No. 24-1189

IN THE

Supreme Court of the United States

CALIFORNIA STEM CELL TREATMENT CENTER, INC., A CALIFORNIA CORPORATION, ET AL.,

Petitioners,

v.

UNITED STATES,

Respondent.

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

BRIEF OF *AMICUS CURIAE* ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS IN SUPPORT OF PETITIONERS

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INTERESTS OF *AMICUS CURIAE*[1]

Amicus Association of American Physicians and Surgeons ("AAPS"), founded in 1943, is a national association of physicians. AAPS is dedicated to protecting the patient-physician relationship, and has repeatedly been a litigant against the Food and Drug Administration (FDA) in prior cases. *See, e.g.*, *Ass'n of Am. Physicians & Surgeons, Inc. v. United States FDA*, 226 F. Supp. 2d 204, 219 (D.D.C. 2002) (holding, in a lawsuit brought by AAPS, that "the FDA exceeded its authority").

The FDA asserts that a patient's own stem cells become "drugs" for control by the FDA under the Food, Drug, and Cosmetic Act (FDCA), such that the FDA blocks their use for the benefit of the same patient in a same-day medical procedure. As a group of physicians and surgeons, AAPS has strong interests in defending the private practice of medicine under state law against this federal interference with access by patients to treatment with cells from their own body.

SUMMARY OF ARGUMENT

The FDA asserts the equivalent of an ownership right – *i.e.*, control – over a patient's own stem cells, and blocks their same-day use in the same patient. By declaring a part of a patient's body to be a "drug" subject to exclusive FDA jurisdiction, the FDA vastly

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[1] *Amicus* provided the requisite ten days' prior written notice to all the parties. Pursuant to Rule 37.6, counsel for *amicus curiae* authored this brief in whole, no counsel for a party authored this brief in whole or in part, and no such counsel or a party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity – other than *Amicus*, its members, and its counsel – contributed monetarily to the preparation or submission of this brief.

expands its own power far beyond any reasonable limit. The FDA essentially attempts to own people's biological cells, akin to their own skin or hair, by unjustifiably classifying them as drugs under the FDA's regulatory scheme. This biological material bears no resemblance to regulated drugs, under any sensible definition or traditional understanding of that term. The FDA's imaginative redefinition of the term "drug" to expand federal power in encroachment on the practice of medicine is beyond Orwellian and enters the realm of dystopian science fiction.

Stem cells are undeniably capable of providing tremendous medical breakthroughs. As a recent editorial in the *New York Times* explained:

> The promise of stem cell therapy is powerful. Scientists can draw versatile cells from the human body and deliver them to repair injuries and fight disease from the inside out. …
>
> Why are scientists excited about them?
>
> ... Unlike many other cells, certain stem cells can also regenerate … to replace other types of cells in your body that have been damaged.

Mohana Ravindranath, "Are Stem Cell Therapies Safe to Try?" *New York Times* (June 5, 2025).

The significance of this case is not adequately measured in purely economic terms, which is substantial enough, but by the enormous potential to improve the health and lives of millions of Americans. By impeding medical progress in using a patient's own stem cells in a same-day operation, the FDA is denying medical care to millions of Americans who suffer from diabetes, cancer, heart disease, and many other deadly conditions. The FDA has shut down access to this care, without any feasible alternative other than forcing

Americans to seek substitute care in foreign countries. With the health of millions of Americans hanging on the precedent of this case, it presents an issue of national importance.

The Ninth Circuit decision below is also in conflict with the reasoning of other circuits and this Court, on the fundamental issue of whether biological, naturally occurring material – one's own stem cells – can be controlled as though they were drugs. If one's own stem cells are a drug for which the FDA can block use by the same patient in a same-day surgical procedure, then it implies an intellectual property right which courts have rejected. Without patentability, there is no way to recoup the enormous costs required to obtain FDA approval of a new drug. The Federal Circuit and this Court have rejected the view that biological, naturally occurring material is intellectual property.

There are no ethical issues implicated by this case, which presents the straightforward issue of whether patients can use their own stem cells for their own potential benefit, in surgical procedures allowed under state law. This Court should grant *certiorari* and answer in the affirmative.

ARGUMENT

The FDA, lacking in any clinical medical expertise or authority to practice medicine, is blocking access to ethical medical care which all concede has enormous potential benefits. The FDA's and the Ninth Circuit's reasoning below fails to comport with any statutory justification, or common sense.

For at least three reasons *certiorari* should be granted here. First, this issue has immense national importance: patients should have access in the United States to advanced medical care, without having to

travel to foreign countries for possibly inferior and more costly alternatives. Second, the reasoning of the decision below conflicts with the Federal Circuit and this Court concerning whether biological, naturally occurring material can be owned or controlled as though it were a drug. Third, the decision below is an unauthorized interference with state autonomy over the practice of medicine.

