Case No. 22-56014

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA,

Plaintiff – Appellant,

v.

CALIFORNIA STEM CELL TREATMENT CENTER, INC., *et al.*,

Defendants – Appellees.

On Appeal from the United States District Court, Central District of California
Case No. 5:18-cv-01005-JGB-KK, The Honorable Jesus G. Bernal

BRIEF OF *AMICUS CURIAE* ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS IN SUPPORT OF DEFENDANTS-APPELLEES, AND IN SUPPORT OF AFFIRMANCE

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CORPORATE DISCLOSURE STATEMENT

Amicus Association of American Physicians and Surgeons is a nonprofit Indiana corporation having its principal place of business in Arizona. It is not a wholly owned subsidiary of any corporation. It does not have any stock and thus no corporate or publicly held entity owns more than 10% of its stock.

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IDENTITY, INTEREST AND AUTHORITY TO FILE[1]

Amicus curiae Association of American Physicians and Surgeons ("AAPS") is a non-profit corporation founded in 1943. AAPS defends the practice of private and ethical medicine, and the U.S. Supreme Court has made use of *amicus* briefs submitted by AAPS in high-profile cases. *See, e.g.*, *District of Columbia v. Heller*, 554 U.S. 570, 704 (2008) (Breyer, J., dissenting). The U.S. Court of Appeals for the Third Circuit cited an *amicus* brief by AAPS in the first paragraph of one of its decisions. *See Springer v. Henry*, 435 F.3d 268, 271 (3d Cir. 2006). The Illinois Supreme Court also addressed an AAPS *amicus* brief. *See Valfer v. Evanston Nw. Healthcare*, 2016 IL 119220, ¶ 33, 402 Ill. Dec. 398, 408, 52 N.E.3d 319, 329 (2016) (discussing an *amicus* brief which was filed by AAPS).

AAPS has members who practice medicine within the jurisdiction of this Court, and who are affected by interference with the practice of medicine by the U.S. Food and Drug Administration (FDA). The decision in this case will likely affect how AAPS members continue to practice with respect to reuse of cells from the same patient.

[1] All parties have consented to the filing of this brief by *Amicus* AAPS. Pursuant to FED. R. APP. P. 29(a)(4)(E), undersigned counsel certifies that: no counsel for a party authored this brief in any respect; and no party, party's counsel, person or entity – other than *Amicus*, its members, and its counsel – contributed monetarily to this brief's preparation or submission.

Amicus AAPS thereby has direct and vital interests in the issues presented here.

SUMMARY OF ARGUMENT

It is beyond the authority of the FDA for it to reach into an operating room and interfere with the reuse of a surgical patient's own stem cells. Major questions doctrine, which is increasingly emphasized by the Supreme Court, precludes this vast expansion in power sought by the FDA to encroach on medical operations themselves. This matter is squarely within the jurisdiction of the State of California, rather than a subagency of the federal government acting without a clear congressional delegation of power. Just as the FDA may not properly regulate tobacco as a drug, as held by the Supreme Court decades ago, the FDA cannot properly assert for itself the power to regulate as a drug the use of a patient's own stem cells to be reinserted back into the same patient's own body.

The Medical Board of California and other state regulatory agencies are the entities best able and authorized to regulate reuse of one's own stem cells during an operation, rather than a federal subagency located on the other side of the country. An amicus brief filed in support of the FDA by the International Society for Stem Cell Research and International Society for Cell & Gene Therapy (collectively, "Societies Amicus") argues that FDA oversight – rather than physician care – is necessary to protect safety and effectiveness. (Societies

Amicus Br. 28-31) That view encroaches on the jurisdiction of state medical boards and state autonomy over this intrinsically local issue, and thereby infringes on federalism at the expense of California and other states. The FDA has never properly been part of a surgical team, and the FDA lacks sufficient expertise or congressionally conferred authority to direct a surgeon as he wields a scalpel. The issue here is quintessentially one within the jurisdiction of the Medical Board of California. Nothing in the Societies Amicus Brief indicates that the FDA has sufficient background or knowledge about the kind of surgical procedures at issue here. The FDA's experience and authority concerns the national marketing and distribution of drugs, not surgical practices far removed from any pharmacies and the interstate sale of drugs.

