No. 24-

IN THE

Supreme Court of the United States

CALIFORNIA STEM CELL TREATMENT CENTER, INC., ET AL.,
Petitioners,

v.

UNITED STATES,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Petitioners are physicians who perform a surgical procedure through which they remove, isolate, and then reimplant a patient's own stem cells to promote natural healing. Claiming authority under the Food, Drug, and Cosmetic Act (FDCA), the Food and Drug Administration (FDA) filed an enforcement action to prevent Petitioners from undertaking the procedure.

The question presented is whether the stem cells used in Petitioners' surgical procedure are "drugs" subject to regulation under the FDCA and, even if they are "drugs" subject to such regulation, whether the FDA had a lawful basis for its enforcement action given the FDA's own "Same Surgical Procedure" exception to the FDCA.

PARTIES TO THE PROCEEDING

Petitioners California Stem Cell Treatment Center, Inc., Cell Surgical Network Corporation, Dr. Elliot B. Lander, and Dr. Mark Berman were the defendants in the district court and the appellees in the court of appeals. Respondent United States of America was the plaintiff in the district court and the appellant in the court of appeals.

CORPORATE DISCLOSURE STATEMENT

No publicly held corporations are involved in this proceeding.

STATEMENT OF RELATED PROCEEDINGS

This case arises out of the following proceedings:

- *United States v. California Stem Cell Treatment Ctr., Inc.*, No. 22-56014, U.S. Court of Appeals for the Ninth Circuit (opinion issued September 27, 2024).

- *United States v. California Stem Cell Treatment Ctr., Inc.*, No. EDCV 18-100, U.S. District Court for the Central District of California (judgment entered August 30, 2022).

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OPINIONS BELOW

The Ninth Circuit's decision is reported at 117 F.4th 1213. The district court's decision is reported at 624 F. Supp. 3d 1177.

JURISDICTION

The Ninth Circuit denied Petitioners' Petition for Rehearing En Banc on December 20, 2024. On February 14, 2025, Justice Kagan granted Petitioners' application to extend the time to file this petition for a writ of certiorari until May 19, 2025. *See* No. 24A784. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Pertinent statutory and regulatory provisions are reproduced in the appendix to this petition.

INTRODUCTION

This case concerns a federal agency grasping for authority it does not have to take actions it may not take. Petitioners are physicians (along with their associated professional-practice entities) who extract, isolate, and then reimplant their patients' own stem cells in a straightforward, same-day procedure used to promote natural bodily healing. The FDA resolved to shut down Petitioners' surgical procedure, and so filed an enforcement action alleging that, in undertaking the procedure, Petitioners had failed to comply with certain labeling and manufacturing requirements imposed by the FDCA.

After a bench trial, the district court correctly ruled that the FDA lacked authority for its enforcement action—but the Ninth Circuit reversed. It held that

when physicians like Petitioners use a patient's own body parts to treat a disease or medical condition, that body part becomes a "drug" covered by the FDCA's stringent labeling and manufacturing requirements, subject only to the grace of the FDA in excepting certain surgeries from FDCA regulation. The Ninth Circuit's decision comes with all the preconditions for the Court's review: It wrongly interprets the applicable statutes and regulations, it creates a split in the case law, and it affects both the American system of government and the American people in important ways.

The Decision Is Wrong. The Ninth Circuit's conclusion that the FDA has authority to regulate stem cells as "drugs" under the FDCA is wrong. No doubt, the FDA has authority under the FDCA to regulate various "articles" falling within the FDCA's broad definition of "drug." *See United States v. Article of Drug . . . Bacto-Unidisk . . .*, 394 U.S. 784, 798 (1969). But broad authority is not unconstrained authority. And this Court also has made clear that the FDA's authority under the FDCA is necessarily limited by related statutes that address other, more specific subject matter. *See Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 144 (2000). Thus, for example, the FDA may not regulate tobacco products as "drugs" under the FDCA but instead must rely on its authority under the Family Smoking Prevention and Tobacco Control Act. *See Food & Drug Admin. v. Wages & White Lion Invs., L.L.C.*, 145 S. Ct. 898, 907-08 (2025). In short, the FDA cannot resort to the FDCA's capacious definition of "drug" where other statutes more particularly address the applicable subject matter.

That principle controls this case. Congress has separately addressed biological products—like a patient's own stem cells—for decades, not under the FDCA, but under a different statute: the Public Health Safety Act (PHSA). The PHSA specifically addresses FDA regulation of biological products, or "biologics," such as viruses, therapeutic serums, toxins, antitoxins, vaccines, blood, blood components, and derivatives. Indeed, over the decades, Congress has periodically adjusted, updated, and refined the list of biological products subject to FDA regulation under the PHSA. For example, after the Fifth Circuit held in *Blank v. United States*, 400 F.2d 302, 304 (5th Cir. 1968) that human blood did not qualify as a "biological product" because such products "were unknown" at the PHSA's enactment, Congress amended the statute's definition to specifically include blood and blood components. *See* Pub. L. No. 91-515, 84 Stat. 1297, 1308 (Oct. 30, 1970). Or, as another example, Congress amended the PHSA in 2010 to add "protein[s]" to the list of regulated biologics. Pub. L. No. 111-148, 124 Stat. 119, 814 (Mar. 23, 2010). In all of this, however, Congress has never included stem cells within the enumerated set of biological products subject to FDA regulation under the PHSA. The plain implication is that Congress has chosen not to delegate to the FDA the authority to regulate stem cells used in procedures like those undertaken by Petitioners—not under the PHSA, and certainly not under the FDCA. The Ninth Circuit erred in holding otherwise.

In fact, the Ninth Circuit erred twice over. Not only did it misinterpret the FDCA, it also disregarded the FDA's own rule—the Same Surgical Procedure

exception, or SSP exception—exempting from any FDA regulation procedures involving the removal and reimplantation of a patient's Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) during a single surgical procedure. *See* 21 C.F.R. § 1271.15(b). Thus, at minimum, the Court should hold that, in the event the FDA has authority to regulate procedures involving stem cells under the FDCA, it overstepped its own rule by exercising that authority in this context—where a patients' own HCT/Ps are removed and reimplanted in a single surgical procedure.

