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 A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

MOTION FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* AND BRIEF *AMICUS CURIAE* OF GOLDWATER INSTITUTE IN SUPPORT OF PETITIONERS

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MOTION FOR LEAVE TO FILE AMICUS CURIAE BRIEF

Pursuant to Rule 21.2(b), the Goldwater Institute respectfully requests leave to submit a brief as amicus curiae in support of the petition for writ of certiorari filed by California Stem Cell Treatment Center, et al.

Rule 37.2 requires that amici notify all parties' counsel of their intent to file an brief in support of a petition for certiorari at least ten days before the date on which a response to the petition is due. A response to the petition was due on June 20, but on June 9, Respondent waived its right to respond. Due to amicus's oversight, amicus notified the parties of its intention to file this brief on June 11. Given the waiver of the right to respond, however, this will not prejudice any party.

Goldwater frequently appears before this Court as counsel for amicus in cases involving medical innovation and the principle of medical autonomy, as detailed in the Interest and Identity of Amicus section below. It writes in support of Petitioner here because the questions presented raise significant issues concerning these vital constitutional questions. In this proposed brief, Goldwater draws on its 35+ years of experience and provides a discussion of first principles to help inform the Court's consideration of the Petition.

Accordingly, Goldwater respectfully asks the Court to grant it leave to file this amicus brief.

Dated: June 20, 2025

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QUESTION PRESENTED

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

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

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INTEREST OF AMICUS CURIAE[1]

The Goldwater Institute ("GI") was established in 1988 as a nonpartisan public policy foundation dedicated to advancing the principles of limited government, economic freedom, and individual responsibility through litigation, research, and policy briefings. Through its Scharf–Norton Center for Constitutional Litigation, GI litigates cases and files amicus briefs when its or its clients' objectives are directly implicated.

Among GI's principal goals is defending the vital principle of healthcare freedom and medical autonomy. GI has litigated and appeared as amicus curiae in many state courts to promote the role of state powers in curbing federal power and the enforcement of state legal protections of individual rights. *See, e.g., State v. Hernandez*, 417 P.3d 207 (Ariz. 2018); *Lathrop v. Deal*, 801 S.E.2d 867 (Ga. 2017); *Ladd v. Real Est. Comm'n*, 230 A.3d 1096 (Pa. 2020). GI participated as amicus in the proceedings below.

GI also developed, drafted, and advocated for passage of 41 state Right to Try laws and the federal Right to Try law, which protect terminally ill patients' right to try safe investigational treatments that have been prescribed by their physician but that the federal Food and Drug

1. Amicus curiae gave counsel of record for all parties notice of its intention to file this brief nine days before the brief's due date. Pursuant to Rule 37.6, counsel for amicus affirms that no counsel for any party authored this brief in whole or in part and that no person or entity, other than amicus, its members, or counsel, made a monetary contribution to the preparation or submission of this brief.

Administration ("FDA") has not yet approved for market. More recently, GI created Right to Try 2.0, which expands Right to Try protections to individualized treatments, based on a single patient's specific genetics. Right to Try 2.0 is law in Arizona and Nevada, and is being considered now by state legislatures across the country.

Finally, GI scholars and attorneys have published policy and legal scholarship on federal impediments to healthcare access and on the principle of medical autonomy. *See, e.g.,* Jeffrey A. Singer, *Your Body, Your Health Care* (2025); Christina Sandefur, *The FDA's Approach to Off-Label Communications: Restricting Free Speech in Medicine?*, Federalist Society Regulatory Transparency Project (May 10, 2018)[2]; Christina Sandefur, *Safeguarding the Right to Try*, 49 Ariz. St. L.J. 513 (2017); Mark Flatten, *Dead on Arrival: Federal "Compassionate Use" Leaves Little Hope For Dying Patients*, Goldwater Inst. (2016).[3]

GI believes its legal and policy expertise will benefit this Court in its consideration of this case.

SUMMARY OF THE ARGUMENT

This case is about whether the FDA can regulate like a drug a purely medical procedure in which a person's own cells are extracted and reinserted into the patient's body without alteration. The District Court said that the

2. https://regproject.org/paper/fdas-approach-off-label-communications-restricting-free-speech-medicine/.