The real issue is not whether these stem cells are in an abstract sense within the meaning of a statutory definition of "drug", but whether these stem cells are within the scope of the statutory authority of the FDA. To decide that, the context of the definition of drug must be analyzed and incorporated. Congress expressly established a sensible limit on the scope of FDA authority to be drugs that are used in the channels of interstate commerce. Extraction from and implantation into the same surgical patient is not interstate commerce. "No person shall introduce or deliver for introduction into ***interstate commerce*** any new drug, unless an approval of an application filed" with the FDA is obtained concerning "such drug." 21

U.S.C. § 355 (emphasis added). Interstate commerce is the lane to which the statutory authority for the FDA is confined by statute, and the stem cell procedures at issue here are outside of that lane.

ARGUMENT

I. Major Questions Doctrine Requires Rejecting the Government's Arguments.

Like the issue of whether the FDA has authority to regulate cigarettes, it is a "major question" as to whether the FDA has authority to interfere with a surgical procedure. Major questions doctrine, which is increasingly emphasized in multiple Supreme Court decisions, traces its roots at least to the decision in 2000 by Justice O'Connor that struck down an attempt by the FDA to regulate tobacco. "Congress must 'speak clearly if it wishes to assign to an agency decisions of vast economic and political significance.'" *BST Holdings, L.L.C. v. OSHA*, 17 F.4th 604, 617 (5th Cir. 2021) (quoting *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014), which cited *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000)). In *Brown & Williamson Tobacco*, the FDA asserted a similarly expansive interpretation of what the statutory term "drug" includes, which the Supreme Court rejected. 529 U.S. at 125-26.

Last year the Supreme Court expressly adopted the "major questions doctrine" that had already been recognized at the Circuit level, and used it to rein

in overreach by another federal agency. "The agency instead must point to clear congressional authorization for the power it claims," Chief Justice Roberts wrote for the court in that seminal decision. *West Virginia v. EPA*, 142 S. Ct. 2587, 2609 (2022) (inner quotation omitted). He rejected objections raised by the dissent on this issue:

> The dissent criticizes us for "announc[ing] the arrival" of this major questions doctrine, and argues that each of the decisions just cited simply followed our "ordinary method" of "normal statutory interpretation" (opinion of Kagan, J.). But in what the dissent calls the "key case" in this area, *Brown & Williamson*, the Court could not have been clearer: "In extraordinary cases . . . there may be reason to hesitate" before accepting a reading of a statute that would, under more "ordinary" circumstances, be upheld. 529 U. S., at 159. Or, as we put it more recently, we "typically greet" assertions of "extravagant statutory power over the national economy" with "skepticism." *Utility Air*, 573 U. S., at 324. The dissent attempts to fit the analysis in these cases within routine statutory interpretation, but the bottom line—a requirement of "clear congressional authorization"—confirms that the approach under the major questions doctrine is distinct.

West Virginia, 142 S. Ct. at 2609 (cleaned up).

That was an energy case, without the additional considerations here of personal autonomy and state jurisdiction which are implicated when the FDA attempts to interfere in surgery. Chief Justice Roberts continued on behalf of the Court in the *West Virginia* case:

> As for the major questions doctrine "label", it took hold because it refers to an identifiable body of law that has developed over a series of significant cases all addressing a particular and recurring problem: agencies asserting highly consequential power beyond what Congress could reasonably be

> understood to have granted. Scholars and jurists have recognized the common threads between those decisions. So have we. See *Utility Air*, 573 U. S., at 324 (citing *Brown & Williamson* and *MCI*); *King* v. *Burwell*, 576 U. S. 473, 486 (2015) (citing *Utility Air*, *Brown & Williamson*, and *Gonzales v. Oregon*, 546 U.S. 243 (2006)).

West Virginia, 142 S. Ct. at 2609 (cleaned up).

