U.S. at 798. The Court explained that "remedial legislation such as the [FDCA] is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health." *Id*.

Defendants conjure purportedly "absurd" results of a broad interpretation of "drugs," painting a picture of doctors having to pause during a vein graft to measure the vein's

[3] The D.C. Circuit in *Regenerative Sciences* also held that the stem cell mixture was a "biological product" under the PHSA. 741 F.3d at 1319 (citing 42 U.S.C. § 262(i)(1)). We are not presented in this appeal with the question whether Defendants' SVF falls under the PHSA, and the FDA has made no arguments based on the PHSA's definition of a biological product. But we note that a product can be both a drug under the FDCA and a biological product under the PHSA. *See id.* at 1319 & n.1; *see also* 42 U.S.C. § 262(j); 21 U.S.C. § 353(g)(1)(A).

active ingredients or adhere a drug label. But "[t]he scope of the offense which Congress defined [in the FDCA] is not to be judicially narrowed as applied to drugs by envisioning extreme possible applications." *United States v. Sullivan*, 332 U.S. 689, 694 (1948). And the FDA has flexibility to tailor its specific requirements upon approval of a new drug.[4] *Id.* at 695; *see also, e.g.*, 21 U.S.C. § 352(e)(1)(B), (f) (explaining that exemptions from labeling requirements may be established). Hypothesized extreme applications of specific requirements are not a reason to infer that Defendants' SVF is not a "drug" under the FDCA.

Defendants next argue that this interpretation of "drugs" would impermissibly intrude upon the practice of medicine, which is regulated by the states. But in *United States v. Kaplan*, 836 F.3d 1199 (9th Cir. 2016), we rejected essentially the same argument. There, we held that a doctor could be criminally prosecuted under the FDCA for reusing in biopsies a "needle guide" that was intended for single use only. *Id.* at 1208-11. We explained that "[t]hough the regulation of the practice of medicine is delegated to the states, when a physician misuses medical devices and threatens public health, the physician may run afoul of the [FDCA]." *Id.* at 1203; *see also United States v. 9/1 Kg. Containers, More or Less, of an Article of Drug for Veterinary Use*, 854 F.2d 173, 176 (7th Cir. 1988) ("To regulate drugs is to be 'involved' in the 'practice of the healing arts.'"); *United States v. Evers*, 643 F.2d 1043, 1048 (5th Cir. 1981) ("Of course, while the [FDCA] was not

[4] Indeed, the FDA has used its flexibility with respect to other autologous (*i.e.*, same-patient) stem cell treatments that have gone through the FDA's approval process for biological products. *See, e.g.*, FDA, ZYNTEGLO, https://www.fda.gov/vaccines-blood-biologics/zynteglo.

intended to regulate the practice of medicine, it was obviously intended to control the availability of drugs for prescribing by physicians.").

Kaplan also invoked the D.C. Circuit's decision in *Regenerative Sciences*, which rejected an argument that "the FDA was improperly attempting to regulate the practice of medicine by regulating the stem cell procedure." *Kaplan*, 836 F.3d at 1210 (describing *Regenerative Scis.*, 741 F.3d at 1319). The D.C. Circuit reasoned that the FDA's focus was the stem cell *mixture*, not the doctor's performance of any procedure. *Regenerative Scis.*, 741 F.3d at 1319. The court noted that the FDCA's regulatory scheme clearly applies to doctors—evidenced by the fact that the Act has specific carve-outs for doctors that "would be unnecessary if the FDCA did not otherwise regulate the distribution of drugs by licensed physicians." *Id.* at 1319-20. And the court observed that narrowing the scope of the FDCA "by classifying the distribution of drugs by doctors as the practice of medicine" would "create an enormous gap in the FDCA's coverage." *Id.* at 1320. Adopting the reasoning of *Regenerative Sciences*, we explained in *Kaplan* that the defendant doctor's practice-of-medicine arguments were "wide of the mark." 836 F.3d at 1210 (quoting *Regenerative Scis.*, 741 F.3d at 1319). *Kaplan* forecloses Defendants' similar argument here.

