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., a California corporation; CELL SURGICAL NETWORK CORPORATION, a California corporation; ELLIOT B. LANDER, M.D., individual; MARK BERMAN, M.D., individual,

Defendants-Appellees.

On Appeal from the United States District Court
for the Central District of California

OPPOSITION TO MOTION TO STAY THE MANDATE

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INTRODUCTION AND SUMMARY

Defendants provide no sound basis for staying the Court's mandate pending a petition for certiorari. Certiorari is not warranted and is unlikely to be granted. This Court's two narrow holdings accord with the decisions of the other courts of appeals to have addressed the questions presented and do not conflict with any decision of the Supreme Court. This case would be a poor vehicle to address several of the issues that defendants wish to raise in the Supreme Court. The interlocutory nature of this case also makes this a particularly poor candidate for certiorari. And for the reasons laid out in this Court's decision, defendants have not met their burden to establish a reasonable probability that if the Supreme Court granted certiorari, it would then reverse.

Defendants have also not established that the equities warrant a stay. Issuance of the mandate in this interlocutory posture would merely transfer the case back to the district court to conduct further proceedings. To the extent defendants believe that a particular course of proceedings is warranted, they are free to coordinate with the government and propose a plan. They may also present an argument to the district court, which can determine for itself the degree to which further proceedings are warranted in parallel with the resolution of any petition for certiorari. The burden of any further proceedings in district court does not constitute irreparable injury. And a stay by this Court would prolong the period that defendants may continue to manufacture and administer adulterated and misbranded cellular-based drugs without

Food and Drug Administration (FDA) review for safety and efficacy—without regard to the district court's judgment of how to conduct its own proceedings.

BACKGROUND

1. As the Court is aware, this case involves the application of the Federal Food, Drug, and Cosmetic Act (FDCA) to human cells, tissues, or cellular or tissue-based products that are intended for use in the treatment of diseases. These products are known as "HCT/P's," a term defined by FDA regulation to refer to "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient," including bone, ligament, skin, heart valves, reproductive tissue, and various cells. 21 C.F.R. § 1271.3(d). FDA regulates, among other things, "biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies." FDA, *About CBER*, https://perma.cc/Y4CT-2Y7U; *see* 4-ER-486-487. These include both "products that are made with [a] patient's own cells or tissues" and "products that are made with donors['] typically or someone else's cells or tissues." 4-ER-487; *see*, *e.g.*, Op. 13 n.4 (noting FDA's approval of "other autologous (*i.e.*, same-patient) stem cell treatments").

FDA has long recognized that different HCT/P's may pose different levels of risk to health and safety. *See* Op. 10. Directly relevant here, FDA has excepted from regulation 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). Consistent with its longstanding approach to the exception, FDA's

guidance states that this exception applies when "cells or tissues . . . are removed from an individual and implanted into the same individual without intervening processing steps beyond rinsing, cleansing, sizing, or shaping," such as "autologous skin grafting" and "coronary artery bypass surgery involving autologous vein or artery grafting." FDA, *Same Surgical Procedure Exception Under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception* 3, 5, 7 (Nov. 2017), https://perma.cc/MC76-C2SB; *see* Op. 32 (Friedland, J., concurring in the result of Part III.C).

2. This case concerns FDA regulation of "certain stem cell mixtures advertised as treatments for a host of medical conditions." Op. 5. Defendants operate two clinics and a network of affiliated businesses that market these treatments to "[p]atients who are looking for non-surgical alternatives to their degenerative disorders." Op. 6 (alteration in original). "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." *Id.*

In 2017, FDA inspected defendants' clinics and concluded that the clinics were manufacturing and administering unapproved drug products. Op. 8. "They found violations of the FDA's manufacturing requirements and a lack of proper documentation of adverse health events related to the clinics' [stromal vascular fraction

(SVF)] treatments." *Id.* FDA filed this lawsuit alleging that defendants are violating the FDCA and seeking an injunction. *Id.*

Following a bench trial, the district court entered judgment for defendants. Op. 8. The court held that defendants' SVF products are not "drug[s]." *Id.* The court did not hold that SVF or the SVF products fail to satisfy any aspect of the FDCA's definition of a "drug." But the court declared that "Defendants are engaged in the practice of medicine, not the manufacture of pharmaceuticals." *Id.* Although that conclusion sufficed to enter judgment for defendants, the district court also held that the same-day treatment falls into FDA's "exception to regulation for certain surgical procedures." Op. 8. That holding was "based" on the court's qualified "factual finding[s]" about defendants' chemical and physical processes and how they affect human cells. *Id.*