I. The FDA's Interference with Use in Patients of Their Own Stem Cells Is an Issue of National Importance.

The national importance of this case can hardly be doubted. The decision below downplayed the significance of this issue compared with the student loan forgiveness controversy, but this issue at bar affects the health of many while the student loan forgiveness dispute had no direct effect on anyone's health. As pointed out by the Petitioner below and acknowledged by the Ninth Circuit, use of a patient's own stem cells has the potential to alleviate or cure:

> Alzheimer's, arthritis, asthma, cancer, macular degeneration, multiple sclerosis, heart problems, pulmonary problems, Crohn's, Parkinson's, and erectile dysfunction.

United States v. Cal. Stem Cell Treatment Ctr., Inc., 117 F.4th 1213, 1216 (9th Cir. 2024). More than a hundred million Americans suffer at some point in their lifetime from one or more of the foregoing conditions; indeed, 41% of Americans are diagnosed with cancer during their lifetimes,[2] and the CDC

[2] Mary C. White, "Age and cancer risk: a potentially modifiable relationship,"46 Am. J. Prev. Med. S7-15 (Mar. 2014)

reports that in the United States "[o]ne person dies every 33 seconds from cardiovascular disease."[3]

Leading medical centers confirm the optimism expressed by Petitioner for treatment with stem cells. The prestigious Cleveland Clinic, for example, states on its website that stem cells:

> repair damaged tissue. Now, stem cells are essential blood cancer and blood disorder treatments. Medical researchers believe stem cells also have the potential to treat many other diseases.

Cleveland Clinic, *Stem Cells.*[4] Similarly, the website of a leading hospital and research center in Los Angeles, *Cedars-Sinai*, gushes with enthusiasm about the potential for use of a patient's own stem cells:

> At the center of the excitement is the discovery that adult cells from patients at any age can be taken "back in time" to create a stem cell that is pluripotent—able to generate any cell of the human body. These are called induced pluripotent stem cells or iPSCs.
>
> Each cell made this way carries the DNA of the donor. So iPSCs are ideal for creating and testing potential treatments that can be exactly tailored to the individual.

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https://pmc.ncbi.nlm.nih.gov/articles/PMC4544764/#:~:text=For%20the%20total%20U.S.%20population,with%20cancer%20is%20approximately%2041%25. (viewed June 19, 2025).

[3] CDC, "Heart Disease Facts," https://www.cdc.gov/heart-disease/data-research/facts-stats/index.html (viewed June 18, 2025).

[4] https://my.clevelandclinic.org/health/body/24892-stem-cells (viewed June 18, 2025).

> "It's like having an avatar of a patient in a dish," says Clive Svendsen, PhD, executive director of the Cedars-Sinai Board of Governors Regenerative Medicine Institute (RMI).

Sarah Spivack LaRosa, "The Untapped Potential of Stem Cells," *Cedars-Sinai Blog* (Oct. 22, 2021).

In 2010, a medical article available at the National Library of Medicine concluded, "What makes stem cell research so exciting is its tremendous potential to benefit human health and the opportunities for interdisciplinary research that it presents." Fiona M. Watt, "The therapeutic potential of stem cells," 365 *Philos. Trans. R Soc. Lond. B. Biol. Sci.* 55-63 (Jan 12, 2010).[5]

But the spectacular advances from use of a patient's own stem cells are all taking place outside of the United States, where the FDA cannot obstruct them. Last September, the renowned *Nature* magazine reported from China that due to reimplantation of her own stem cells, "[a] 25-year-old woman with type 1 diabetes started producing her own insulin less than three months after receiving a transplant of reprogrammed stem cells. … 'I can eat sugar now,' said the woman" more than a year later and "'I enjoy eating everything.'" "Stem cells reverse woman's diabetes — a world first," 63 *Nature* 271-72 (September 2024) (available on *Lexis*). *Nature* similarly reported from Japan this year that "[a] paralysed man can stand on his own after receiving an injection of neural stem cells to treat his spinal-cord injury. … Another man can now move his arms and legs following the treatment." Smriti Mallapaty, "Paralysed man stands again after

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[5] https://pmc.ncbi.nlm.nih.gov/articles/PMC2842697/ (viewed June 18, 2025).

receiving 'reprogrammed' stem cells," 640 *Nature* 18-19 (March 2025) (available on *Lexis*) (adding that not all such treatments have succeeded).