3. https://goldwaterinstitute.org/wp-content/uploads/2016/02/Dead-On-Arrival-Report.pdf.

first of the two treatments in question—which consists of removing fat tissues from a patient, extracting the patient's own stromal vascular fraction (SVF) cells from the tissue, and relocating those cells back into the patient's body around an injured area, *United States v. California Stem Cell Treatment Center, Inc.,* 624 F. Supp.3d 1177, 1180–81 ¶¶ 7-8, 13 (C.D. Cal. 2022)—is a surgical procedure, and not a "drug" within the FDA's drug regulation authority. *Id.* at 1187–88 ¶ 22.

Further, the second treatment—which consists of removing fat tissue, extracting mesenchymal stem cells ("MSC") cells from it, storing those cells, and allowing them to naturally replicate before implanting the cells back into the patient's body, *id.* at 1182 ¶¶ 20–21—also did not constitute the administering of a drug, because allowing a patient's own cells to replicate is simply the practice of medicine, not the manufacture of a pharmaceutical. *Id.* at 1189 ¶ 30.

That decision was not only legally correct, but better serves the goal of patient autonomy, which is both the ethical and constitutional lodestar at which drug regulation properly aims. The Court of Appeals' reversal of that decision undermines that purpose. Allowing the FDA to restrict access to a treatment that consists solely of a patient's own cells exceeds its statutory authority, undermines patients' right to medical autonomy—and the right to protect one's own life—and intrudes on the practice of medicine, an area historically regulated by the states. If this Court allows that decision to stand, it will hinder medical innovation, block access to necessary, potentially life-saving treatments, and empower the FDA to expand its reach far beyond statutory limits.

ARGUMENT

I. Allowing the FDA to regulate an individual's own cells as a drug encroaches on patients' medical autonomy.

Whatever deference administrative agencies are entitled to, an agency has no authority to interpret a statute beyond the bounds of reasonableness. *Kisor v. Wilkie*, 588 U.S. 558, 575 (2019). Nowhere has the importance of that boundary been clearer than in this case. The Court of Appeals' affirmance of the FDA's determination that a treatment which involves a patient's *own cells* qualifies as a "drug" for purposes of regulation not only exceeds the agency's statutory authority, but intrudes on the right to medical autonomy.

That right is a constitutionally protected liberty interest implicit in the concept of ordered liberty and deeply rooted in this nation's history and tradition. *See* Jeffrey Singer, *Your Body, Your Health Care* 7-13 (2025). This Court has acknowledged that an individual has a constitutionally protected liberty interest in *refusing* lifesaving medical treatment when it is not wanted, *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261, 278–79 (1990), and that unjustified intrusions into the body violate due process. *Rochin v. California*, 342 U.S. 165, 172–74 (1952) (stating that people cannot be subjected to medical procedures against their will). The right to medical privacy and the right "to care for one's health and person and to seek out a physician of one's own choice," *Doe v. Bolton,* 410 U.S. 179, 218-219 (1973) (Douglas, J., concurring), are also grounded in the law's basic respect for the patient's fundamental right to decide for herself what medical procedures she undergoes.

It is no surprise that this right is valued so highly. The most basic of all rights is the right to one's own body. Indeed, the Due Process Clause even protects a person's right to cut or not cut his own hair. *Griffin v. Tatum*, 425 F.2d 201, 203 (5th Cir. 1970). If a patient has a constitutionally protected interest in something as trivial as a haircut, then she certainly has an interest in using her own body in an effort to defend herself against a disease; especially where, as here, the treatments involve an individual's own unaltered cells to treat degenerative disorders that can be life-threatening.

The right of patient autonomy is "the fundamental principle of medical ethics." Jessica Flannigan, *Pharmaceutical Freedom: Why Patients Have a Right to Self-Medicate* xii (2017). And it is reflected also in such legal doctrines as self-defense and liability for interference with rescue. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 480 (D.C. Cir. 2006).[4] Courts have even recognized legal privilege to violate others' property rights in cases of emergency. *See generally* John Alan Cohan, *Private and Public Necessity and the Violation of Property Rights*, 83 N.D. L. Rev. 651, 657 (2007). If one has a right to kill another or destroy another's property to safeguard one's life and freedom, *see, e.g., Montana v. Egelhoff*, 518 U.S. 37, 56 (1996) (noting that "the right to have a jury consider self-defense evidence … is fundamental" and supported by the "historical record"), then one must have at least