The rationale expressed by the Supreme Court for the major questions doctrine is "both separation of powers principles and a practical understanding of legislative intent." *Id.* The principle of separation of powers that undergirds major questions doctrine should fully protect state jurisdiction and personal autonomy here. *See, e.g.*, *City & Cty. of S.F. v. Trump*, 897 F.3d 1225, 1235 n.5 (9th Cir. 2018) (enjoining an Executive Order based on separation of powers, while noting the connection with federalism). As summed up by Justice Gorsuch in his concurrence, joined by Justice Alito, in the landmark *West Virginia v. EPA* decision last year:

> To resolve today's case the Court invokes the major questions doctrine. Under that doctrine's terms, administrative agencies must be able to point to clear congressional authorization ***when they claim the power to make decisions of vast economic and political significance***.

West Virginia v. EPA, 142 S. Ct. at 2616 (inner quotations omitted, emphasis added). Interference by the FDA in surgical operations is likewise an issue of "vast economic and political significance," as it implicates the ability of many thousands of Americans to obtain surgery using their own biological cells.

More recently, the Supreme Court again invoked major questions doctrine to decide a high-profile case, while citing an additional recent precedent for this overarching doctrine. *See Biden v. Nebraska*, 143 S. Ct. 2355, 2023 U.S. LEXIS 2793, *44 (2023) (citing as authority for this doctrine the eviction moratorium decision of *Ala. Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 210 L. Ed. 2d 856 (slip op., at 6)). Major questions doctrine "emphasize[s] the importance of context when a court interprets a delegation to an administrative agency. Seen in this light, the major questions doctrine is a tool for discerning—not departing from—the text's most natural interpretation." *Biden v. Nebraska*, 2023 U.S. LEXIS 2793, at *44 (Barrett, J., concurring).

This Ninth Circuit, too, has embraced major questions doctrine with the narrow exception of presidential actions themselves, which are not at issue here. *See Mayes v. Biden*, 67 F.4th 921, 934 (9th Cir. 2023) (recognizing the major questions doctrine, but holding that "the Doctrine does not apply to Presidential actions"). The actions by the FDA at issue here are far removed from any action taken by the president himself. Indeed, the FDA is merely a subagency within the Department of Health and Human Services. *See, e.g.*, Lewis A. Grossman, "Life, Liberty, [and the Pursuit of Happiness]: Medical Marijuana Regulation in Historical Context," 74 Food Drug L.J. 280, 295 (2019) (Law Professor Grossman describing the FDA as "a subagency of HHS"). If major questions doctrine

applies to any entity, it surely applies to this subagency as it attempts to interfere with surgery performed on the other side of the country for patients, after their informed consent and as fully allowed by California itself.

Congress has rejected, in its authorization of the FDA, "any intent to directly regulate the practice of medicine." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 351 n.5 (2001). If Congress wants the FDA to be alongside surgeons in every operating room whenever there is reuse of a patient's own stem cells, then this is a major question that Congress could delegate to the FDA only by clearer terms than it has.

II. The Medical Board of California Has the Proper Jurisdiction over This Surgery, Which Is Authority that the FDA Should Not Usurp.

A federal subagency should not be usurping the authority of the Medical Board of California over surgery done entirely within California, by physicians licensed by this medical board, on consenting adult patients who have not objected or complained. The FDA remains free to use its formidable influence to urge a state medical board to prohibit this type of surgery, but the FDA cannot properly take this authority away from the state medical board. Yet that is essentially the position of the government here, and implicitly that of its supporting Societies Amicus Brief.

As unmentioned by the Societies Amicus Brief, the Medical Board of California is in a far better position to evaluate safety and effectiveness of the surgery at issue there. Unlike the FDA, the medical board can obtain and review medical records about the surgery; interview patients and review their outcomes; hold hearings with the physicians who are doing these surgeries; obtain expert opinions by other California physicians; and institute an administrative proceeding in order to elicit all relevant testimony and culminate with a reasoned opinion by an administrative law judge. Yet the Societies Amicus Brief seems to assume that sole protector of safety and effectiveness here can only be the FDA employees, many lacking in a medical degree. The Societies Amicus Brief implies that if the FDA is not granted full authority to interfere with these procedures then many patients could be harmed. These procedures "jeopardize the safety of patients, which is why FDA regulation is required," the Societies Amicus Brief insists. (Societies Amicus Br. 3)