The Decision Creates A Split. Not only did the Ninth Circuit reach the wrong answer, the way that it reached that answer diverges from other courts. In condoning the FDA's enforcement action, the Ninth Circuit held that it need not reconcile the scope of the FDA's claimed authority under the FDCA with the FDA's differing authority under the PHSA because, in the Ninth Circuit's view, a "product can be both a drug under the FDCA and a biological product under the PHSA." Pet.App.12a n.3. That reasoning only deepens the confusion among the lower courts concerning the scope of, and the relationship between, the FDA's authority (or lack thereof) under Congress's differing statutory delegations.

On the one hand, the Ninth Circuit here and the D.C. Circuit in a similar case involving stem cell-based surgical procedures construed the FDCA to authorize the regulation of stem cells as "drugs" without regard to how that construction may bear on or even obviate the PHSA. *See United States v. Regenerative Scis., LLC*, 741 F.3d 1314, 1319 (D.C. Cir. 2014).

On the other hand, other decisions have taken a more careful approach to delineating the source of the FDA's authority. For example, the D.C. Circuit in a related context rejected the FDA's claimed authority to regulate "devices" as "drugs" under the FDCA. As the court explained, Congress enacted statutory regimes plainly distinguishing between drugs (under one part of the FDCA), devices (under another part of the FDCA), and biological products (under the PHSA), and the FDA thus cannot attempt to regulate in a way that is indifferent to those differing regimes. *See Genus Med. Tech. LLC v. U.S. Food & Drug Admin.*, 994 F.3d 631 (D.C. Cir. 2021). An earlier case from the Second Circuit is aligned. There, the FDA sought to regulate the packaging of iron supplements under its FDCA authority to regulate dietary supplements for "adulteration." The court held the FDCA did not confer that authority. The court emphasized that supplement packaging was already within the ambit of a "detailed regulatory scheme" separately laid out in the Poison Prevention Packaging Act, reinforcing that the more general FDCA provisions did not cover the subject matter. *See Nutritional Health Alliance v. U.S. Food & Drug Admin.*, 318 F.3d 92, 104 (2d Cir. 2003). And other decisions in similar contexts employ similar reasoning. *See, e.g.*, *Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms.*, 124 F.4th 898, 918 (Fed. Cir. 2024) ("Even though the FDCA defines 'drug' broadly as something that treats disease . . . , the statutory context demonstrates that a drug is a narrower class of medical product.").

The Court should take this opportunity to bring clarity to the law. It can do so by confirming that the FDA and the lower courts cannot ignore one statute in

interpreting another and, as particularly relevant here, cannot interpret "drug" under the FDCA so broadly that it would obviate other statutes or portions of statutes more specifically governing the relevant subject matter—whether biological products or anything else.

The Decision Is Important. Last, the Ninth Circuit's decision is important. The decision is important first because of how it affects our system of government. The Ninth Circuit has allowed the FDA to regulate beyond the bounds that Congress has set, and in an area—surgical procedures—traditionally left to state medical boards. The FDA's encroachment into the surgical suite, over and against both Congress and traditional state authority, sets a dangerous precedent for federal agency overreach into other areas of state-regulated professional conduct.

The Ninth Circuit's decision is also important because of how it affects ordinary Americans. The decision threatens to stifle innovation in the burgeoning field of regenerative medicine, which relies on the human body's natural ability to heal itself using its own cells and tissues. By imposing stringent manufacturing and labeling requirements designed for mass-produced pharmaceutical drugs, the FDA's current approach, now approved by the Ninth Circuit, could render many such personalized medical treatments impossible. Ultimately, patients who could benefit from innovative treatments using their own stem cells—treatments that do not have the financial backing of traditional patentable pharmaceutical innovations—may be denied access to these therapies, notwithstanding that they have been

shown to be safe and effective in numerous peer-reviewed studies.

This Court should grant the petition to correct the Ninth Circuit's misinterpretation of the FDCA and the FDA's own SSP exception, and to reaffirm the limits of federal agency power over the practice of medicine. By doing so, the Court can ensure that patients retain access to safe, effective, and innovative treatments like those offered by Petitioners.

STATEMENT OF THE CASE

This case concerns the authority of the Secretary of Health and Human Services, through the FDA, to regulate a patient's own body parts—in particular, the patient's stem cells—as "drugs" under the FDCA, 21 U.S.C. § 301, *et seq*.

Petitioners are board-certified physicians who use a patient's autologous (*i.e.*, the patient's own) stem cells to promote natural bodily healing. In 2018, the FDA filed the underlying enforcement action, seeking a court order permanently enjoining Petitioners from performing surgical procedures involving their patients' stem cells.

Since 1902, Congress has authorized the FDA to regulate a class of naturally derived substances as "biologics" under the PHSA (and preceding statutes), 42 U.S.C. § 201, *et seq*. And although Congress has periodically amended the PHSA to modify the enumerated list of regulated biologics, a patient's own stem cells do not fall within the current list of regulated biologics. Importantly, the FDA failed to preserve any argument to the contrary below.

Unable to rely on any authority from the PHSA, the FDA instead sought to enjoin Petitioners' practice of

their surgical procedure by claiming authority under the FDCA, which subjects "drugs" to strict manufacturing and labeling requirements. According to the FDA, Petitioners failed to comply with FDCA requirements designed for products manufactured and sold on a mass scale—requirements the FDA's former deputy commissioner has recognized "can't be readily satisfied when it comes to treatments that are personalized to individual patients." Scott Gottlieb & Coleen Klasmeier, *The FDA Wants to Regulate Your Cells*, WALL STREET J. (Aug. 7, 2012).