4. The en banc court reversed *Abigail Alliance*—see 495 F.3d 695 (D.C. Cir. 2007) (en banc)—but in doing so, did not deny that the right to patient autonomy is fundamental; rather, it held that the right to use medication that had not been approved for sale was not constitutionally protected.

the same right to avail herself of treatments using no more than one's own cells—which pose no risk of harm to others—to combat a degenerative disease. Likewise, if people can be held liable for interfering with effort to rescue others in peril, *see, e.g.*, *Ross v. United States*, 910 F.2d 1422, 1433 (7th Cir. 1990); *United States v. Lawter*, 219 F.2d 559, 562 (5th Cir. 1955); *Sneider v. Hyatt Corp.*, 390 F. Supp. 976, 980 n.2 (N.D. Ga. 1975), then a patient must have a right to take steps in accordance with a physician's recommendations to preserve her life and health.

Deference to the FDA here would interfere with this principle of autonomy and with the basic right to take medical treatment to save one's own life. Such a step fails the reasonableness requirement for deference.

In rejecting the Petitioners' argument that the procedure falls within the "single surgical procedure" exception, the Ninth Circuit expressed concerns that the procedure "introduces risk," possibly risks "greater than that associated with conventional surgery," all "with no FDA oversight." Pet. App. 28a. But the risks of a medical procedure are a matter for physicians, not for the FDA—which has no jurisdiction to "oversee" the practice of medicine. *Cf. Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (recognizing that FDA has no power to "interfer[e] with the practice of medicine.").

In any event, FDA regulation will not prevent all risks. The FDA itself admits that even under its drug regulations, "there is never 100% certainty when determining reasonable assurance of safety and effectiveness." *See generally* U.S. Food & Drug Admin., *Factors to*

Consider When Making Benefit–Risk Determinations in Medical Device Premarket Approval and De Novo Classifications: Guidance for Industry and Food and Drug Administration Staff 11 (2019).[5] What *is* certain is that subjecting *a purely surgical procedure* to regulations intended for new *drugs* will needlessly force patients to wait—perhaps for years—to receive the treatment, and bar some of them from receiving it altogether.

It is a matter of common knowledge that the FDA's drug approval process is excessively risk-averse. The Agency "has little incentive to avoid the 'unseen' error of blocking new medicines that could ease the suffering of millions of people," Avik S. A. Roy, *Stifling New Cures: The True Cost of Lengthy Clinical Drug Trials,* Manhattan Institute 11 (2012)[6]; Singer, *supra* at 65-80. The reason is simple: if the agency approves a bad drug, it risks punishment or embarrassment, whereas if it fails to approve a good drug, it suffers no such penalty.

In other words, as Professor Sunstein has noted, the "precautionary principle" imposes hidden barriers against innovation and hides the costs of inaction—which can be quite severe. *See generally* Cass R. Sunstein, *Beyond the Precautionary Principle*, 151 U. Pa. L. Rev. 1003 (2003). All the FDA's incentives are therefore on the delay side. The consequence is to retard progress and to deprive suffering patients of the medicine they need.

But the FDA does not have all the information necessary to make the "right" decision about patient

5. https://www.fda.gov/media/99769/download.

6. https://media4.manhattan-institute.org/pdf/fda_05.pdf.

treatments. That Agency does not evaluate patients, or discuss options with them, the way physicians do—precisely because it is not supposed to be engaged in the practice of medicine. Instead, as discussed in the next section, the FDA was created for the purpose of informing patients so that they would be able to make their own choices wisely. The problem of adulterated or mislabeled medicines, of course, is that adulteration or false advertising deprives patients of the information necessary to make their own decisions. The FDA's role is therefore supposed to be to protect the patient. That mission becomes distorted when the FDA goes further and makes decisions *for* the patient—as if the patient existed for the regulator, and not the regulator for the patient.

In fact, requiring the procedures at issue in this case to be regulated like drugs may actually lull patients into a false sense of security. "Instead of doing their own due diligence and research, the overwhelming majority of people simply concern themselves with whether or not the FDA says a certain product is okay to use." Connor Boyack, *FDA: Fostering a False Sense of Security,* Connor's Conundrums (June 21, 2009).[7]

That is precisely why the decision should belong to the person whose life it is—especially when the treatment involves nothing more than one's own cells.

7. https://connorboyack.com/blog/fda-fostering-a-false-sense-of-security/.