Really? The Medical Board of California has been endangering patients by allowing these procedures for many years? The Medical Board of California has vastly greater experience and access to patients and medical expert opinions than does the FDA, a subagency located more than 2,500 miles away in Maryland along the D.C. Beltway. Moreover, the California legislature and the People of California have not hesitated to exercise their authority to allow or prohibit stem

cell treatments as they deem appropriate, after benefiting from legislative hearings and public debate on the topic.[2] The Medical Board of California is the better entity for overseeing this surgery, yet neither the Society Amicus Brief nor the government even acknowledges this. While presumably Congress could preempt this field with federal legislation, it has wisely chosen not to.

A recent decision by the U.S. Supreme Court illustrated its preference to defer to state decision-making, rather than override that at the federal level. In affirming this Ninth Circuit, the Court upheld California Proposition 12 to ban the sale of any pork in California unless, *inter alia*, the pig was born to a sow that could freely roam with two-dozen square feet of space. "A substantial harm to interstate commerce remains nothing more than a speculative possibility," concluded Supreme Court Justices in upholding this law. *Nat'l Pork Producers Council v. Ross*, 143 S. Ct. 1142, 1163 (2023) (plurality decision by Gorsuch, J., joined as to this statement by Justices Thomas and Barrett) Any pork produced in other states which fails to satisfy this animal rights criterion triggers a criminal violation punishable by a $1,000 fine and a 180-day prison sentence.

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[2] For example, the People of California created California's Stem Cell Agency in 2004, when 59% of the voters supported Proposition 71 (California Stem Cell Research and Cures Initiative). This ballot initiative established "a 29-member governing Board composed of researchers, business leaders and patient advocates."
https://www.cirm.ca.gov/about-cirm/history/ (viewed July 27, 2023).

California reportedly imports 99.8% of its pork,[3] but the Court nevertheless deferred to California to regulate the sale of products imported from other states. Surely if California has authority to regulate the spacing of pigs on farms in Iowa then California is capable of regulating surgical procedures performed within its own borders. In the absence of a specific congressional preemption on this issue, and there is none, the authority over these surgical procedures properly belongs with the State of California rather than the FDA.

III. The FDA's Relevant Authority Is Limited to Interstate Commerce Concerning the Adulteration or Misbranding of Drugs, None of Which Is Implicated or Even Argued by the Government.

The proper authority of the FDA concerning the adulteration or misbranding of drugs is limited by the statutory scheme to interstate commerce, which is far removed from the facts of this case. Indeed, the government waived any objection to the factual finding below that there was no adulteration relating to one type of procedure by defendants.

The government overly relies on decisions from other Circuits that did not address the issues salient to this appeal. In addition, as discussed below, the other decisions are not persuasive here.

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[3] Ariane de Vogue and Tierney Sneed, "Supreme Court upholds California's anti-animal cruelty law for pork," *CNN* (May 11, 2023). https://www.cnn.com/2023/05/11/politics/supreme-court-pork-california-regulations/index.html (viewed Aug. 1, 2023).

A. The Context of the FDA's Authority Is Limited to the Adulteration or Misbranding of Drugs in Interstate Commerce, Which Is Not Argued by the Government Here.

The FDA's relevant authority has long been limited to activities in the channel of interstate commerce, and specifically to prohibit the adulteration or misbranding of such drugs. For example, the list of actions prohibited by the FDA contains dozens of express limitations on conduct, particularly adulteration and misbranding, within the channels of interstate commerce. *See* 21 U.S.C. § 331. The limitation of FDA authority to this lane of interstate commerce is prominently featured in the first four statutory bans on activities, and elsewhere throughout this section:

> (a) The introduction or delivery for ***introduction into interstate commerce*** of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.
>
> (b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in ***interstate commerce***.
>
> (c) The receipt in ***interstate commerce*** of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.
>
> (d) The introduction or delivery for introduction into ***interstate commerce*** of any article in violation of section 404, 415, 505, or 564.