At bottom, this case presents the question whether, in relying on the FDCA (and ignoring its own Same Surgical Procedure exception to FDCA), the FDA has identified a lawful basis for its decision to regulate Petitioners' procedure. The answer is that it has not.

A. Legal Background.

This case chiefly implicates two statutes, the PHSA and the FDCA, along with one set of regulations, the FDA's rules concerning HCT/Ps and the Same Surgical Procedure exception to those rules.

1. Congress Delegates Authority To The FDA To Regulate Biologics Under The PHSA.

The PHSA authorizes the FDA to regulate certain naturally derived substances, termed "biological products" or "biologics." *See* 42 U.S.C. § 262. Biologics are "derived from natural, biological sources such as animals or microorganisms" and "thus differ from traditional drugs, which are typically synthesized from chemicals." *Sandoz Inc. v. Amgen Inc.*, 582 U.S. 1, 6 (2017).

The PHSA is the successor to the first premarket approval statute in history: the Biologics Control Act of 1902. Passed in response to deaths from tetanus contamination of smallpox vaccines and diphtheria antitoxins, the Biologics Control Act required that facilities manufacturing certain biological products be inspected before a federal license may be issued to market them. *See* Food & Drug Admin., *Science and the Regulation of Biological Products* 13 (2002). The scope of the Act, however, was limited to "any virus, therapeutic serum, toxin, antitoxin, or analogous product." 57 Cong. Ch. 1378, July 1, 1902, 32 Stat. 728.

Congress revised and recodified the Biologics Control Act by passing the PHSA in 1944. Like its predecessor, the PHSA prohibited the manufacture and sale of certain "biological products" by unlicensed establishments. Pub. L. No. 78-410 § 351, 58 Stat. 682, 702-03 (1944).

At different points, Congress has modified the definition of "biological products" subject to FDA regulation under the PHSA. *See* Pub. L. No. 91-515, 84 Stat. 1297, 1308 (Oct. 30, 1970) (blood); Pub. L. No. 111-148, 124 Stat. 119, 814 (Mar. 23, 2010) (proteins). As currently constituted, however, the PHSA defines "biological product" to encompass only "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. § 262(i)(1). To sell a covered biological product, an establishment

must obtain a license and "plainly mark[]" each product with its proper name, the manufacturer's information, and the product's expiration date. *Id.* § 262(a)(1).

2. Congress Delegates Authority To The FDA To Regulate Drugs Under The FDCA.

In the wake of a mass poisoning from the use of an antimicrobial drug (a preparation of sulfanilamide using diethylene glycol), Congress enacted the FDCA in 1938. *See* Roseann B. Termini & Anthony Knabb diDonato, *The Role and Mission of the United States Food and Drug Administration*, 7 BIOTECHNOLOGY & PHARM. L. REV. 901, 905-06 (2014). The purpose of the FDCA was to protect public health by ensuring that drugs are safe, effective, and properly labeled. *See Brown & Williamson*, 529 U.S. at 133.

The FDCA defines "drugs" to mean "(A) articles recognized in the official United States Pharmacopœia, official Homœopathic Pharmacopœia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C)." 21 U.S.C. § 321(g)(1).

The FDCA establishes various requirements for drugs, which are implemented by FDA regulations. As relevant here, the FDCA prohibits any person from taking any act with respect to a drug that results in

the drug "being adulterated or misbranded." 21 U.S.C. § 331(k).

A "drug" is "adulterated" if, among other things, the facilities or controls used for its manufacture do not conform to Current Good Manufacturing Practices (cGMP). 21 U.S.C. § 351(a)(1)(B). The FDA's cGMP regulations establish standards for, *inter alia*, drug manufacturing facilities, personnel, and sanitation. *See, e.g.*, 21 C.F.R. § 211.42 (facilities), § 211.22 (quality control unit), § 211.28 (personnel responsibilities), and §§ 211.48 & 211.50 (sanitation).

A "drug" is "mislabeled" unless it includes a label with the drug's established name, quantity, and proportion of active and inactive ingredients. 21 U.S.C. § 352(e)(1)(A). In addition, the drug must be labeled with "adequate directions for use." *Id.* § 352(f). Adequate directions include, among other things, the dosage, frequency, and duration of administration, time of administration in relation to time of meals, and route or method of administration. 21 C.F.R. § 201.5.

3. The FDA Exempts Certain Procedures Involving Human Cells, Tissues, And Cellular And Tissue-Based Products Under The Same Surgical Procedure Exception.

In 1997, the FDA issued a guidance document announcing its intention to regulate certain human cells and tissues, or HCT/Ps. *See* FDA, Proposed Approach to Regulation of Cellular and Tissue-Based Products (Feb. 28, 1997), https://www.fda.gov/media/70704/download. According to the FDA, HCT/Ps are "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).

In 2001, the FDA issued a final rule implementing its proposed approach to the regulation of HCT/Ps. Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing, 66 Fed. Reg. 5447 (Jan. 19, 2001) (codified at 21 C.F.R. Part 1271). Rather than tie the rule to the different subject matter covered by the PHSA, the FDCA, or any other statute, the rule established a tiered, risk-based framework. *Id.* at 5448. Under the rule, certain "minimally manipulated" HCT/Ps are regulated solely under the PHSA. 21 C.F.R. § 1271.10(a). The FDA regulates HCT/Ps that do not meet these criteria as biological products under the PHSA and as drugs or devices under the FDCA. *Id.* § 1271.20.