3. This Court reversed those two holdings and remanded to the district court for further proceedings. Op. 27. The unanimous panel held that defendants' SVF products fit within the statutory definition of a "drug," which refers to "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." Op. 11 (quoting *United States v. Article of Drug, Bacto-Unidisk*, 394 U.S. 784, 789 (1969) (quoting 21 U.S.C. § 321(g)(1))). The Court explained that its decision was in accord with a decision of the D.C. Circuit on the same issue. Op. 11-12 (citing *United States v. Regenerative Scis., LLC*, 741 F.3d 1314, 1319 (D.C. Cir. 2014)). And the Court rejected defendants' arguments

that the statutory definition "should not be read literally" because it would lead to "'absurd' results," Op. 12, "intrude upon the practice of medicine," Op. 13-14, or run afoul of the major questions doctrine, Op. 14-17. This Court cited Supreme Court decisions making clear that "'Congress fully intended that the Act's coverage be as broad as its literal language indicates'" and that the statute should not be "'judicially narrowed . . . by envisioning extreme possible applications,'" which can instead be addressed by FDA's "flexibility to tailor its specific requirements." Op. 12-13 (first quoting *Bacto-Unidisk*, 394 U.S. at 798, and then quoting *United States v. Sullivan*, 332 U.S. 689, 694 (1948)). This Court stressed the critical distinction between FDA's regulation of a product, such as a "stem cell *mixture*," and the regulation of "the practice of medicine." Op. 13-14 (quotation marks omitted). The Court also emphasized that the major-questions doctrine does not apply because, among other things, regulation of novel cellular treatments "does not present a matter of extreme 'economic and political significance.'" Op. 15 (quoting *West Virginia v. EPA*, 597 U.S. 697, 721 (2022)).

The unanimous panel also agreed with FDA that defendants are not covered by the regulatory exception relied on by the district court. Judge Sung, writing for herself and Judge Wardlaw, held that while FDA's and defendants' interpretation of the governing regulation are both textually plausible, FDA's reading is "more straightforward and consistent with the [regulation's] plain text," Op. 22, and is "the only interpretation that makes sense" given the context, structure, history, and purpose of the regulatory scheme, Op. 27; *see* Op. 17-27. They thus "agree[d] with the Eleventh

Circuit's reasoning and conclusion" in "an exceedingly similar case." Op. 27 n.13 (citing *United States v. US Stem Cell Clinic, LLC*, 998 F.3d 1302, 1305, 1310 (11th Cir. 2021)). Judge Friedland "agree[d] with the majority's conclusion" but arrived there based on "different reason[ing]." Op. 28 (Friedland, J., concurring in the result of Part III.C). She concluded that the regulation is ambiguous but deferred to FDA under *Kisor v. Wilkie*, 588 U.S. 558 (2019). Op. 28-34. Judge Friedland explained that "FDA's interpretation is the agency's 'authoritative' or 'official position,'" it implicates FDA's "substantive expertise" in a "'complex and highly technical regulatory program,'" and it "reflects 'fair and considered judgment' and does not present unfair surprise." Op. 32-33 (some quotation marks omitted) (quoting *Kisor*, 588 U.S. at 572, 577, 579).

4. Defendants filed a petition for rehearing en banc. On December 20, 2024, the Court denied that petition. The Court's order explained that "no judge ha[d] requested a vote on whether to rehear the matter en banc." Order (Dec. 20, 2024).

ARGUMENT

To obtain a stay of the mandate pending a petition for a writ of certiorari, a movant "must show that the petition would present a substantial question and that there is good cause for a stay." Fed. R. App. P. 41(d)(1). A movant must establish a reasonable probability that four Justices of the Supreme Court will vote to grant certiorari; a fair prospect that a majority of the Supreme Court will vote to reverse; and a likelihood that irreparable harm will result absent a stay. *Conkright v. Frommert*, 556 U.S. 1401, 1402 (2009) (Ginsburg, J., in chambers). In "a close case," a court may also

"balance the equities" and weigh "the relative harms" to the parties, "as well as the interests of the public at large." *Id.*.* Defendants have not made any of these required showings.