21 U.S.C. § 331 (emphasis added).

Yet the government's appellate brief does not argue that there was any improper adulteration or misbranding by defendants, or that anything was shipped

in interstate commerce. Nowhere in that statute granting authority to the FDA does it include surgical procedures, stem cells, or autologous use of tissue. It is baffling that the FDA would demand an over-extension of its authority so far beyond what Congress in great detail enumerated as the parameters of the FDA's reach. "A new drug may not ***be introduced into interstate commerce*** without the approval of the FDA." *United States v. Cole*, 84 F. Supp. 3d 1159, 1165 (D. Or. 2015) (citing 21 U.S.C. §§ 331(d), 355(a), emphasis added). FDA statutory authority begins and ends with drugs that are "introduced into interstate commerce," unlike the stem cells at issue here.

The government quotes Section 331 and cites it a second time (Govt Br. 3, 23), while omitting the essential point here: an operating room patient's stem cells are not FDA-regulated drugs because they are never introduced into interstate commerce. The government even emphasizes, "as directly relevant here," the provision in Section 331 that the "FDCA [Federal Food, Drug, and Cosmetic Act] prohibits any person from taking any act with respect to a drug 'while such article is held for sale ... after shipment ***in interstate commerce'*** that results in the drug 'being adulterated or misbranded.'" (Govt. Br. 3, quoting Section § 331(k), emphasis added). But the only time that the government mentions adulteration or misbranding in its brief is when it quotes the statute. The government fails to contest, and thus waives, the factual finding by the district court that defendants

"do not adulterate, manufacture, process or store the patient's adipose tissue during the Expanded MSC Surgical Procedure." *United States v. Cal. Stem Cell Treatment Ctr.*, 624 F. Supp. 3d 1177, 1183 (C.D. Cal. 2022). "Our circuit has repeatedly admonished that we cannot 'manufacture arguments for an appellant' and therefore we will not consider any claims that were not actually argued in appellant's opening brief." *Indep. Towers of Wash. v. Washington*, 350 F.3d 925, 929 (9th Cir. 2003) (quoting *Greenwood v. Fed. Aviation Admin.*, 28 F.3d 971, 977 (9th Cir. 1994)).

Context matters enormously when correctly interpretating a statutory scheme, which in this case requires construing the scope of FDA authority as delegated by Congress. As the Ninth Circuit has repeatedly emphasized:

> In construing the provisions of a statute, "we begin with well-settled canons of statutory interpretation." *Zazzali v. United States* (*In re DBSI, Inc.*), 869 F.3d 1004, 1010 (9th Cir. 2017). "A primary canon of statutory interpretation is that the plain language of a statute should be enforced according to its terms, ***in light of its context***." *ASARCO, LLC v. Celanese Chem. Co.*, 792 F.3d 1203, 1210 (9th Cir. 2015).

Wadler v. Bio-Rad Labs., Inc., 916 F.3d 1176, 1186 (9th Cir. 2019) (emphasis added). *See also Brown & Williamson Tobacco,* 529 U.S. at 126 ("Such authority [asserted by the FDA] is inconsistent with the intent that Congress has expressed in the ***FDCA's overall regulatory scheme*** ...") (emphasis added); *Woelke & Romero Framing v. NLRB*, 456 U.S. 645, 653-54 (1982) (rejecting a literal reading of a

statute because it "must be interpreted in light of the statutory setting and the circumstances surrounding its enactment," which are essential to proper statutory interpretation) (quoting *Connell Constr. Co. v. Plumbers & Steamfitters Local Union No. 100*, 421 U.S. 616, 628 (1975)).

"It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme. A court must therefore interpret the statute as a symmetrical and coherent regulatory scheme." *Brown & Williamson Tobacco*, 529 U.S. at 133 (inner quotations and citations omitted). "It is a 'familiar rule, that a thing may be within the letter of the statute and yet not within the statute, because not within its spirit, nor within the intention of its makers.'" *National Woodwork Mfrs. Assn. v. NLRB*, 386 U.S. 612, 619 (1967) (quoting *Holy Trinity Church v. United States*, 143 U.S. 457, 459 (1892)).