No matter whether the HCT/P receives more minimal regulation under the PHSA or more stringent regulation under the FDCA, the rule excepts from regulation the removal and implantation of HCT/Ps as part of the same surgical procedure. 21 C.F.R. § 1271.15(b). This Same Surgical Procedure, or SSP, exception provides: "You are not required to comply with the requirements of this part if you are 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." *Id.* The FDA explained that this exception "is intended to exclude from regulation … those establishments that remove and implant autologous HCT/Ps during a single surgical procedure, such as skin grafts and vascular grafts used in artery bypass surgery." 66 Fed. Reg. at 5466. The FDA further explained that

this exception "is based on the low risk of transmission of communicable disease posed by such autologous use." *Id.*

B. Factual Background

In 2010, Drs. Mark Berman and Elliot Lander founded California Stem Cell Treatment Center for the purpose of treating patients with their own healing stem cells. CA9.ER.1377.[1] Dr. Berman, who passed away in 2022, was board certified in head and neck surgery, as well as cosmetic surgery, and a fellow of the American College of Surgeons. *Id.* at 927-928. Dr. Lander, who was President Ford's personal physician for nine years, is a board certified urologist and fellow of the American College of Surgeons. *Id.* at 1257-1258.

Since 2010, Drs. Berman and Lander have safely performed thousands of procedures involving their patients' own stem cells. *Id.* at 1014-1015. The procedure is a "simple surgical technique" performed as a single outpatient procedure. *Id.* at 972; *id.* at 6 ¶ 7. A licensed physician collects a patient's stem cells from adipose (fat) tissue, isolates the stem cells from the surrounding tissue, and relocates the same cells back into the patient's body. *Id.* at 7-8.

A patient's cells are not altered in any way during the procedure, and the procedure "does not create any new material or introduce any foreign body into the body." *Id.* at 8. The procedure neither changes the size, genetic makeup, or biological characteristics of the cells, nor affects their ability to proliferate. *Id.*

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[1] "CA9.ER" refers to the Excerpts of Record filed with the court below and available at CA9 Dkt. No. 14.

Rather, the same cells that naturally occur in the extracted adipose tissue are reimplanted into the "same patient during the same procedure." *Id.* at 6.

The regenerative effects of the surgical procedure have been documented in peer-reviewed literature. For example, Drs. Berman or Lander performed the surgical procedure on approximately 2,580 patients suffering from knee osteoarthritis, a degenerative form of arthritis. *Id.* at 1299. Approximately 82% of the patients avoided surgery with sustained results of greater mobility and less pain, and the study demonstrated both good safety and efficacy. *See id.*

In another peer-reviewed publication, Dr. Lander utilized the surgical procedure on approximately 109 patients with interstitial cystitis, a chronic condition causing unremittent severe pelvic pain that patients describe as "the worst urine infection of their lives." *Id.* at 1270-1271. Medications and other surgeries have been largely ineffective in treating interstitial cystitis. *Id.* at 1270. But with the surgical procedure performed by Drs. Berman or Lander, over 71% of patients reported that their pain had decreased, with no serious adverse events one year later. *See* Elliot B. Lander, et al., Personal Cell Therapy for Interstitial Cystitis with Autologous Stromal Vascular Fraction Stem Cells, THERAPEUTIC ADVANCES IN UROLOGY, at 1, 2, Aug. 17, 2019.

C. Procedural Background

The FDA filed an enforcement action against Petitioners in the Central District of California on May 9, 2018. CA9.ER.67. The FDA alleged that the stem cells Petitioners derive from adipose tissue are "drugs" under the FDCA, and are adulterated in

violation of the FDCA because they are not manufactured in conformity with current good manufacturing practice. *Id.* at 78 ¶ 47. The FDA further alleged that the stem cells are misbranded because the cells and their labeling failed to bear adequate usage directions. *Id.* at 80 ¶ 52. The FDA therefore sought an order permanently enjoining Petitioners from "doing any act" with respect to a patient's cells that results in adulteration or misbranding under the FDCA. *Id.* at 83-84.

Following a seven-day bench trial, where multiple experts testified about Petitioners' surgical procedure, the district court ruled for Petitioners. *Id.* at 3-21. The district court held that the stem cells used in Petitioners' surgical procedure are not a "drug" under the FDCA, and that Petitioners are engaged in the practice of medicine, not the manufacture of pharmaceuticals. *Id.* at 13. The court further held that, in all events, Petitioners' procedure is exempt from FDA regulation under the Same Surgical Procedure exception. *Id.* at 14-15. Specifically, the court held that because Petitioners' procedure involves reinjecting unaltered cells, or "such cells," into the patient during the same surgical procedure, the procedure is within the SSP exception. *Id.* at 15.

The Ninth Circuit reversed. Pet.App.5a. The panel held, first, that "the plain text" of the FDCA defines the term "drug" broadly enough to include a patient's own body parts used in surgery to cure, mitigate, or treat disease. Pet.App.11a. Thus, unless the FDA exercises its "flexibility to tailor" the FDCA's "specific requirements" to a particular surgical procedure, a physician who uses a patient's own body parts to treat disease must comply with the FDCA's adulteration

and misbranding standards. Pet.App.13a. The Ninth Circuit was unmoved by how its unconstrained interpretation of "drug" might interact with the PHSA, explaining that a "product can be both a drug under the FDCA and a biological product under the PHSA." Pet.App.12a n.3.

Two judges of the panel held, second, that the FDA's Same Surgical Procedure exception does not apply if a surgical procedure "involves more than minimal manipulation of" a patient's cells or tissues. Pet.App.25a. In their view, the Same Surgical Procedure only applies to procedures that "involve relatively low risk." Pet.App.28a. These two judges then strayed from the district court's findings by holding without evidence that processing cells "introduces risk." *Id.*

One judge diverged from her colleagues' reasoning, but also held the Same Surgical Procedure exception did not apply under *Kisor* deference. Pet.App.33a. In particular, she found the Same Surgical Procedure exception is genuinely ambiguous, but deferred to the FDA's reading that the Same Surgical Exception does not apply when a physician removes tissues including cells, and then implants cells (but not tissues) back into the patient. Pet.App.35a.