As a final effort to resist the FDA's interpretation, Defendants invoke the major questions doctrine, which, when it applies, requires an agency to "point to 'clear congressional authorization' for the power [the agency] claims." *West Virginia v. EPA*, 597 U.S. 697, 723 (2022) (quoting *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014)). But this is far from the sort of "extraordinary case[]" that would give us "'reason to hesitate before

concluding that Congress' meant to confer such authority." *Id.* at 721 (quoting *Brown & Williamson Tobacco Corp.*, 529 U.S. at 159). The FDA is not asserting authority over surgery as a general category. Rather, it is asserting authority over doctors' creation or use of products that fall within Congress's definition of "drugs." That is unlike the situations in which the major questions doctrine has been applied.

First, this case does not present a matter of extreme "economic and political significance." *Id.* (quoting *Brown & Williamson Tobacco Corp.*, 529 U.S. at 160); *cf. id.* at 724-25 (reasoning that carbon emission standards were meant to "substantially restructure the American energy market"); *Biden v. Nebraska*, 143 S. Ct. 2355, 2373 (2023) (noting that the significance of the student loan forgiveness program was "staggering by any measure," with an economic impact amounting to "nearly one-third of the Government's $1.7 trillion in annual discretionary spending"); *Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 594 U.S. 758, 764 (2021) (per curiam) (describing the "sheer scope" of an eviction moratorium, which covered at least 80% of the country).

Second, the FDA's regulation of human cell and tissue products does not represent a sudden assertion or "transformative expansion" of authority. *West Virginia*, 597 U.S. at 724 (quoting *Util. Air.*, 573 U.S. at 324). The FDA's assertion of power rests on key provisions of the FDCA, not a rarely used "gap filler." *Id.* And the FDA's regulation of human cell and tissue products is longstanding. As early as 1993, the FDA was regulating "somatic cell therapy products," including "autologous" cell therapies (*i.e.*, therapies using a patient's own cells), as "drugs" under the FDCA. *Application of Current Statutory Authorities to*

Human Somatic Cell Therapy Products and Gene Therapy Products, 58 Fed. Reg. 53248, 53249 (Oct. 14, 1993). In 1997, the FDA proposed its current "unified approach to the regulation of both traditional and new [human cellular and tissue-based] products." FDA, *Proposed Approach to Regulation of Cellular and Tissue-Based Products* 6 (Feb. 28, 1997) ("*Proposed Approach*"); 66 Fed. Reg. at 5447-69 (finalizing the rule in 2001).

Third, unlike in the only Supreme Court case addressing the major questions doctrine in the context of the FDCA, there is no mismatch between Defendants' SVF and the statutory scheme. In *Brown & Williamson Tobacco Corp.*, the Court held that the FDA did not have authority over tobacco products. 529 U.S. at 161. The Court reasoned that faithful application of the FDCA—which requires that the FDA balance a product's therapeutic benefits against the risk of harm—would require an outright ban on tobacco products because they cannot safely be used for *any* therapeutic benefit. *Id.* at 141-43. But a ban would have contradicted Congress's clear intent in tobacco-specific legislation to permit the sale of tobacco products. *Id.* at 143. Thus, "there is no room for tobacco products within the FDCA's regulatory scheme." *Id.* Here, by contrast, SVF fits comfortably within the FDCA because it is sold and administered to patients for therapeutic purposes, and there is no reason to think that Congress intended it to be outside the FDCA's scope. In fact, recent legislation suggests that Congress presupposes that the FDA regulates stem cell therapies. *See* 21st Century Cures Act, Pub. L. No. 114-255, § 3033, 130 Stat. 1033, 1101-03 (2016) (codified as amended at 21 U.S.C. § 356) (amending a section of the FDCA to create an expedited review process for

"regenerative advanced therapies," including "cell therapy" and "human cell and tissue products").

Consistent with the Supreme Court's instruction that the FDCA's definition of "drug" is "as broad as its literal language indicates," *Bacto-Unidisk*, 394 U.S. at 798, we hold that Defendants' SVF is a "drug."

* * *

Part III.C:

SUNG, Circuit Judge, with whom WARDLAW, Circuit Judge, joins:

C.

