No. 22-56014

In the
United States Court of Appeals for the Ninth Circuit

UNITED STATES,

Appellant,

v.

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

Appellees.

On Appeal from the United States District Court for the
Central District of California
No. EDCV 18-1005 JGB Jesus G. Bernal

APPELLEES' MOTION FOR STAY OF MANDATE PENDING FILING AND DISPOSITION OF PETITION FOR A WRIT OF CERTIORARI

Celeste M. Brecht
JONES DAY
150 West Jefferson, Suite 2100
Detroit, MI 48226
+1.313.733.3939
cbrecht@jonesday.com

Ramanda R. Luper
JONES DAY
555 Flower Street
Los Angeles, CA 90071
+1.213.489.3939
rluper@jonesday.com

Nathaniel P. Garrett
JONES DAY
555 California Street, 26th Floor
San Francisco, CA 94104
+1.415.626.3939
ngarrett@jonesday.com

Counsel for Appellees
CALIFORNIA STEM CELL TREATMENT CENTER, INC., CELL SURGICAL NETWORK CORPORATION, and DR. ELLIOT B. LANDER, M.D.

INTRODUCTION

Pursuant to Federal Rule of Appellate Procedure 41(d)(2)(A) and Ninth Circuit Rule 41-1, Defendants-Appellees respectfully submit this motion for a stay of the mandate pending the filing and disposition of their petition for a writ of certiorari in the United States Supreme Court.

The Court issued judgment in this appeal on September 27, 2024. Appellees filed a timely petition for rehearing en banc on November 11, 2024. The Court denied that petition on December 20, 2024. Appellees intend to timely file a petition for a writ of certiorari with the Supreme Court on the issues raised in the rehearing petition. A stay is warranted because Appellees' petition would not be frivolous or filed merely for delay, and because Appellees will suffer irreparable harm if the mandate issues before the Supreme Court has an opportunity to consider the petition.

ARGUMENT

Under Rule 41(d)(2)(A), a party may move to stay the mandate pending the filing of a petition for a writ of certiorari in the Supreme Court if the petition "would present a substantial question" and "there

is good cause for a stay." Fed. R. App. P. 41(d)(2)(A). In the Ninth Circuit, a motion to stay the mandate may be denied if the petition "would be frivolous or filed merely for delay." Ninth Cir. R. 41-1. Appellees' petition would not be frivolous or filed merely for delay, and satisfies the criteria of Rule 41(d)(2)(A)—it presents at least two substantial questions, and there is good cause for the stay.

I. APPELLEES' PETITION WILL PRESENT AT LEAST TWO SUBSTANTIAL QUESTIONS.

The "substantial question" standard is not onerous. It does not require courts to conclude that the applicant is likely to succeed on the merits. Instead, "the applicant must show a reasonable probability that four justices will vote to grant certiorari and a reasonable possibility or 'fair prospect' that five justices will vote to reverse the circuit court's judgment." 20A Moore's Federal Practice - Civil § 341.14[2]; *see also Maryland v. King*, 133 S. Ct. 1, 2 (2012) (Roberts, C.J., in chambers) (same); *Books v. City of Elkhart*, 239 F.3d 826, 828 (7th Cir. 2001) (same); *Baldwin v. Maggio*, 715 F.2d 152, 153 (5th Cir. 1983) (stating that a court need only identify "'a reasonable probability that four members of the [Supreme] Court would consider the underlying issue sufficiently meritorious for the grant of certiorari'" and "'a significant

possibility of reversal'" (quoting *Barefoot v. Estelle*, 463 U.S. 880, 895 (1983)). As the Supreme Court has explained in describing a similar standard:

> [The applicant] need not show that he should prevail on the merits. He has already failed in that endeavor. Rather, he must demonstrate that the issues are debatable among jurists of reason; that a court could resolve the issues in a different manner; or that the questions are adequate to deserve encouragement to proceed further.

Barefoot, 463 U.S. at 893 n.4 (internal quotation marks and alterations omitted).

Here, Appellees intend to file a petition for a writ of certiorari that will present at least two substantial questions of federal law that are likely to be reviewed by the Supreme Court.

First, Defendants will ask the Supreme Court to decide whether the term "drug" in the Food, Drug, and Cosmetic Act provides the Food and Drug Administration with clear congressional authorization to regulate a surgical procedure performed by licensed physicians that uses a patient's own cells and tissues to treat disease. This substantial question implicates the proper interpretation of the FDCA, the scope of the FDA's authority in regard to the practice of medicine, the appropriate federal-state balance in an area traditionally within the

police powers of the states, and the constitutional rights of patients and physicians.

This substantial question, in turn, raises a number of additional and important questions. For example, there is a significant question whether the panel's decision conflicts with the Supreme Court's precedent requiring a clear statement of congressional intent before finding that a federal statute regulates an area traditionally reserved to the states, such as the practice of medicine. *See, e.g., Gonzales v. Oregon*, 546 U.S. 243, 274-75 (2006); *Gregory v. Ashcroft*, 501 U.S. 452, 460-61 (1991). There is also a significant question whether the panel's decision conflicts with the Supreme Court's precedent applying the "major questions" doctrine, which cautions against reading a statute to confer extraordinary or transformative power on an agency without clear congressional authorization, especially when the agency seeks to end an ongoing debate of political significance at the state level. *See, e.g.*, *W. Virginia v. EPA*, 597 U.S. 697, 724-25 (2022); *Alabama Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 594 U.S. 758, 764-65 (2021). There is a further significant question whether the panel's decision conflicts with Supreme Court precedent recognizing 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. *See, e.g.*, *Cruzan by Cruzan v. Dir. Mo. Dep't of Health*, 497 U.S. 261, 269 (1990); *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 851 (1992).