REASONS FOR GRANTING THE PETITION

I. The Ninth Circuit's Holding That Stem Cells Are "Drugs" Under The FDCA Requires Review And Reversal.

The Ninth Circuit has ruled that when a physician uses a patient's own body part to treat disease, that body part is a "drug" subject to FDA authority under the FDCA, and thus subject to the many pre-approval,

manufacturing, and labeling guidelines that come with that statute. The Ninth Circuit's ruling rests on a deeply flawed approach to the interpretation of the FDCA, conflicts with the decisions of other courts and, unless reversed by this Court, will empower to FDA to serve as an über-medical board, capable of regulating disfavored surgical procedures out of existence.

A. The Ninth Circuit's Decision Is Wrong.

The Ninth Circuit concluded that a patient's body parts, when used to treat disease, constitute a "drug" under the "plain text" of the FDCA because they are "'article[s] 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.'" Pet.App.11a (quoting 21 U.S.C. § 321(g)(1)). In reaching that holding, the Ninth Circuit made clear that it was indifferent to how the FDCA relates to the PHSA. As noted, the Ninth Circuit gave short shift to the notion that the FDCA should be interpreted in light of the PHSA's separate regulatory regime for certain biological products, instead holding that a "product can be both a drug under the FDCA and a biological product under the PHSA." Pet.App.12a n.3.

This mechanical and context-avoidant reading cannot be squared with the "overall regulatory scheme." *Brown & Williamson*, 529 U.S. at 160; *Maslenjak v. United States*, 582 U.S. 335, 345, (2017) (explaining that a court must "make sense rather than nonsense out of the *corpus juris*"). As this Court explained in *Brown & Williamson*, when determining whether Congress has specifically addressed the question at issue, a court "should not confine itself to examining a particular statutory provision in

isolation. The meaning—or ambiguity—of certain words or phrases may only become evident when placed in context." 529 U.S. at 132. Similarly, "the meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand." *Id.* at 133. In *Brown & Williamson*, the Court applied that rule to reject the FDA's argument that cigarettes are a "drug" because tobacco is an article intended to affect the structure of any function of the body of man. *See* 529 U.S. at 162 (Breyer, J., dissenting) ("[T]obacco products (including cigarettes) fall within the scope of this statutory definition, read literally[.]").

Indeed, the Court rejected the FDA's "expansive construction of the statute" for two reasons. *Id.* at 160. First, the Court noted that, after adoption of the FDCA, Congress had addressed tobacco and health through other legislation. 529 U.S. at 137. By creating a "distinct regulatory scheme to address the problem of tobacco and health," Congress precluded "any role for the FDA" in regulating tobacco through the FDCA. *Id.* at 144. Second, the Court identified a mismatch between the FDCA's substantive provisions and the FDA's assertion of jurisdiction over tobacco. *Id.*at 133-43. For example, the FDCA deems a drug misbranded if dangerous to health when used in the manner suggested in the labeling, but "there are no directions that could make tobacco products safe for obtaining their intended effects." *Id.* at 135. As the Court explained, it would be incongruous for Congress to have intended to regulate tobacco as a drug when tobacco products cannot satisfy the FDCA's requirements for sale. *Id.* at 136-37.

The Ninth Circuit's expansive construction of "drug" as including a patient's own body parts when used to treat disease suffers from the same two defects.

As for the first defect—ignoring a distinct statutory regime: Both before and after Congress authorized the FDA to regulate "drugs," it enacted more specific legislation to address public health and biologics, *i.e.*, "biological product[s] used in medicine." Biologic, Merriam-Webster's Collegiate Dictionary 123 (11th ed. 2020). But, importantly, Congress has delegated to the FDA authority to regulate only certain biological products, including viruses, vaccines, antitoxins, and blood. 42 U.S.C. § 262(i)(1). While Congress has given the FDA authority to regulate many such biological products, it has declined to give the FDA authority to regulate other biological products used to treat medical conditions, including a patient's own skin, hair, veins, bones—and of course stem cells.[2]

The Ninth Circuit's interpretation of "drug" to cover *any* article used to treat or mitigate disease renders the PHSA all but superfluous—notwithstanding that it was stated in the Senate debate on the FDCA that

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[2] In the PHSA, Congress separately authorized the FDA to make and enforce regulations necessary to "prevent the introduction, transmission, or spread of communicable diseases." 42 U.S.C. § 264(a). For this reason, Petitioners do not dispute the FDA's authority to enact regulations governing *allogeneic* cells and tissues (*i.e.*, body parts derived from a donor), which may raise communicable disease concerns. Surgical procedures involving *autologous* cells and tissues are not subject to this provision of the PHSA because they pose a low risk of communicable disease. 66 Fed. Reg. at 5467.

no new authority was provided for FDA supervision of human biologics. *See* 79 Cong. Rec. 5018 (1935). Even more, the Ninth Circuit's interpretation extends the FDA's jurisdiction beyond the specific biological products identified by Congress. *See Bilski v. Kappos*, 561 U.S. 593, 607–08 (2010) (the canon against interpreting any statutory provision in a manner that would render another provision superfluous "of course, applies to interpreting any two provisions in the U.S. Code, even when Congress enacted the provisions at different times"). The Ninth Circuit's decision, then, all but obviates the PHSA.

In holding otherwise, the Ninth Circuit cited a provision from the PHSA, 42 U.S.C. § 262(j), as well as a provision from the FDCA, 21 U.S.C. § 353(g). *See* Pet.App.12a n.3. Neither provision supports the Ninth Circuit's decision. To the contrary, both provisions underscore the Ninth Circuit's error.

The first provision, from the PHSA, 42 U.S.C. § 262(j), directs that the FDCA "applies to a biological product subject to regulation under this section." That is, the provision makes clear that biologics subject to the PHSA may also be subject to the FDCA. *See generally* H.R. Rep. No. 1364 (Apr. 20, 1944) (explaining that purpose of provision was to confirm "that products subject to this section are not exempted from" certain FDCA requirements). But the Ninth Circuit's decision adopts the inverse rule—that a biologic *not* subject to the PHSA may nonetheless be subject to the FDCA. That is wrong.