A. Defendants have not established a reasonable likelihood that the Supreme Court will grant their petition for a writ of certiorari or a fair prospect that if the Supreme Court did so, it would reverse this Court's decision. For one thing, this case is interlocutory, which is often reason enough to decline plenary review. *See, e.g.*, *National Football League v. Ninth Inning, Inc.*, 141 S. Ct. 56, 57 (2020) (Kavanaugh, J., respecting the denial of certiorari); *Abbott v. Veasey*, 580 U.S. 1104, 1005 (2017) (Roberts, C.J., respecting the denial of certiorari); *Mount Soledad Mem'l Ass'n v. Trunk*, 567 U.S. 944, 945 (2012) (Alito, J., respecting the denial of the petitions for writs of certiorari). In any event, this Court's two narrow holdings—that defendants' SVF products are "drugs" under the FDCA and that FDA has not excepted these products from regulation—are correct and do not conflict with the decision of another court of appeals or of the Supreme Court. *See* Sup. Ct. R. 10(a); *see also* Stephen M. Shapiro et al.,

* The government has not been able to locate this Court's recitation of the standard for staying its own mandate. But the courts of appeals uniformly apply this same standard. *See, e.g.*, *Moore v. Whitmer*, No. 21-1755, 2023 U.S. App. LEXIS 1583, at *2 (6th Cir. Jan. 20, 2023); *American Axle & Mfg., Inc. v. Neapco Holdings LLC*, 977 F.3d 1379, 1380 (Fed. Cir. 2020); *In re A.F. Moore & Assocs., Inc.*, 974 F.3d 836 (7th Cir. 2020) (per curiam); *United States v. Silver*, 954 F.3d 455,458 (2d Cir. 2020) (per curiam); *Nara v. Frank*, 494 F.3d 1132, 1133 (3d Cir. 2007); *John Doe I v. Miller*, 418 F.3d 950, 951 (8th Cir. 2005); *United States v. Bogle*, 855 F.2d 707, 709 (11th Cir. 1988); *Baldwin v. Maggio*, 715 F.2d 152, 153 (5th Cir. 1983).

Supreme Court Practice § 4.3, at 241 (10th ed. 2013). This case would also be a poor vehicle to address several of the issues that defendants reference in their motion.

1. This Court's decision that defendants' SVF products are drugs under the FDCA's statutory definition is correct and does not warrant further review. *Cf.* Mot. 3-5. As this Court noted, the D.C. Circuit "[c]onsider[ed] a similar stem cell treatment" in *United States v. Regenerative Sciences, LLC*, 741 F.3d 1314 (D.C. Cir. 2014), and held that it satisfies the plain-language definition of "drug." Op. 11-12. And in an "exceedingly similar case regarding 'body-fat derived stem cell therapy'" (Op. 27 n.13), the Eleventh Circuit explained why a product like the ones at issue here qualifies as a drug. *See United States v. US Stem Cell Clinic, LLC*, 998 F.3d 1302, 1305-1306 (11th Cir. 2021). No court of appeals has disagreed.

That uniform position is correct, and there is no pressing need for the Supreme Court to intervene in the absence of a conflict. The FDCA defines the term "drug" as including articles that are "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," or that are "intended to affect the structure or any function of the body," and any components of such articles. 21 U.S.C. § 321(g)(1)(B)-(D). Defendants create and administer substances that do not exist anywhere in the body, sometimes in their own clinics while patients sit in a waiting room and other times in a laboratory on the other side of the country. *See* Op. 7. "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." Op. 11. Those substances

are "drugs" under the statutory definition and are properly regulated as such. This Court correctly explained that "[t]he word 'drug' is a term of art for the purposes of the [FDCA]" and that "Congress fully intended that the Act's coverage be as broad as its literal language indicates." Op. 11-12 (second alteration in original) (quoting *United States v. Article of Drug, Bacto-Unidisk*, 394 U.S. 784, 793, 798 (1969)). And this Court properly rejected defendants' request for an atextual exception to the statutory definition of a drug, based on "purportedly 'absurd' results" that could arise from "[h]ypothesized extreme applications" of the statute. Op. 12-13.

Defendants' passing references (Mot. 3-5) to "surgical procedure[s]" and "the practice of medicine" do not establish any likelihood that the Supreme Court would grant certiorari and reverse. But they do underscore why this would be a poor vehicle to address any broader issues about the application of the FDCA. This case is not about regulating a medical procedure; rather, this case is about regulating products. *See* Op. 13-14. And it is not absurd or intrusive on the states' "police powers" (Mot. 4, 7) to ensure that defendants cannot market products as treating a wide range of diseases without properly demonstrating to FDA that these products are safe and effective for those intended uses. The same is true of ensuring that defendants cannot market adulterated or misbranded versions of those products. *See Wyeth v. Levine*, 555 U.S. 555, 566 (2009) (explaining that the FDCA protects people from the risks of "unsafe drugs and fraudulent marketing" and accordingly "supplement[s] the protection for consumers already provided by state regulation").