II. Permitting the FDA to treat a surgical procedure as the manufacture of a drug intrudes upon state power to oversee the practice of medicine.

Regulating the surgical procedures at issue in this case as if it was a drug would improperly interfere with the practice of medicine—quintessentially a matter of state law. *Cf. Planned Parenthood of Cincinnati Region v. Strickland*, 531 F.3d 406, 412 (6th Cir. 2008). Neither procedure involves the creation of a new drug, or of any new product that did not previously exist in the patient. It involves only the *relocation* of a patient's *own* cells, which is a medical procedure.

During the SVP procedure, physicians use surgical tools to extract the tissues and cells from the patient and relocate those cells in the patient's body. *Cal. Stem Cell Treat. Ctr.*, 624 F. Supp.3d at 1181–82 ¶ 15. The cells are not altered during the procedure, *id.* at 1182 ¶ 17, and the procedure does not create any material that did not previously exist within the patient. *Id.* at ¶ 18. When additional cells are needed via the MSC procedure, the cells are allowed to naturally replicate, and they have the same characteristics as the cells that were removed. *Id.* at 1183 ¶ 23.

States have always had the responsibility for regulating the practice of medicine. Traditionally, "the State is primarily the judge of regulations required in the interest of public safety and welfare," *Graves v. Minnesota*, 272 U.S. 425, 428 (1926), particularly in medicine. *See also Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 387 (2002); *Semler v. Or. State Bd. of Dental Exam'rs,* 294 U.S. 608, 611 (1935). "[R]egulation of health and safety

is 'primarily, and historically, a matter of local concern,'" and the states have "'great latitude … to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.'" *Gonzales v. Oregon*, 546 U.S. 243, 270–71 (2006) (citations omitted).

Moreover, federal law makes clear that Congress did *not* intend for federal agencies to effectively override state authority to regulate the practice of medicine. *See* 21 U.S.C. § 396. Ensuring that the states retain their role in overseeing the practice of medicine is especially critical given the breathtaking growth in the FDA's scope of power since its inception. When federal drug regulations were first adopted, they focused on ensuring that products marketed to the public at large were safe and correctly labeled. *See* Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768. The goal was to give patients the truthful information they need to make informed decisions about the medicines they might take. Manufacturers were not then required to submit information to the federal government as a prerequisite to marketing. Michelle Meadows, *Promoting Safe and Effective Drugs for 100 Years*, FDA Consumer Mag., at 2 (Jan.-Feb. 2006).[8]

Although federal law has gradually shifted to require the FDA to regulate not just safety, but also efficacy, Congress' goal remains the same: to ensure that patients can, in consultation with their (state-regulated) physicians, make the best decisions possible *for themselves*—not to tell patients what they can and cannot do with their own bodies. Congress's adoption of the Right to Try Act

8. https://www.fda.gov/files/Promoting-Safe-and-Effective-Drugs-for-100-Years-%28download%29.pdf.

(21 U.S.C. § 360bbb-0) simply restated this goal as the lodestar for federal regulation of medicine.

The limited scope of FDA power *vis-à-vis* physicians is also made clear by the legal treatment of "off-label uses." Under the law, a physician may prescribe an FDA-approved product for any purpose or use, even if it is not the purpose for which the FDA approved that product. *See* 21 C.F.R. § 312.2(d) ("This part does not apply to the use in the practice of medicine for an unlabeled indication of a new drug product approved [by the FDA]."). True, the FDA has repeatedly sought to punish pharmaceutical manufacturers from truthfully communicating to physicians information about these "off-label uses," thereby intruding into regulation of the practice of medicine. But courts have repeatedly struck down those efforts as violating the First Amendment. *See United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012); *Amarin Pharma, Inc. v. FDA*, 119 F. Supp.3d 196 (S.D.N.Y. 2015).

This simply reflects the typical tendency of the FDA to expand its authority beyond its statutory ambit—and even beyond constitutional limitations—at the expense of patients' interests. Like the Caronia and Amarin courts, this Court should say no. Allowing the FDA to subject medical procedures to its labyrinthine regulations for the manufacture and sale of new drugs is unlawful—and a threat to the constitutional right of patient autonomy.

III. For the FDA to treat biological materials and surgical procedures like drugs is a regulatory mismatch and needlessly harms patients.