The second provision, from the FDCA, 21 U.S.C. § 353(g), addresses certain "combination products," or products that "constitute a combination of a drug, device, or biological product." But a patient's own

stem cells are not the combination of a "drug," a "device," or a "biological product." So the provision does not apply. In any event, the provision shows that Congress has specifically directed the FDA how to regulate products that may implicate more than one statutory definition—and the direction is not to indiscriminately classify products more naturally described as biologics or devices as "drugs" simply because they may "affect the structure or any function" of the human body. 21 U.S.C. § 321(g)(1).

As to the second defect—ignoring a mismatch in substantive provisions and the claimed jurisdiction: There is a fundamental discordance between the FDCA's substantive provisions and the FDA's asserted jurisdiction over a patient's body parts used to treat disease. Under the Ninth Circuit's reading, the FDA can require physicians who use autologous tissues or cells to treat disease to label those tissues and cells with information about the dose, frequency, and route of administration. *See* 21 C.F.R. § 201.5. As a matter of "common sense" (*Brown & Williamson*, 529 U.S. at 133), it strains credulity that Congress intended for surgeons performing hair transplant surgery to halt the proceedings to label the patient's hair follicles before reattachment.

Likewise, if the FDCA's manufacturing guidelines were applied to autologous cells and tissues, surgical operating rooms would require the same quality assurance program as a sterile manufacturing facility. As a result, the physician would be required to test an "adequate number" of her patient's tissues and cells to determine an appropriate expiration date for those body parts. 21 C.F.R. § 211.166(b). Before completing the surgery, the physician would be

obligated to swab the patient's tissue or cells to test for microbial contamination. *Id.* § 211.165(b). And after completing each surgery, the physician must prepare a log that includes the name and strength of the patient's tissue or cells, its active ingredients and weight, and a statement of "theoretical yield," whatever that might mean in this context. *Id.* § 211.186. Given the apparent absurdity of extending the term "drug" to all biologically-derived articles, including a patient's own body parts, the Ninth Circuit erred in holding that Congress delegated such sweeping authority to the FDA "in so cryptic a fashion." *Brown & Williamson*, 529 U.S. at 160.

In sum, then, for the two basic reasons the Court ruled against the FDA in *Brown & Williamson*, it must also rule against the FDA here: The FDA cannot advance such a broad interpretation of "drug" under the FDCA—one that "might include everything from room air conditioners to thermal pajamas." *Id.* at 168 (Breyer J., dissenting). Indeed, to construe the FDCA to constitute such a "vast" delegation of authority would transgress the Constitution. *See Gundy v. United States*, 588 U.S. 128, 151 (2019) (Gorsuch J., dissenting).

B. The Ninth Circuit's Decision Creates A Split.

In reaching its decision that stem cells count as drugs under the FDCA, and that "a product can be both a drug under the FDCA and a biological product under the PHSA," Pet.App.12a n.3, the Ninth Circuit only increased the confusion concerning the relationship between the differing statutes and

provisions under which Congress has delegated the FDA regulatory authority.

Take, for example, the D.C. Circuit's decision in *Genus*. There, the FDA argued that it enjoyed the discretion "to classify as a 'drug' a product that meets the statutory definition of a 'device." 994 F.3d at 632. In particular, the FDA argued that if a medical product satisfies the statutory definitions of both a "drug" and a "device," the FDA has "broad discretion to regulate the product under either regime," notwithstanding the fact that drugs are more heavily regulated than devices. *Id.*

The D.C. Circuit rejected the FDA's argument, holding that because the FDCA's definition of a "device" is drawn more narrowly than its definition of "drug," "the specific must govern the general." *Genus*, 994 F.3d at 638. As the D.C. Circuit explained, the FDCA's structure and purpose confirm that a medical product meeting the definition of "device" cannot also be regulated as a "drug." After all, Congress subjects devices to fewer regulatory hurdles; "[i]t would make little sense, then, for the Congress to have constructed such elaborate regulatory regimes—carefully calibrated to products' relative risk levels—only for the FDA to possess the authority to upend the statutory scheme by reclassifying *any* device as a drug, no matter its relative risk level." *Id.* at 641.

The Ninth Circuit's conclusion that a product "can be both a drug under the FDCA and a biological product under the PHSA" (Pet.App.12a n.3) cannot be squared with the reasoning of *Genus*. As in *Genus*, Congress has adopted a definition to govern naturally derived biological products that is more specific than the FDCA's definition of drug. And as in *Genus*,

Congress has established "two distinct regulatory tracks, one for drugs and one for [biologic products]." 994 F.3d at 641. Biologic products regulated by the PHSA—such as viruses, vaccines, and blood—are approved through a Biologics License Application (42 U.S.C. § 262(a)); chemical drugs are approved through the New Drug Application process (21 U.S.C. § 355(a)).

And the differing decisions do not stop with *Genus*. Just last year, the Federal Circuit rejected the contention that the definition of "drug" in the FCPA can be interpreted divorced from the wider statutory context—explaining that, "[e]ven though the FDCA defines 'drug' broadly as something that treats disease . . . , the statutory context demonstrates that a drug is a narrower class of medical product." *Teva Branded*, 124 F.4th at 918. And earlier, the Second Circuit rejected a similar attempt by the FDA to rely on its broad authority under the FDCA where a more tailored statute instead evinced Congress's delegation decision. Specifically, the court held that the FDA could not regulate the packaging of certain dietary supplements for "adulteration" under the FDCA given that the Poison Prevention Packaging manifested a "detailed regulatory scheme" concerning such packaging questions. *See Nutritional Health Alliance*, 318 F.3d at 104.

The bottom line is that there is a split of authority—and at minimum, a lack of clarity—about how far the FDA can push its expansive authority to regulate "drugs" under the FDCA in the face of other more specific statutes or provisions addressing other more specific subject matter.

C. The Ninth Circuit's Decision Is Important.

The Ninth Circuit's decision is important because of how it upends the traditional federal-state balance when it comes to the regulation of the practice of medicine, and because of how it all but forecloses the ability of ordinary Americans to receive the benefits of regenerative procedure offered by Petitioners.