Defendants argue that even if their SVF is a "drug," their same-day SVF treatment is completely exempt from FDA regulation under what is called the "same surgical procedure" exception ("SSP exception").[5] The SSP exception applies to "an establishment that removes HCT/P's from an individual and implants such HCT/P's into the same individual during the same surgical procedure." 21 C.F.R. § 1271.15(b). The FDA maintains that the SSP exception does not apply to Defendants' same-day SVF treatment. On appeal, the parties do not dispute the facts about the same-day SVF treatment. Rather, they offer competing interpretations of the SSP exception. For the reasons explained below, we conclude that the FDA's interpretation is correct, and we hold that Defendants' same-

[5] Defendants do not challenge the district court's conclusion that their use of SVF in the "expanded" version of the treatment, which involves shipping the tissue to a cell bank and culturing cells, does not fall under the SSP exception.

day version of the SVF treatment does not qualify for the SSP exception.

1.

"If [a] regulation is unambiguous and 'there is only one reasonable construction of [the] regulation,' then we" simply apply that meaning. *Mountain Cmtys. for Fire Safety v. Elliott*, 25 F.4th 667, 675 (9th Cir. 2022) (quoting *Kisor v. Wilkie*, 588 U.S. 558, 575 (2019)). If the text seems to have more than one plausible meaning, then we must try to resolve the ambiguity by "carefully consider[ing] the text, structure, history, and purpose of [the] regulation." *Kisor*, 588 U.S. at 575 (internal quotation marks and citation omitted). If, after "exhaust[ing] all the 'traditional tools' of construction," we determine that "the interpretive question still has no single right answer," then we consider whether the agency's interpretation is reasonable, and if so, whether it is entitled to deference under *Auer v. Robbins*, 519 U.S. 452 (1997). *Id.* at 575–76. But, in many cases, our tools of construction will resolve the seeming ambiguity "out of the box, without resort to *Auer* deference." *Id.* at 575.

2.

Again, the SSP exception applies to: "[A]n establishment that removes HCT/P's from an individual and implants such HCT/P's into the same individual during the same surgical procedure." 21 C.F.R. § 1271.15(b). "HCT/Ps" are defined as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient." *Id.* § 1271.3(d).

The FDA and Defendants agree on several important points. First, they agree that the SSP exception applies to a

procedure only if the removed HCT/P and the implanted HCT/P are "the same." Second, they agree that fat tissue is an HCT/P, and that the SVF procedure removes fat tissue, but implants SVF. Third, they agree that Defendants subject the removed fat tissue to significant processing to produce SVF. Fourth, they agree that fat tissue and SVF are not the same. In the FDA's view, all this adds up to an easy case: Because fat tissue and SVF are not the same, the SSP exception does not apply to the SVF procedure.

But, Defendants point out (and the FDA does not dispute) that the cells they extract from the fat tissue are also, by definition, HCT/Ps. Consequently, the SVF procedure can be characterized as removing two different kinds of HCT/Ps: the fat tissue and the cells within the fat tissue. When determining whether a procedure removes and implants the same HCT/Ps, Defendants argue that the SSP exception requires us to compare the implanted HCT/P with the HCT/P that was "the target of the removal, rather than the largest system removed." Under that interpretation of the SSP exception, the SVF procedure removes and implants the same HCT/Ps because it targets the cells within fat tissue for removal and implants those cells. And, under that interpretation, the SVF procedure removes and implants the same HCT/Ps even though Defendants subject the removed fat tissue to significant processing to extract and isolate the targeted cells. In Defendants' view, the SSP exception applies no matter how much processing the removed tissue undergoes, so long as the extracted cells are implanted in the same surgical procedure.[6]

[6] It is undisputed that Defendants' same-day treatment involves the same patient and the "same surgical procedure" as required for the SSP exception.

The FDA maintains that the SSP exception requires us to view the removed HCT/P as a whole, before it has undergone any significant processing. Under that interpretation, the HCT/P removed by the SVF procedure is the fat tissue, not the cells.

Thus, the parties' interpretive dispute boils down to the following question: When determining whether the removed and implanted HCT/Ps are the same, which removed HCT/P is the correct comparator? Do we consider the HCT/P that was removed as a whole, before any significant processing? Or only the portion of the removed HCT/P that will be implanted, even if extensive processing is needed to extract that portion from the whole?