Second, Appellees will ask the Supreme Court to decide whether the FDA's interpretation of the same surgical procedure exception in the FDCA, which excludes surgical procedures that involve processing of a patient's own cells and tissues, is consistent with the text, structure, history, and purpose of the exception and the HCT/P regulations. This substantial question implicates the proper interpretation of the FDA's regulations, the scope of agency deference, and the implications of the FDA's interpretation for other surgical procedures that involve processing of a patient's own cells and tissues.

This substantial question also raises a number of additional, important questions. There is a significant question whether the panel's decision conflicts with the plain meaning of the same surgical exception, which applies when an establishment removes HCT/Ps from an individual and implants such HCT/Ps into the same individual

during the same surgical procedure. *See* 21 C.F.R. § 1271.15(b). There is also a significant question whether the panel's decision conflicts with the context, structure, history, and purpose of the same surgical exception and the HCT/P regulations, which indicate that the FDA intended to exempt from regulation surgical procedures that use a patient's own cells and tissues, regardless of the degree of processing, as long as they are not biologically altered. *See, e.g.*, 66 Fed. Reg. 5447, 5458 (Jan. 19, 2001); FDA, Proposed Approach to Regulation of Cellular and Tissue-Based Products (Feb. 28, 1997). There is a further significant question whether the panel's decision conflicts with the Supreme Court's precedent requiring courts to apply the ordinary tools of statutory and regulatory interpretation before deferring to an agency's interpretation of an ambiguous regulation, and to reject an agency's interpretation that is unreasonable, inconsistent, or contrary to the regulation's purpose. *See, e.g.*, *Kisor v. Wilkie*, 588 U.S. 558, 583-84 (2019); *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 321-22 (2014).

The above two substantial questions—including the embedded additional questions—are of exceptional importance to the development of the law, the protection of individual rights, and the regulation of the

medical profession. The panel's decision effectively grants the FDA sweeping and unprecedented authority to regulate any surgical procedure that uses a patient's own cells and tissues to treat disease, without any clear congressional authorization or any meaningful limit on the FDA's discretion. The panel's decision also deprives patients of the opportunity to benefit from innovative and potentially life-saving treatments that use their own body parts, without any compelling public health or safety justification. The panel's decision further undermines the states' ability to license, regulate, and discipline physicians who perform such treatments, without respect for the states' traditional police powers or the appropriate federal-state balance. The Supreme Court is likely to grant review of these questions, as they implicate fundamental issues of statutory and constitutional interpretation, federalism, and individual liberty.

II. THERE IS GOOD CAUSE FOR A STAY.

Appellees also meet the "good cause" prong of Rule 41(d)(2). Good cause is established based on the "equities in the case." Knibb, *Federal Court of Appeals Manual* § 34:13, at 924 (6th ed. 2013). A court must "balance the equities of granting a stay by assessing the harm to each

party if a stay is granted," "tak[ing] into consideration the public interest." *Books*, 239 F.3d at 829; *see also* 20A Moore's Federal Practice - Civil § 341.14[2] (stating that the court should take both "irreparable injury" and the "public interest" into account).

Here, there is good cause because Appellees will suffer irreparable harm if the mandate issues before the Supreme Court has an opportunity to consider the petition for a writ of certiorari. If the mandate issues, the United States will seek to force Appellees to cease offering their stem cell treatments to patients who are seeking alternatives to traditional medical and surgical treatments for degenerative disorders. That harm is irreparable because it cannot be remedied by monetary damages or reversed by a favorable decision from the Supreme Court. Moreover, Appellees' patients will also suffer irreparable harm if they are denied access to the stem cell treatments that may improve their health and quality of life.

By contrast, the FDA will not suffer any significant harm from a brief stay of the mandate. The FDA has not shown any imminent or substantial threat to public health or safety from Appellees' stem cell treatments, which use only the patient's own unaltered cells and tissues

and do not pose any risk of communicable disease transmission. The FDA has also not shown any prejudice or hardship from awaiting the Supreme Court's review of the petition for a writ of certiorari. The balance of equities and the public interest thus favor a stay of the mandate, which means that there is a good cause to issue the stay.

CONCLUSION

For these reasons, Appellees respectfully request that this Court stay the issuance of the mandate in this case pending the filing and disposition of a petition for a writ of certiorari in the Supreme Court.

December 26, 2024

Respectfully submitted,

s/ Nathaniel P. Garrett

Nathaniel P. Garrett
JONES DAY
555 California Street, 26th Floor
San Francisco, CA 94104
+1.415.626.3939
ngarrett@jonesday.com

Counsel for Appellees CALIFORNIA STEM CELL TREATMENT CENTER, INC., CELL SURGICAL NETWORK CORPORATION, and DR. ELLIOT B. LANDER, M.D.