In *Gregory v. Ashcroft*, 501 U.S. 452, 459-60 (1991), this Court held that to preserve the "proper balance between the States and the Federal Government," courts must "be certain of Congress' intent" before finding that it "legislate[d] in areas traditionally regulated by the States." Thus, when a federal agency "intrudes into an area that is the particular domain of state law," Supreme Court precedent "require[s] Congress to enact exceedingly clear language." *Alabama Ass'n of Realtors v. Dep't of Health & Hum. Servs.,* 594 U.S. 758, 764 (2021) (internal quotation marks and citation omitted).

"Since colonial times, the regulation of professions," including the practice of medicine, "has been seen as a state activity in the United States." Edward P. Richards, *The Police Power & the Regulation of Medical Practice*, 8 ANNALS OF HEALTH L. 201, 202 (1999). Thus, state lawmakers, not the federal government, are "the primary regulators of professional [medical] conduct." *Conant v. Walters*, 309 F.3d 629, 639 (9th Cir. 2002). As this Court explained in *Gonzales v. Oregon*, 546 U.S. 243, 269-70 (2006), "the structure and limitations of federalism" allow the States "great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." Thus,

when Congress "wants to regulate medical practice," it must do so "by explicit language." *Id.* at 272.

As the district court found, Petitioners are engaged in the practice of medicine, not the manufacture of pharmaceuticals. CA9.ER.13. The point of Petitioners' procedure is to transpose a patient's own bodily components, which is the very definition of surgery. *See* Am. Med. Ass'n, Definition of Surgery H-475.983 (2013) ("Surgery . . . is the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or *transposition* of live human tissue.") (emphasis added). The FDA cannot regulate the purported "drug" (the stem cells themselves) without necessarily interfering with the surgical procedure by which Petitioners remove and reimplant those stem cells.

Accordingly, the Ninth Circuit should have required "exceedingly clear language" authorizing the FDA's intrusion into the surgical suite, but did not. *Alabama Ass'n of Realtors,* 594 U.S. at 764. Indeed, the FDA's assertion of jurisdiction comes with none of the "telling clues" establishing that Congress has delegated to an agency authority over an important area of regulation. *W. Virginia v. Env't Prot. Agency*, 597 U.S. 697, 746 (2022) (Gorsuch, J., concurring); *see also id.* at 732 (majority op.) (requiring "clear congressional authorization" for an agency to resolve "major questions").

First, Congress does not "typically use oblique or elliptical language to empower an agency to make a 'radical or fundamental change' to a statutory scheme." *West Virginia*, 597 U.S. at 723. Here, this Court has already concluded that the statutory

provision at issue—the FDCA's definition of "drug"—is a "cryptic" grant of authority. *Brown & Williamson*, 529 U.S. at 160.

Second, "courts may examine the age and focus of the statute the agency invokes in relation to the problem the agency seeks to address." *West Virginia*, 597 U.S. at 747 (Gorsuch, J., concurring). Here, the FDA's attempt to transform an 85-year-old statute focused on tainted, chemically-synthesized products to one governing a surgeon's use of a patient's own cells and tissues is strong evidence that the FDA is overstepping its jurisdictional bounds.

Third, in examining whether a jurisdictional grant provides an agency with clear congressional authorization, "courts may examine the agency's past interpretations of the relevant statute." *West Virginia*, 597 U.S. at 747 (Gorsuch, J., concurring). Here, almost sixty years transpired between the enactment of the FDCA in 1938 and the FDA's 1997 announcement that it had "designed a new regulatory framework for cells and tissues." *See Proposed Approach to Regulation of Cellular and Tissue-Based Products; Availability and Public Meeting*, 62 Fed. Reg. 9721, 9721 (Mar. 4, 1997).

Fourth, critical judicial examination of an agency's assertion of jurisdiction "may be merited when there is a mismatch between an agency's challenged action and its congressionally assigned mission and expertise." *West Virginia*, 597 U.S. at 748 (Gorsuch, J., concurring). Here, the FDA does not have expertise over the risks of surgical procedures; those risks fall squarely within the ambit of state public health authorities' expertise. *See* Richard A. Epstein, *The FDA's Misguided Regulation of Stem-Cell Procedures*,

17 The Manhattan Institute Legal Policy Report 1, 15 (2013).

Not only does the Ninth Circuit's decision wrongly permit the FDA to intrude without congressional permission into an area long left to state regulation, that intrusion will all but end the "earnest and profound debate across the country" concerning regenerative medicine. *See Gonzales*, 546 U.S. at 267. Regenerative medicine—using the human body to naturally heal itself—is a burgeoning field of medical practice, a market estimated at $35.63 billion in 2024. Biospace, *U.S. Regenerative Medicine Market Size to Hit USD 80.74 Bn by 2033* (June 14, 2014). With enforcement actions like the one in this case, the FDA seeks to end the debate at the federal level at a time when States and state medical boards are reaching their own conclusions about whether, and to what extent, to regulate regenerative surgeries. *See, e.g.*, Fed'n of State Medical Boards, *Regenerative and stem cell therapy practices: Report and Recommendations for the Workgroup to Study Regenerative and Stem Cell Therapy Practices* (2018) (developing best practices for state medical boards in regulating treatments received at stem cell clinics in the United States); Cal. Bus. & Prof. Code § 684 (adopting requirements for licensed health care practitioners who perform stem cell therapies).

Early studies have shown the promise of regenerative medicine. Drs. Berman and Lander themselves have been involved in peer-reviewed studies documenting the benefits of regenerative medicine for an array of chronic conditions. *See* CA9.ER.1299 (osteoarthritis); *id.* at 1270-1271 (interstitial cystitis). There is no reason to preclude

Americans from accessing these benefits consistent with the applicable law and licensing regimes of their respective States.

II. At Minimum, The Ninth Circuit's Interpretation Of The Same Surgical Procedure Exception Requires Review And Reversal.