Each party argues that its interpretation is compelled by the regulation's text. The FDA focuses on the word "such," which is used to refer back to something already mentioned—an antecedent. *Such*, Black's Law Dictionary (12th ed. 2024) (defining "such" as "[t]hat or those; having just been mentioned"). Therefore, the phrase "removes HCT/P's from an individual and implants such HCT/P's into the same individual" means that, to fall under the SSP exception, the HCT/P implanted must be the same HCT/P removed. But, as discussed above, Defendants concede that the removed and implanted HCT/P must be the same, and instead argue that the implanted SVF should be compared to the cells within the removed tissue, not the tissue as a whole. The term "such" does not tell us which comparator to use.

For their part, Defendants focus on the regulatory definition of HCT/Ps. Recall that the FDA defines HCT/Ps as "articles 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).

Defendants first argue that the definition signals that the focus in the SSP exception should be on the article that the doctor "intend[s] for implantation"—here, the cells. But the HCT/P definition includes an article that "contain[s]" the cells that are intended for implantation. And here, the removed fat tissue contains the cells that are intended for implantation. Thus, even if the doctor's intent is relevant, the fat tissue could still be the correct comparator.

Defendants next argue that the FDA's focus on the largest system removed would render part of the HCT/P definition superfluous. The definition refers to "cells *or* tissues," and Defendants argue that cells can generally only be removed from the body within tissue or other larger systems. It is true that isolated cells would rarely fall under the SSP exception as interpreted by the FDA. But rarely does not mean never. As the FDA points out, at least one type of cell can be removed in isolation,[7] and the regulation addresses an area of evolving science. Moreover, the HCT/P definition does not apply solely to the SSP exception—it applies across numerous provisions regulating cells or cell-based products. *Id.* § 1271.3 (establishing definitions that apply across 21 C.F.R. pt. 1271); *see also, e.g.*, *id.* § 1271.145 (providing that HCT/Ps must be stored "in a way that prevents the introduction, transmission, or spread of communicable diseases"). Thus, even if the inclusion of "cells" in the definition of "HCT/P" served no purpose in the context of the SSP exception, the word "cells" would not be superfluous in the context of those other provisions.

In sum, neither party's textual arguments fully resolve the interpretive dispute. Although the FDA's reading is

[7] The FDA's expert testified that she was aware of one type of cell that can be removed in isolation: an ovocyte, or egg cell.

more straightforward and consistent with the SSP exception's plain text, Defendants' reading is plausible. So, we consider the SSP exception's context and structure.

The SSP exception is part of a broader framework that regulates the "manufacture" of HCT/Ps. "Manufacture means, but is not limited to, any or all steps in the recovery, processing, storage, labeling, packaging, or distribution of any human cell or tissue . . . ." *Id.* § 1271.3(e). As noted above, this framework establishes three tiers of regulation for HCT/Ps: 1) full regulation; 2) limited exemption from regulation; and 3) complete exemption from regulation. HCT/Ps are subject to full regulation unless they qualify for an exception. *Id.* § 1271.20. To qualify for limited exemption from regulation, an HCT/P must meet the criteria set out in § 1271.10(a); in relevant part, the HCT/P cannot be more than "minimally manipulated."[8] There are several ways to qualify for complete exemption, including by meeting the requirements for the SSP exception at issue here. *See id.* § 1271.15.[9]

The FDA points out that when an HCT/P is more than "minimally manipulated," it is subject to full regulation. Thus, the FDA argues, the SSP exception should not be interpreted as completely exempting procedures that involve substantial manipulation of HCT/Ps. Defendants, however,

[8] HCT/Ps in this category must also be "intended for homologous use only," meaning the HCT/P must perform the "same basic function" when reimplanted; must "not involve the combination of the cells or tissues with another article;" and must "not have a systemic effect" (with some additional nuances to those requirements). 21 C.F.R. §§ 1271.10(a)(2)-(4), 1271.3(c).