Even if there were an atextual limitation on the term "drug" to accommodate some narrow circumstances that bear none of the hallmarks of drug manufacturing and all of the hallmarks of surgery, such a limit would have no application in this case, where defendants tout that they have the "technology to produce a solution rich with your own stem cells" and market their treatments as "non-surgical alternatives" for a long list of diseases. Op. 6. This case would thus be a poor vehicle for the Supreme Court to consider such issues. This case would also be a particularly poor vehicle because "recent legislation suggests that Congress presupposes that the FDA regulates stem cell therapies." Op. 16 (citing the 21st Century Cures Act, Pub. L. No. 114-255, § 3033, 130 Stat. 1033, 1101-1103 (2016)); *see FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133, 143 (2000) (interpreting the terms "drug" and "device" in light of "subsequent statutes" that "more specifically address the topic at hand").

This case also does not plausibly implicate "the 'major questions' doctrine." Mot. 4. FDA regulation of defendants' SVF products is not "a matter of extreme 'economic and political significance'" or "a sudden assertion or 'transformative expansion' of authority." Op. 14-16 (quoting *West Virginia v. EPA*, 597 U.S. 697, 721, 724 (2022)). And it "fits comfortably" within the statutory scheme because the products are "sold and administered to patients for therapeutic purposes" and, as noted, recent legislation presumes that products like defendants' would require FDA approval. Op. 16-17; *see Brown & Williamson Tobacco Corp.*, 529 U.S. at 141-158.

Nor is the Supreme Court likely to grant certiorari and reverse based on "the right of individuals to control what may be done with their own bodies, and to make autonomous medical decisions in consultation with their physicians." Mot. 4-5 (citing, *inter alia*, *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 851 (1992)). One of the cases that defendants rely on was just recently overruled by the Supreme Court. *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 231 (2022). And because the Supreme Court is a court of "review, not of first view," *Moody v. NetChoice, LLC*, 603 U.S. 707, 726 (2024), it is particularly unlikely to address an issue that was barely mentioned in defendants' appellate brief and was not passed upon by this Court.

2. This Court's decision that the same surgical procedure exception, 21 C.F.R. § 1271.15(b), does not apply here is also correct and does not warrant further review. *Cf.* Mot. 5-6. As this Court noted, the Eleventh Circuit reached the same conclusion in "an exceedingly similar case." Op. 27 n.13 (citing *US Stem Cell Clinic*, 998 F.3d at 1305, 1310). This Court's opinion made clear that it "agree[d] with the Eleventh Circuit's reasoning and conclusion." *Id.*; *see also* Op. 28, 31 n.2 (Friedland, J., concurring in the result of Part III.C) ("agree[ing] with [that] conclusion" and "agree[ing] with parts of the Eleventh Circuit's analysis" but ultimately "arriv[ing] at this conclusion for a different reason"). No court of appeals has disagreed.

That conclusion is correct, and there is no pressing need for the Supreme Court to intervene in the absence of a conflict. The same surgical procedure exception applies when an establishment "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 "more straightforward" reading of this text renders it inapplicable here. Op. 22; *see* Op. 27. Defendants' businesses remove adipose tissue, or fat, and then implant SVF and therefore do not implant "such" HCT/P. Defendants acknowledge that they remove adipose tissue, that adipose tissue is an HCT/P, and that the SVF that they implant is not adipose tissue. The fact that defendants remove, embedded within the adipose tissue, each of the individual cells that end up in the final SVF products they create does not entitle them to rely on the exception. That reading of the plain text is confirmed by the context, structure, history, and purpose of FDA's regulations, all of which show that the agency sought to limit this exception to a narrow subset of medical procedures that involve little or no processing of tissue. Op. 22-27. In any event, even if the regulation were ambiguous, FDA's reading of the regulation would be entitled to deference. Op. 32-33 (Friedland, J., concurring in the result of Parti III.C). FDA's interpretation has been consistent throughout the 20-year lifespan of this rule; it implicates FDA's scientific, health, and safety expertise; and it reflects the agency's considered views. Under these circumstances, as the Supreme Court recently confirmed, deference is appropriate to FDA's official, considered, and expert view. *See Kisor v. Wilkie*, 588 U.S. 558, 570-580 (2019).