Although federal law entrusts the FDA with the regulation of drugs, it provides numerous exclusions and exemptions in order to ensure that the Agency does not aggrandize to itself the power to regulate medicine—and to ensure that products and procedures that are *not* drugs are not subjected to a convoluted and cumbersome regulatory regime that was not intended for anything other than drugs. The overriding reason for confining the FDA's authority in this way was to preserve and promote the goal of patient medical autonomy.

The Federal Food, Drug, and Cosmetic Act ("FDCA") gives the FDA authority to regulate "drugs," which are defined to include any "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," or that is "intended to affect the structure or any function of the body." 21 U.S.C. § 321(g)(1)(B)–(C). A product is a "biological product," and not a "drug," if it is "[m]inimally manipulated" and intended for "homologous use" only—that is, intended to perform "the same basic function" that it performed prior to the treatment. 21 C.F.R. § 1271.3(c)–(d). And even if a product is deemed a drug for purposes of federal law, it may nevertheless be exempt from FDA regulation if it consists of human cells, tissues, or cellular or tissue-based products (HCT/Ps) that "an establishment … removes … from an individual and implants … into the same individual during the same surgical procedure." 21 C.F.R. § 1271.15(b).

That description plainly applies to the treatment at issue here. Removing tissue from a patient, cleaning it,

allowing it to grow, and reinserting it into the patient is not administering to that patient something derived from another source. It is more like the kind of cosmetic surgery that involves removing fat from one part of the body and placing it in another, or the kind of heart surgery in which an artery is removed from the patient's leg and used to replace a faulty artery in the chest. Such procedures are certainly subject to regulation—but they are subject to regulation as medicine, not as the administration of a manufactured product. It bears emphasizing that the fact that a product does not fit the definition of a "drug" (or is exempt) under the FDCA does not mean it is unregulated. Biological products are subject to their own, more tailored, regulations under the Public Health Service Act ("PHSA"). 42 U.S.C. § 262(i)(1); *see also* 21 C.F.R. § 1271.10(a)(1)–(2).[9]

The fact that these other statutes and regulations exist shows that Congress was well aware of the dividing line between the regulation of products and the regulation of the practice of medicine. The former falls within the federal ambit. But the regulation of the practice of medicine is a state matter—which, again, Congress expressly recognized in 21 U.S.C. § 396, which disclaims any intent to federalize regulation of the practice of medicine.

Not only would it be regulatory mismatch—fitting a square peg into a round hole—to subject a procedure involving the removal and re-insertion of a patient's own

9. Here, the parties storing the patient's cells are registered with and inspected by the FDA, and the practitioners performing the procedures are licensed. *Cal. Stem Cell Treat. Ctr.*, 624 F. Supp.3d at 1183 ¶¶ 28, 30.

unaltered cells to regulations intended for manufactured drugs, but it would intrude into both the professional judgment of physicians and into the right of patients to decide for themselves what medical treatments to undergo.

What's more, it could hinder medical innovation, to the detriment of patients.

The regulatory pathway for approval of drugs is a cumbersome multi-step process that—after basic research and animal testing have been completed—consists of three phases, and sometimes more. To simplify what is often a complicated system, the first phase consists of basic safety evaluations in a clinical trial. U.S. Food & Drug Admin., *The Drug Development Process: Clinical Research* (2018).[10]

The second phase, which can take two or more years, assesses efficacy in addition to safety. The third stage tests the drug against placebos as well as the currently available treatments. These tests can take four years or more. For some drugs, there is yet another phase of clinical trials. Cong. Budget Office, *Research and Development in the Pharmaceutical Industry* 22–23 (Pub. No. 2589 (2006))[11]; U.S. Food & Drug Admin., *The Drug Development Process*. In total, these phases can take over a decade to complete. And until the multi-stage testing process is finished—until the FDA approves a drug for sale—pharmaceutical manufacturers may not sell it, and doctors may not prescribe it.

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10. http://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm#Clinical_Research_Phase_Studies.

11. https://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/76xx/doc7615/10-02-drugr-d.pdf.