The Secretary of Health and Human Services (HHS), Robert F. Kennedy, Jr., has talked about how he had to travel to Antigua to receive stem cell injections that he said were very successful for treating his medical condition. "He had to go to Antigua for stem cell treatment – it helped him, but it shouldn't require leaving the country," "Robert F. Kennedy Jr.: How to Fix America's Health Crisis as HHS Secretary | Ultimate Human," *Podcast with Gary Brecka* (#169) (May 30, 2025).[6]

The national importance of this issue is further underscored by the fact that at least 40 top professional athletes have received stem cell treatments for physical ailments, including Jack Nicklaus, Tiger Woods, Peyton Manning, Kobe Bryant, Stephen Curry, and Alex Rodriguez. Yet many of them have had to travel to foreign countries such as Germany (*e.g.*, Nicklaus, Bryant, and Rodriguez) to obtain this treatment. Cade Hildreth, "40 Pro Athletes Who Have Had Stem Cell Treatments," *Bioinformant* (Jan. 30, 2025).

The Ninth Circuit erred in viewing the issue of significance in only economic terms, comparing this case unfavorably to the student loan forgiveness case, rather than in terms of medical care potentially helping millions of Americans:

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[6] https://podcastnotes.org/ultimate-human-podcast-with-gary-brecka/robert-f-kennedy-jr-how-to-fix-americas-health-crisis-as-hhs-secretary-ultimate-human-podcast-with-gary-brecka-169/ (viewed June 5, 2025).

> this case does not present a matter of extreme "economic and political significance." [*West Virginia v. EPA*, 597 U.S. 697, 721 (2022)] (quoting *Brown & Williamson Tobacco Corp.*, 529 U.S. at 160); *cf. id.* at 724-25 (reasoning that carbon emission standards were meant to "substantially restructure the American energy market"); *Biden v. Nebraska*, 600 U.S. 477, 143 S. Ct. 2355, 2373, 216 L. Ed. 2d 1063 (2023) (noting that the significance of the student loan forgiveness program was "staggering by any measure," with an economic impact amounting to "nearly one-third of the Government's $1.7 trillion in annual discretionary spending"); *Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 594 U.S. 758, 764, 141 S. Ct. 2485, 210 L. Ed. 2d 856 (2021) (per curiam) (describing the "sheer scope" of an eviction moratorium, which covered at least 80% of the country).

Cal. Stem Cell Treatment Ctr., 117 F.4th at 1220-21.

Any of the many millions of Americans suffering from cancer, heart disease, diabetes, or the multitude of other serious conditions treatable with their own stem cells would view access to advancements in medical treatment for their conditions to be at least as important as the economic issues of student loans or the moratorium on evictions. The FDA's interference with access to stem cell treatments in the United States, such that Americans have to do without or take risks in seeking it in foreign countries, is as significant (if not more so) as forgiving some college loans.

Moreover, the financial impact of the FDA's interference at issue in this case is profound. The global market for stem cell treatments is predicted to

grow to $48.8 billion by 2034.[7] This interference by the FDA, not for any ethical reason and without congressional authority, is harmful to patients, physicians, federalism, and the national economy. A grant of *certiorari* is essential here to end this irrational interference by the FDA with medical care using patients' own stem cells under the proper jurisdiction of state medical boards.

II. The Decision Below Implicitly Conflicts with the Federal Circuit on the Issue of Intellectual Property in Naturally Occurring Biological Matter.

Implicit in the decision below is that there is a proprietary substance created by extracting a patient's stem cells, such that it becomes a "drug" requiring approval by the FDA under the FDCA. Obtaining approval of a drug by the FDA is very expensive, and makes sense only if the drug is protectible intellectual property. *See* Olivier J. Wouters et al., "Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018," 323 *JAMA* 844-853 (Mar. 3, 2020) (for obtaining FDA approval of a new drug, the average expense is $1.3 billion, not merely million).[8] Items that are naturally occurring and beneficial to health, such as ordinary apples or water, cannot be a "drug" for FDA approval under the FDCA because they are not protectable as

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[7] "Stem Cells Market Size to Reach USD 48.83 Billion By 2034 - Exclusive Report by Precedence Research," *Biospace* (Dec. 13, 2024) https://www.biospace.com/press-releases/stem-cells-market-size-to-reach-usd-48-83-billion-by-2034-exclusive-report-by-precedence-research (viewed June 5, 2025).

[8] https://pmc.ncbi.nlm.nih.gov/articles/PMC7054832/#joi200015r3 (viewed June 18, 2025).

intellectual property and thus cannot be marketed as a proprietary substance.

The sweeping terminology in the FDCA, as quoted below, cannot be reasonably interpreted as including commonly occurring natural material like stem cells:

> "Drug[s]" are defined in the Act as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," or "intended to affect the structure or any function of the body." [*United States v. Article of Drug, Bacto-Unidisk*, 394 U.S. 784, 789 (1969)] (quoting 21 U.S.C. § 321(g)(1)). An "article" is just a general term for "a particular thing." *Samsung Elecs. Co. v. Apple Inc.*, 580 U.S. 53, 59, 137 S. Ct. 429, 196 L. Ed. 2d 363 (2016) (quoting J. Stormonth, A Dictionary of the English Language 53 (1885)).