[9] Defendants do not dispute that they manufacture HCT/Ps; they argue only that they qualify for the SSP exception.

point out that the limited exemption expressly incorporates the minimal manipulation requirement, *see* 21 C.F.R. § 1271.10(a), but the SSP exception does not, *see id.* § 1271.15(b). That omission, Defendants argue, implies that a surgical procedure can qualify for the SSP exception *regardless of* how much an HCT/P is manipulated. That is, a surgical procedure could "alter the relevant biological characteristics"[10] of the cells or tissues that are implanted and still qualify for the SSP exception.[11] In Defendants' view, "it is not strange at all that some procedures would be exempted under the SSP exception, even if they would not qualify for the [limited] minimal manipulation exemption" provided for under § 1271.10(a), because the limited exemption is "available to establishments that transfer HCT/Ps from one donor to a different recipient," while the SSP exemption is available only to establishments that remove HCT/Ps and implant them back into the same patient.

In our view, the FDA's understanding of the regulatory framework makes more sense: The tiered structure more strongly implies that a surgical procedure cannot qualify for the SSP exception if it involves more than minimal manipulation of HCT/Ps. But, even assuming the FDA is right about that point, the SVF procedure could still qualify for the SSP exception—if the correct comparator is the cells, not the fat tissue. That's because the regulations define "minimal manipulation" differently for structural tissue (which includes fat tissue), *see id.* § 1271.3(f)(1), and cells

[10] 21 C.F.R. § 1271.3(f) (defining minimal manipulation).

[11] Although Defendants maintain that the SVF procedure does *not* biologically alter the stromal vascular cells targeted for implantation, under their interpretation of the SSP exception, that fact is irrelevant.

or nonstructural tissues, *see id.* § 1271.3(f)(2). For fat tissue, minimal 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." *Id.* § 1271.3(f)(1). But for cells, minimal manipulation means "processing that does not alter the relevant biological characteristics of cells." *Id.* § 1271.3(f)(2). It is undisputed that Defendants' SVF procedure significantly alters the removed fat tissue to produce the implanted SVF. But, the district court specifically found that the procedure does not biologically alter the cells that Defendants extract from the fat tissue, and the FDA has not challenged that finding on appeal. Thus, if the targeted cells are the correct comparator, as Defendants argue, then the SVF procedure does not involve more than minimal manipulation.

All this means that we still need to figure out whether the correct comparator is the removed HCT/P as a whole or only the portion targeted for removal. Because neither the SSP exception nor the related regulations expressly answer that question, we turn to the regulations' purpose and history.

When the FDA first proposed the HCT/P regulatory framework, it explained that, "[i]n the past, most human tissue used in medicine was comprised of such body components as skin, bone, corneas, and heart valves that were transplanted for replacement purposes, and semen and ova implanted for reproductive purposes." *Proposed Approach* at 8. And, the "FDA's regulation of the conventional tissues used for replacement purposes ha[d] focused on preventing the transmission of communicable disease . . . ." *Id.* However, "[i]n recent years, scientists ha[d] developed innovative methods of manipulating and using human cells and tissues for therapeutic uses," and the

FDA identified several public health and regulatory concerns associated with the use of such products. *Id.* at 9. Thus, the FDA proposed regulating cells and tissues "with a tiered approach based on risk and the necessity for FDA review." *Id.*

A chief purpose of the regulations would be "ensuring that clinical safety and effectiveness is demonstrated for tissues that are highly processed." *Id.* at 6. The FDA stated its intent to "require that cells and tissues be handled according to procedures designed to prevent contamination and to preserve tissue function and integrity." *Id.* at 6-7. The FDA explained, "Improper handling can alter or destroy the integrity or function of cells or tissues. Improper handling also can allow cells or tissues to become contaminated (e.g., bacterial contamination during collection, processing, storage, or transplantation, or cross contamination from other contaminated tissues)." *Id.* at 15.

In this context, the FDA also stated that it "would not assert any regulatory control over cells or tissues that are removed from a patient and transplanted back into that patient during a single surgical procedure," because "[t]he communicable disease risks, as well as safety and effectiveness risks, would generally be no different from those typically associated with surgery." *Id.* at 12.[12] The

[12] Defendants argue that their interpretation of the SSP exception is supported by the FDA's statement that "[a]utologous use of *cells* and tissues harvested and transplanted in a single surgical procedure would be subject to no FDA oversight." *Proposed Approach* at 15 (emphasis added). They assert that the FDA must have known that cells generally cannot be removed from the body in isolation, so the FDA must have intended for the SSP exception to cover procedures that process tissue to extract cells. Because that assertion is unfounded, Defendants' argument

FDA identified "skin or vein grafts" as examples of surgical procedures that would qualify for complete exemption from regulation. *Id.* at 20.