Here the "regulatory scheme" limits FDA authority to what is introduced into interstate commerce, and it is not justified to lift the statutory definition of "drug" entirely out of the statutory framework in which it sits. It is hardly logical for the government to pluck a definition out of one statutory provision and then pretend that the scope of subagency authority extends as far as the definition can be enlarged, without the contextual limits imposed repeatedly throughout the remainder of the statute. Under this approach by the FDA, nearly everything under

the sun would be subject to prohibition by the FDA, even though never possibly used in the channels of interstate commerce. Grandma's homegrown, homemade chicken soup for a sick grandchild – or anything analogous – would become a "drug" subject to prohibition by the FDA under its expansive interpretation. That cannot be correct.

This is not a philosophical question about how far Congress can expand federal regulation under the Commerce Clause, if it chooses. Rather, the issue here is how far Congress did go in delegating power to the FDA, and the answer is not as far as a surgery patient's own stem cells. Instead, Congress expressly limited FDA authority to the channels of interstate commerce, including what may enter into those channels. Congress established and circumscribed FDA authority in a way not to intrude on state authority over this quintessentially local issue of how a patient's own cells are used during surgery.

Precedents confirm that FDA authority is limited to interstate commerce. In ruling for a defendant-claimant as to eggs demanded by the FDA for its seizure, a federal court held:

> [T]he eggs in Actions Nos. 852 and 853 have never been outside the State of Wisconsin. They have never been offered to a common carrier for shipment, and in fact never left the property of the claimant. … No shipping instructions were ever given and no bill of lading was ever issued. Additional marking and labeling remained to be added. It is my opinion that the eggs in Actions Nos. 852 and 853 had not been introduced into and were not in interstate commerce.

United States v. 184 Barrels Dried Whole Eggs, 53 F. Supp. 652, 653 (E.D. Wis. 1943). *See also United States v. Vepuri*, No. 22-1562, 2023 U.S. App. LEXIS 18429, at *2, *16-17 (3d Cir. July 20, 2023) (dismissing under 21 U.S.C. § 355(e) a portion of an indictment based on the court's analysis of what "was introduced into interstate commerce").

B. The Other Circuit Decisions Heavily Relied on by the Government Are Unpersuasive on This Appeal.

The government relies on a nearly decade-old decision in the D.C. Circuit, which in turn depended on two Supreme Court decisions extending federal authority under the Commerce Clause to regulate home-grown marijuana intended solely for local personal use, and a farmer's wheat grown solely for consumption on his own farm. *United States v. Regenerative Sciences, LLC*, 741 F.3d 1314, 1320 (2014) (citing *Gonzales v. Raich*, 545 U.S. 1, 32-33 (2005), and *Wickard v. Filburn*, 317 U.S. 111, 128-29 (1942)). The issue here is not about the Commerce Clause, but whether the FDA was actually granted authority to prohibit a surgical activity rather than a shipment in interstate commerce, based on a statute that limits to channels of interstate commerce the delegation of authority to the subagency. Home-grown marijuana can reportedly have a personal medical use, but the FDA's authority under Section 331 could not plausibly be extended so far as to authorize the FDA to ban local use of marijuana in California. To the extent *Regenerative*

Sciences is read to allow so much federal interference, then this D.C. Circuit decision is not controlling or good law here.

Writing for the D.C. Circuit, Judge Thomas B. Griffith further held that if any ingredient of a mixture was shipped in interstate commerce, then the interstate commerce requirement of Section 331(k) is fully satisfied. *See Regenerative Sciences*, 741 F.3d at 1320-21. But there the Court identified a key ingredient shipped in interstate commerce. This Court should reject the notion that the use of any ingredient from interstate commerce, no matter how immaterial or easily replaceable by in-state material, should trigger FDA authority to ban a surgical procedure. At a minimum, if FDA authority is upheld on this tenuous basis then a surgeon should be given an opportunity to use only in-state materials rather than be subjected to a complete ban of a procedure by the FDA under this rationale. Here, at issue is a medical procedure that incidentally uses materials to improve the treatment, in sharp contrast with the manufacturing for resale of dangerous heroin using ingredients shipped from other states. *See Baker v. United States*, 932 F.2d 813, 814 (9th Cir. 1991). As explained in Point II above, the Medical Board of California has full authority over surgical procedures, in contrast with the production and sale of heroin in the *Baker* case.