No doubt recognizing that its assertion of broad authority under the FDCA to regulate the use of HCT/Ps threatened to interfere with a range of surgical procedures, the FDA adopted a regulation excepting from regulation under the FDCA any "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). Thus, even if a patient's own stem cells qualify as "drugs" under the FDCA, this Same Surgical Procedure exception exempts procedures like Petitioners' from FDA oversight as matter of the FDA's own regulatory apparatus. The Ninth Circuit, however, disagreed, and held that the SSP exception does not apply to Petitioners' procedure. At minimum, the Court should reverse this aspect of the Ninth Circuit's decision, which empowers the FDA to act as a federal medical board with virtually limitless power to approve or prohibit—on an ad hoc enforcement basis—particular surgical procedures as it sees fit.

The Government does not dispute that Petitioners' procedure satisfies the most important aspects of the SSP exception—that Petitioners remove and implant stem cells into the *same individual* from whom they were removed during the *same procedure*. The dispute turns on the narrow question whether

Petitioners remove HCT/Ps and reimplant "*such* HCT/P's" into the same individual during the same procedure. Petitioners plainly do, a conclusion that follows from a straightforward analysis of the two words at issue: "such" and "HCT/P's."

"HCT/P" is an acronym for "[h]uman cells, tissues, or cellular or tissue-based products." 21 C.F.R. § 1271.3(d). But not any cell or tissue qualifies as an HCT/P. Rather, HCT/Ps are limited to those "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). Adipose tissue is one HCT/P involved in the surgical procedure, because it is an "article[] *containing* … human cells … that are intended for implantation." But the stem cells are themselves another HCT/P because they are "articles … *consisting* of human cells … that are intended for implantation."

The SSP exception applies, therefore, if Petitioners reimplant either "such" adipose tissue or "such" cells contained in the adipose tissue back into the patient. Pet.App.19a. The word "such" is unambiguous. In legal parlance, "such" refers to an antecedent: "[t]hat or those; having just been mentioned." Such, BLACK'S LAW DICTIONARY (11th ed. 2019). Thus, the SSP exception requires only that the HCT/P Petitioners reimplant—*i.e.*, the stem cells—be the same stem cells that were removed from the patient.

As the district court found, the stem cells removed are the same stem cells reimplanted; the cells "are not altered, chemically or biologically, at any point during the … Surgical Procedure." CA9.ER.8 ¶ 17. And the

surgical procedure "does not create any new material or introduce any foreign body into the body." *Id.* at 8.

The Ninth Circuit disagreed because it interpreted the SSP exception not to apply if a surgical procedure involves "significant processing" of cells or tissues because processing "introduces risk." Pet.App.28a. This ruling has no basis in the text of the regulation—indeed, it turns the regulations governing cells and tissues on their head. The FDA has a *different* regulation that subjects certain "manipulated" HCT/Ps to regulation. *See* 21 C.F.R. § 1271.10(a). Critically, however, the SSP exception does not include a manipulation requirement.

Indeed, the panel's interpretation defies the FDA's stated purpose when adopting the SSP exception two decades ago. At the time, the FDA exempted such procedures from oversight because they pose a low risk of communicable disease. 66 Fed. Reg. at 5467. When adopting the HCT/P regulations, the FDA observed that "[i]mproper handling" can alter or destroy the integrity or function of cells and cause them to become contaminated. 1997 Proposed Approach at 15. Even so, the FDA announced that "[a]utologous use of cells and tissues harvested and transplanted in a single surgical procedure" would *not* be subject to FDA handling and processing controls. *Id.* The risks of transmitting communicable disease because of processing warrants FDA oversight only if the cells are not reimplanted in a single surgical procedure. *Id.*; *see also id.* at Table 1, Row B1 (cells removed from and transplanted back into the same person in the same surgical procedure not subject to processing controls).

With the Ninth Circuit's interpretation, the FDA now will be able to bar disfavored surgical procedures by imposing manufacturing and labeling guidelines with which physicians cannot possibly comply, simply by asserting in a given enforcement action that the surgery involves excessive "processing." Given that most modern surgeries require numerous "steps," and therefore involve some amount of "processing," the FDA will now be the arbiter of whether patients can benefit from surgical techniques selected and employed by their physicians.

In light of the importance of the issue, the Court should at minimum grant certiorari to confirm that the SSP exception means what it says, and that the FDA is not entitled to act as a federal medical board with virtually limitless power over particular surgical procedures.

III. This Case Presents An Excellent Vehicle.

This case presents an excellent vehicle to address whether the stem cells used in Petitioners' medical procedure are subject to regulation under the FDCA as "drugs" and, even if they are, whether the FDA had a lawful basis for its enforcement action given its own SSP exception.

To begin, the case went to trial and the record is fully developed. The parties litigated the merits of the FDA's claims and Petitioners' defenses in a seven-day bench trial, where multiple experts testified about the nature and safety of the surgical procedure.

Moreover, the case is simplified by the FDA's forfeiture of any argument that a patient's own stem cells may be regulated as "biological products" under the PHSA. As explained above, Congress generally

has chosen to regulate biologically derived products under the PHSA, not the FDCA. But the FDA cannot invoke the PHSA as an alternative or supplemental source of authority to regulate Petitioners' surgical procedure because it failed to raise and thus the district court did not address any such argument. *See* CA9.ER.12-21. The FDA compounded this forfeiture by failing to provide any reasoned argument on appeal that the stem cells isolated through Petitioners' procedure qualify as "biologic products" under the PHSA. Given this forfeiture, the Court can focus on the scope of the FDCA, and the implications of the Ninth Circuit's erroneous construction of that statute and the FDA's attendant HCT/P regulations and SSP exception. *See Nevada Comm'n on Ethics v. Carrigan*, 564 U.S. 117, 128 (2011).

CONCLUSION

For these reasons, the Petition for a Writ of Certiorari should be granted.

May 2025

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