Cal. Stem Cell Treatment Ctr., 117 F.4th at 1218-19. Rather than expand FDA power over virtually every "article" or "thing", the intended regulatory scheme of the FDA inherently limits the scope of a "drug" to what can be marketed as a proprietary substance, *i.e.*, patentable subject matter. *See, e.g.*, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 580 (2013) ("a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated").

A patient's stem cells extracted for reinsertion into himself are "a product of nature." The reasoning below conflicts with the Federal Circuit that has applied *Myriad Genetics* to nature, which is what a patient's own stem cells are. Under the *Myriad Genetics* line of decisions in the Federal Circuit there is no stem cell "drug" about which Petitioner could own and seek approval. *See, e.g.*, *ChromaDex, Inc. v. Elysium*

Health, Inc., 59 F.4th 1280, 1284 (Fed. Cir. 2023) ("The claimed compositions remain indistinguishable from natural milk because, other than separation from some other components, the isolated [nicotinamide riboside] is no different structurally or functionally from its natural counterpart in milk.").

III. The FDA Improperly Usurps the Authority of the California and Other State Medical Boards.

Congress has rejected, in the authority it has granted to the FDA, "any intent to directly regulate the practice of medicine," which is left to the States. *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 use of a patient's own stem cells, then Congress needs to do so by clearer terms than it has.

Federal agencies may not properly expand their authority with strained new interpretations of old statutes. In *MCI Telecommunications Corp. v. American Telephone & Telegraph Co.*, 512 U.S. 218 (1994), this Court rejected an attempt by the FCC to expand its discretionary power based on a reinterpretation of vague statutory language. *See id.* at 231. Similarly, in the landmark tobacco case, this Court denied the FDA's attempt to expand its authority because:

> [t]o find that the FDA has the authority to regulate tobacco products, one must not only adopt an extremely strained understanding of "safety" as it is used throughout the Act – a concept central to the FDCA's regulatory scheme – but also ignore the plain implication of Congress' subsequent tobacco-specific legislation. It is therefore clear, based on

> the FDCA's overall regulatory scheme and the subsequent tobacco legislation, that Congress has directly spoken to the question at issue and precluded the FDA from regulating tobacco products.

FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 160-61 (2000).

It has long been well-established that states, not the federal government, properly regulate the practice of medicine. As this Court explained more than 70 years ago:

> It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power. The state's discretion in that field extends naturally to the regulation of all professions concerned with health.

Barsky v. Bd. of Regents, 347 U.S. 442, 449 (1954). *See also Whalen v. Roe*, 429 U.S. 589, 603 n.30 (1977) ("It is, of course, well settled that the State has broad police powers in regulating the administration of drugs by the health professions."). The California medical board can and does suspend the medical license of any physician who is harming patients. The FDA does not properly regulate surgical procedures in California, and the decision below extending FDA authority into the operating room was in error.

Petitioner objected below on this basis but the Ninth Circuit failed to adequately address this fundamental issue. Instead, the court relied on inapposite decisions such as one holding that "while the [FDCA] was not intended to regulate the practice of medicine, it was obviously intended to control the

availability of drugs for prescribing by physicians." *United States v. Evers*, 643 F.2d 1043, 1048 (5th Cir. 1981) (quoted by *Cal. Stem Cell Treatment Ctr.*, 117 F.4th at 1220). But no one here disputes the authority of the FDA "to control the availability of drugs for prescribing by physicians." If the FDA confined its interference to drug distribution, then it would not be interfering in the operating room in this case where no prescription or distribution of any drugs is at issue.

As summed up by Justice Gorsuch in his concurrence, joined by Justice Alito, in the recent seminal *West Virginia v. EPA* decision:

> [A]dministrative 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, 597 U.S. at 735 (Gorsuch and Alito, JJ., concurring, inner quotations omitted and emphasis added). Yet the decision below sidestepped this ruling by holding that stem cell treatments do not have "vast economic and political significance." *Cal. Stem Cell Treatment Ctr.*, 117 F.4th at 1220-21. As discussed in Point I above, stem cell potential does indeed have enormous significance.

Finally, it is worth pointing out that 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"). For a mere subagency, lacking in any surgical expertise, to interfere with surgery performed on the other side of the country for patients, is an improper usurpation of

the rightful authority of California and other states to regulate the practice of medicine within their borders.

CONCLUSION

For the above reasons and those set forth by Petitioner, the Court should grant *certiorari*.

Respectfully submitted,

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