Consistent with the FDA's proposal, the final rule established "a tiered, risk-based regulatory scheme that . . . tailor[s] the degree of scrutiny afforded to different HCT/P's to the risks associated with each of them." *See* 66 Fed. Reg. at 5464. The SSP exception is at the bottom tier: procedures covered by the SSP exception are completely exempt from regulation. This means that covered procedures should involve relatively low risk—risk no greater than that typically associated with conventional surgery. And, because processing HCT/Ps introduces risk, covered procedures should not involve significant processing.

Defendants' interpretation of the SSP exception conflicts with the HCT/P regulations' structure and purposes. Under their interpretation, the SSP exception would exempt surgical procedures that subject HCT/Ps to substantial processing, even if such processing introduces risk far greater than that associated with conventional surgery. HCT/Ps could be subjected to any number of processing steps to isolate, extract, or potentially even recombine its subcomponents (perhaps in ways currently unimaginable) with no FDA oversight, so long as those subcomponents

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is unpersuasive. As noted above, egg cells can be removed in isolation, and the FDA was anticipating scientific advances when it proposed the HCT/P regulations. *See id.* at 8 (discussing implantation of ova for reproductive purposes); *id.* at 27 (discussing intent to balance protecting public health with encouraging research and innovation).

came from the same person and were removed and implanted on the same day.[13]

The FDA's interpretation is more consistent with the SSP exception's plain meaning. And it is the only interpretation that makes sense in light of the HCT/P regulations' tiered, risk-based framework, and its purpose and history. The seeming textual ambiguity is resolved in the FDA's favor.[14] When determining whether a surgical procedure "removes HCT/P's and implants such HCT/P's," the removed HCT/P must be viewed as a whole, before any significant processing. For Defendants' SVF procedure, the removed HCT/P is the fat tissue, not the cells targeted for implantation. Because the SVF procedure removes fat tissue but implants SVF, the procedure is not exempt from regulation under the SSP exception.

* * *

We REVERSE and REMAND for further proceedings.[15]

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[13] In an exceedingly similar case regarding "body-fat derived stem cell therapy," the Eleventh Circuit agreed with the FDA that, to qualify for the SSP exception, "'such HCT/Ps' must be in their original form (rather than subjected to extensive processing)." *United States v. US Stem Cell Clinic, LLC*, 998 F.3d 1302, 1305, 1310 (11th Cir. 2021) ("hold[ing] the same surgical procedure exception unambiguously does not apply"). We agree with the Eleventh Circuit's reasoning and conclusion.

[14] Because no genuine ambiguity remains, we do not need to decide whether the FDA's interpretation is entitled to *Auer* deference.

[15] Defendants shall bear all costs of appeal. *See* Fed. R. App. P. 39(a)(3).

FRIEDLAND, Circuit Judge, concurring in the result of part III.C:

I agree with the majority's conclusion that Defendants' same-day version of the SVF treatment does not fall under the SSP exception, but I would arrive at this conclusion for a different reason. I believe that the SSP exception provision is ambiguous, and that we owe deference to the FDA's interpretation of it.

1.

When the meaning of a regulation is in doubt, "we must 'look to the administrative construction of the regulation.'" *Goffney v. Becerra*, 995 F.3d 737, 744 (9th Cir. 2021) (quoting *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 413-14 (1945)). The practice of deferring to agency interpretations of ambiguous regulations is commonly known as *Auer* deference. *Id.* (citing *Auer v. Robbins*, 519 U.S. 452 (1997)).

An agency is entitled to *Auer* deference only when the regulation in question is "genuinely ambiguous," meaning that it is "susceptible to more than one reasonable reading." *Kisor v. Wilkie*, 588 U.S. 558, 566, 573 (2019). In cabining the scope of *Auer* deference, the Supreme Court has cautioned that we "cannot wave the ambiguity flag just because [we] found the regulation impenetrable on first read." *Id.* at 575. Instead, we must first "exhaust all the traditional tools of construction" by examining the "text, structure, history, and purpose of a regulation." *Id.* (quotation marks omitted). "[O]nly when that legal toolkit is empty and the interpretive question still has no single right answer" can we consider deferring to an agency's reasonable interpretation. *Id.* at 575-76. Before deferring, we must also

confirm that "the interpretation is the agency's authoritative or official position, the interpretation in some way implicates the agency's substantive expertise, and the agency's reading of its rule reflects the agency's fair and considered judgment." *Nat'l Parks Conservation Ass'n v. FERC*, 6 F.4th 1044, 1050-51 (9th Cir. 2021) (citing *Kisor*, 588 U.S. at 574-79).