The government also relies heavily on an Eleventh Circuit decision concerning stem cells, but that decision emphasized the following:

> There was a time when a court faced with a regulation that seemed "impenetrable on first read" might simply "wave the ambiguity flag" and defer to the agency's interpretation. No longer.

United States v. US Stem Cell Clinic, Ltd. Liab. Co., 998 F.3d 1302, 1308 (11th Cir. 2021) (quoting *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019)). There is no deference to the government in its expansive interpretation of its own authority under a congressional statute. Rather, this is an issue for this Court to decide without deferring to a subagency. The Eleventh Circuit decision never addressed the infringement on federalism and patient autonomy that the FDA's strained interpretation of the federal statutes entails. Major questions doctrine, federalism, and the context of the statute upon which the FDA claims authority to regulate this surgical procedure were not at issue or were overlooked in the *US Stem Cell Clinic* decision. If taken to its logical conclusion, the Eleventh Circuit decision would enable the FDA to commandeer many aspects of an operating room contrary to the express federal prohibition on the FDA interfering with the practice of medicine. *See, e.g.*, 21 U.S.C. § 396 ("Nothing in this Act [FDCA] shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.").

The Eleventh Circuit found on different facts and arguments there that the FDA has authority over stem cell material based on considering it be a drug, but

the court's reasoning did not consider the context in which the authorizing statute must be properly interpreted: drugs distributed in the channel of interstate commerce. A patient's own stem cells for reimplantation in himself or herself is about as far removed from distribution of a product in the channel of interstate commerce as can be imagined. The Eleventh Circuit decision cannot be controlling here in light of how it did not address that essential context. Moreover, the Eleventh Circuit erred in disqualifying the stem cells from the two recognized exceptions by failing to recognize that the stem cells, at least in this case at bar, are not materially adulterated and altered as reinserted, and indeed the government does not argue on appeal here that they were. *See US Stem Cell Clinic*, 998 F.3d at 1304 (11th Cir. 2021) (discussing and rejecting two exceptions to the FDA regulation of stem cells, but without addressing adulteration or any material change in the material when reused).

This Court "'may affirm on any grounds supported by the record.'" *Corales v. Bennett*, 567 F.3d 554, 562 (9th Cir. 2009) (quoting *Olsen v. Idaho State Bd. of Med.*, 363 F.3d 916, 922 (9th Cir. 2004), which cited *Simo v. Union of Needletrades*, 322 F.3d 602, 610 (9th Cir. 2003)). Congress did not extend FDA authority to surgical reuse of the patients' own stem cells in light of the statutory limitation of FDA authority to drugs in the channel of interstate commerce. The statutory framework and its repeated focus on goods introduced into interstate

commerce demonstrate that Congress did not authorize the FDA to reach so intrusively into an operating room as to block reuse of a patient's own cells during a procedure. "The federal government regulates the manufacture, labeling, and sale of pharmaceuticals pursuant to the" FDCA, not far more than that as demanded by the government here. *Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 707 (2d Cir. 2019).

CONCLUSION

For the foregoing reasons and those cited in the Appellees' brief, the decision below should be fully affirmed.

Respectfully submitted,

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Dated: August 2, 2023

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CERTIFICATE OF COMPLIANCE

1. This brief has been prepared using Times New Roman 14-point, proportionately spaced, serif typeface, in Microsoft Word.

2. This brief complies with FED. R. APP. P. 29(a)(5) and 32(a)(7)(B) because it contains a total of 5,040 words, excluding material not counted under Rule 32(f).

Dated: August 2, 2023

/s/ Andrew L. Schlafly
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