Because these stages of approval can take so long, patients often find themselves blocked from using drugs that have not only passed basic safety but are currently being administered to other patients in Phase 3 or Phase 4 clinical trials. During this delay, patients' only opportunity to obtain access is to either qualify for participation in a clinical trial—something most patients cannot do, because they are either not *sick enough* to qualify, or are *too sick* to qualify—or through the "compassionate use" process, which is a mechanism that requires such burdensome pre-approvals that it is essentially futile in most circumstances. *See* Mark Flatten, *Dead on Arrival: Federal "Compassionate Use" Leaves Little Hope for Dying Patients*, *supra*.[12]

Under compassionate use, if (1) a physician determines that there is no comparable or satisfactory alternative therapy for a patient's serious disease, and (2) that risks of the investigational drug are comparable to the risks of the disease, and (3) the FDA determines that there is sufficient evidence of safety and efficacy to support the use and that the use will not interfere with completion of clinical trials, and (4) the sponsor submits an appropriate protocol, *then* the patient *could* obtain the medicine. 21 U.S.C. § 360bbb(b)(1)-(2). Under emergency use authorization, the FDA can authorize general public access to investigational drugs, if it makes findings that the sponsor is proceeding with clinical trials and is actively pursuing marketing approval. *Id.* § 360bbb(c).

Beneficial as these alternatives are, their applicability is extremely limited. For example, "compassionate use,"

12. https://goldwaterinstitute.org/wp-content/uploads/2016/02/Dead-On-Arrival-Report.pdf.

is so cumbersome that the paperwork required to obtain it can take 100 hours for a doctor to complete. Alexander Gaffney, *From 100 Hours to 1: FDA Dramatically Simplifies Its Compassionate Use Process,* Regulatory Affairs Prof'l Soc'y: Regulatory Focus Blog (Feb. 4, 2015).[13] Before they complete an application, they must obtain information that is often inaccessible, such as technical or proprietary data on the drug, which may not be available to the doctor. *See* Flatten, *supra* at 9. For this reason, many—perhaps most—doctors and patients don't bother trying to apply in the first place.[14] And even where an application is approved, the doctor must also abide by burdensome protocols and data-reporting requirements, essentially making him responsible for overseeing (and often funding) a miniature clinical trial for a single patient. *Id.*

Additionally, a separate committee at a hospital or medical clinic—the Institutional Review Board ("IRB")—must weigh the ethical considerations associated with the patient's use of the treatment. *Id.* Because there are no requirements on how often IRBs must meet, or how quickly they must respond to these requests, people in rural areas or far from a major university hospital,

13. https://web.archive.org/web/20181128144735/https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2015/2/from-100-hours-to-1-fda-dramatically-simplifies-its-compassionate-use-process.

14. This explains the misleading statistic sometimes offered by federal regulators, to the effect that most "compassionate use" applications are approved. The reason is that very few are ever submitted, due to the near impossibility of completing an application in the first place.

typically have few opportunities to even obtain IRB review, which adds still more delay to the process. *Id*. These and other complications mean that only about 1,200 patients per year were even able to apply for compassionate use, *id*. at 5—even though over half a million Americans die annually of cancer alone. *See* Am. Cancer Soc'y, *Cancer Facts & Figures* 1 (2025).[15]

Emergency Use Authorization is similarly cumbersome, and often applied arbitrarily, as indicated by the Ninth Circuit's ruling in a years-long FOIA case seeking information about the circumstances under which the FDA granted an authorization to the drug ZMapp in 2014. *Goldwater Inst. v. U.S. Dep't of Health & Hum. Servs*., 804 F. App'x 661 (9th Cir. 2020).

As a result of the complexities of the FDA's drug approval process, countless patients suffer and die, unable to access medicines that could help them. Patients in the midst of life-threatening illnesses do not have the luxury of waiting for lawyers or federal bureaucracy. Thus, needlessly subjecting medical procedures to the FDA's drug regulation scheme is more than just a question of administrative law. To impose such regulatory burdens also clashes with the principle of patient autonomy. That would needlessly subject patients to a system that undermines individual choice and personal dignity, cedes deeply personal decisions to bureaucrats, and leaves patients in unnecessary pain.

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15. https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/2025-cancer-facts-figures.html.

CONCLUSION

The FDA's expansive reading of its authority and its attempt to characterize the process of removing and reinserting a patient's own cells as the creation of a drug, rather than the performance of a procedure, seriously undercuts patients' medical autonomy rights and the role of the states in supervising the practice of medicine.

The petition for certiorari should be *granted*.

Dated: June 20, 2025

Respectfully submitted,

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