2.

As to the text of the HCT/P regulations, I agree with the majority's thoughtful analysis, which concludes that the text does not provide a clear answer to the interpretive dispute. My analysis diverges from the majority's only when we turn to the purpose and history of the HCT/P regulations. Although the majority concludes that the regulations' purpose and history support the FDA's interpretation, I believe that evidence cuts both ways, leaving the SSP exception genuinely ambiguous.

The FDA's reading of the SSP exception, focusing on the tissue removed from the body rather than only the targeted cells within that tissue, appears to be consistent with the purpose of the HCT/P regulations. In its 1997 proposal for the current regulatory approach, the FDA stated it was concerned with the "clinical safety and effectiveness . . . [of] tissues that are highly processed" and the risk that processing and/or improper handling could result in contamination or damage to tissue or cell function and integrity. FDA, *Proposed Approach to Regulation of Cellular and Tissue-Based Products* 6, 7 (1997) ("*Proposed Approach*"); *see also id.* at 9 (listing overarching public health concerns). The FDA's concern with contamination and safety, particularly when an HCT/P is processed and manipulated, is consistent with requiring an HCT/P to be in its "original

form" as it was in the body for it to be excepted from regulation. FDA, *Same Surgical Procedure Exception Under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception* 5 (2017).

But other statements by the FDA in the leadup to the promulgation of the HCT/P regulations support Defendants' argument that the SSP exception was always meant to capture targeted cells. For example, the FDA stated that "[a]utologous use of *cells* and tissues harvested and transplanted in a single surgical procedure would be subject to no FDA oversight." *Proposed Approach* at 15 (emphasis added). Defendants point out that the FDA must have known that cells generally cannot be removed from the body in isolation, so some processing would be required.[1]

Additionally, the FDA's *Proposed Approach* indicated that certain amounts of cell and tissue processing could occur without there being a concerning amount of manipulation. Within the context of creating a regulatory framework to prevent "product contamination" and loss of "product integrity and function" in the processing of HCT/Ps, the FDA identified example procedures that it considered "minimal manipulation." *Id.* at tbl. 1; *id.* at 16. These included "extraction or separation of cells from structural tissue, in which the remaining structural tissue's characteristics relating to carrying out reconstruction and/or repair were unaltered," and "selection of stem cells from

[1] Although the FDA was aware that one type of cell—egg cells, or oocytes—can be removed in isolation, it likely was not referring to egg cells in the context of the SSP exception. Egg cells generally would not be removed and then implanted in the same person during a single surgical procedure. In vitro fertilization, for example, cannot be accomplished within a single surgical procedure.

amongst lymphocytes and mature cells of other lineages." *Id.* at 16, 18. Compared to Defendants' same-day SVF procedure, these example procedures seem to present comparable levels of complexity and risk for contamination or damage to product function and integrity. In contrast, the FDA identified procedures such as cell "expansion, encapsulation, activation, or genetic modification," as involving concerning amounts of manipulation. *Id.* at 17-18; *Establishment Registration and Listing for Manufacturer of Human Cellular and Tissue-Based Products*, 63 Fed. Reg. 26744, 26748 (May 14, 1998) (same). Particularly given the district court's factual finding that the targeted cells are not altered by Defendants' same-day SVF procedure, the distinctions in levels of manipulation discussed in the *Proposed Approach* suggest that the procedure does not trigger the FDA's core regulatory concerns, supporting Defendants' interpretation of the SSP exception.