Defendants' largely unexplained references (Mot. 5-6) to "plain meaning" and other context and history do not establish any likelihood that the Supreme Court would grant certiorari and reverse. Defendants provide no reason to think that FDA's

longstanding interpretation, *see* Op. 33 (Friedland, J., concurring in the result of Part III.C), has any disruptive "implications" for "other surgical procedures" (Mot. 5). Nor do they suggest that their contrary interpretation has any limiting principle other than that the cells involved cannot themselves be "biologically altered" (Mot. 6). Defendants thus urge that so long as they create and implant a product that comprises unaltered cells or other tissue "subcomponents" taken "from the same person" and "on the same day"—"perhaps in ways currently unimaginable"—FDA has entirely excepted them from regulation, regardless of whether the resulting article bears any resemblance to the tissue that was removed and regardless of the risks posed by the new substance. Op. 26-27. That is not a position likely to invite Supreme Court review or a favorable ruling in that Court. This case is also a poor vehicle for addressing how the regulation applies to substances that comprise cells or tissues that "are not biologically altered" (Mot. 6). That is because while the district court found that the "SVF Cells are not altered, chemically or biologically," 1-ER-8, the court also qualified its finding by stating that "surface marker expression remains *similar*, and their viability does *not significantly* change," 1-ER-16-17 (emphases added). In any event, there is no sound reason for the Supreme Court to grant plenary review to determine whether FDA has correctly construed its own regulations.

B. Defendants have also failed to demonstrate irreparable harm or otherwise establish that the balance of equities weighs in favor of a stay. They object that after the mandate issues, this case will proceed on remand, where the government "will seek"

judgment in its favor and an injunction. Mot. 8. But the fact that there will be further stages of this case is hardly an injury that warrants relief that is reserved for "extraordinary cases," *Conkright*, 556 U.S. at 1402. Defendants are free to coordinate with the government about the next steps in this litigation and to present arguments regarding the appropriate course of further proceedings to the district court, which may then assess the equities. The burden of doing so or of participating in any further proceedings does "not constitute irreparable injury." *FTC v. Standard Oil Co.*, 449 U.S. 232, 244 (1980); *see Coinbase, Inc. v. Bielski*, 599 U.S. 736, 746 (2023). If the district court issues a final judgment in the government's favor and an injunction while defendants' certiorari petition is still pending, defendants are free to move for a stay then, rather than speculate about what may happen "if" that occurs. Mot. 8. Even if defendants' fears are borne out and the district court issues an injunction while the certiorari petition is still pending and then denies a stay, such a determination would reflect that court's judgment in light of "Congress' policy choice, articulated in a statute, as to what behavior should be prohibited," *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 497 (2001). No sound basis exists for this Court, which has unanimously disagreed with defendants' arguments, to pretermit that determination.

In any event, the greater harm to the public interest and to the government—which merge here, *see Nken v. Holder*, 556 U.S. 418, 435 (2009)—would be further delays while defendants continue to manufacture and administer adulterated and misbranded cellular-based drugs and to do so without FDA review for safety and efficacy. "The

public has a strong interest in the enforcement of the FDCA to protect public health." *MediNatura, Inc. v. FDA*, 998 F.3d 931, 945 (D.C. Cir. 2021); *see also Abney v. Amgen, Inc.*, 443 F.3d 540, 553 (6th Cir. 2006) (stressing the "strong" public interest in FDA's "decid[ing] what drugs meet baseline levels of safety and efficacy"). The record here also includes examples of patients suffering serious complications after undergoing defendants' SVF treatments. *See* 10-ER-1499-1500; *see, e.g.*, 8-ER-1099-1102; 10-ER-1515-1519; 10-ER-1561-1562; *see also* 7-ER-860-861 (noting the absence of proper procedures to identify, record, and track adverse events). This case has been pending for over six years, while defendants continue to create, sell, and administer their "stem cell treatments" (Mot. 8). *See* Op. 6, 8. While the district court can determine, in the first instance, how to balance the management of its docket with the need to effectuate this Act of Congress, there is no basis for further delay in this Court.

CONCLUSION

Defendants' motion to stay issuance of the mandate should be denied.

Respectfully submitted,

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JANUARY 2025

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 27(d)(2) because it contains 4,007 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in Garamond 14-point font, a proportionally spaced typeface.

s/ Adam Jed
ADAM C. JED