Because the HCT/P regulations' text, structure, purpose, and history do not determine whether we should view the relevant antecedent HCT/P as the targeted cells or the whole system removed from the body, I believe our "legal toolkit is empty and the interpretive question still has no single right answer." *Kisor*, 588 U.S. at 575. I view the SSP exception as genuinely ambiguous because both the FDA's and Defendants' interpretations are reasonable.[2]

[2] I recognize that in a similar case, the Eleventh Circuit agreed with the FDA's interpretation of the SSP exception and concluded that the exception was unambiguous. *See United States v. US Stem Cell Clinic, LLC*, 998 F.3d 1302, 1308-10 (11th Cir. 2021). Although I agree with parts of the Eleventh Circuit's analysis, for the reasons explained I do not agree that the tools of interpretation lock in the FDA's reading as the only reasonable one.

3.

Because I conclude that the SSP is ambiguous, I now discuss the remaining criteria for deferring to an agency's interpretation of a regulation and explain why they lead me to ultimately agree with the majority that the FDA's interpretation prevails.

First, there is no doubt that the FDA's interpretation is the agency's "'authoritative' or 'official position.'" *Id.* at 577 (quoting *United States v. Mead Corp.*, 533 U.S. 218, 257-59, 258 n.6 (2001) (Scalia, J., dissenting)). The Supreme Court in *Kisor* explained that an "authoritative" interpretation is one "actually made by the agency . . . rather than any more ad hoc statement not reflecting the agency's views." *Id.* The FDA's interpretation of the SSP exception comes from an official guidance document, drafted and finalized "consistent with FDA's good guidance practices regulation." *Same Surgical Procedure Exception: Questions and Answers Regarding the Scope of the Exception; Guidance for Industry; Availability*, 82 Fed. Reg. 54289, 54290 (Nov. 17, 2017) (citing 21 C.F.R. § 10.115(a)). That regulation states that such guidance documents "describe the agency's interpretation of or policy on a regulatory issue" and "represent the agency's current thinking." 21 C.F.R. § 10.115(b)(1), (d)(3). The FDA's interpretation of the SSP exception thus "emanate[s] from those actors, using those vehicles, understood to make authoritative policy in the relevant context."[3] *Kisor*, 588 U.S. at 577.

[3] Contrary to Defendants' assertions, an agency interpretation need not establish legally enforceable responsibilities to be sufficiently authoritative for *Auer* deference purposes. *See, e.g.*, *Auer*, 519 U.S. at 462 (deferring to an amicus brief).

The FDA's interpretation also implicates its substantive expertise in protecting public health by assessing and addressing risks. *See, e.g.*, 21 U.S.C. § 393. The HCT/P framework is a "complex and highly technical regulatory program" that reflects such risk assessments. *Kisor*, 588 U.S. at 572 (quoting *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994)). Courts are not in a good position to assess which protocols, procedures, or uses of human cell and tissue products pose health risks warranting regulation. The interpretive issue in this case certainly does not "fall more naturally into a judge's bailiwick." *Id.* at 578.

Finally, the FDA's reading of the SSP exception reflects "fair and considered judgment" and does not present unfair surprise. *Id.* at 579 (quoting *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155 (2012)). The FDA has taken the position that fat-derived SVF does not fall within the SSP exception since at least 2014, when it first issued draft guidance in response to "numerous inquiries regarding HCT/Ps manufactured from [fat] tissues." FDA, *Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) From Adipose Tissue: Regulatory Considerations* 2, 7-8 (2014); *Human Cells, Tissues, and Cellular and Tissue-Based Products From Adipose Tissue: Regulatory Considerations; Draft Guidance for Industry; Availability*, 79 Fed. Reg. 77414 (Dec. 24, 2014) (announcing draft availability). Indeed, Defendants admitted that they were aware that one of their affiliates received a warning letter from the FDA in 2015 stating that their use of fat-derived SVF violated the FDCA. Based on that history, the FDA's current interpretation is not merely a "convenient litigating position." *Kisor*, 588 U.S. at 579 (quoting *Christopher*, 567 U.S. at 155).

* * *

Because I conclude that the SSP exception is ambiguous, the FDA's interpretation is reasonable, and all the remaining criteria for *Auer* deference are satisfied, I would defer to the FDA's interpretation. Under that interpretation, the antecedent HCT/P here is the removed fat tissue, and the SVF implanted is not "such HCT/P." Thus, I agree with the majority that Defendants' treatments do not fall under the SSP exception.