No.

In the Supreme Court of the United States

ABIGAIL ALLIANCE FOR BETTER ACCESS TO DEVELOPMENTAL DRUGS, *ET AL.*,
PETITIONERS,

v.

ANDREW C. VON ESCHENBACH, *ET AL.*,
RESPONDENTS.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the Due Process Clause protects the right of a terminally ill patient with no remaining approved treatment options to attempt to save her own life by deciding, in consultation with her own doctor, whether to seek access to investigational medications that the Food and Drug Administration concedes are safe and promising enough for substantial human testing.

PARTIES TO THE PROCEEDING BELOW

In the United States Court of Appeals for the District of Columbia Circuit, the appellants were the Abigail Alliance for Better Access to Developmental Drugs and the Washington Legal Foundation. The appellees were Dr. Andrew von Eschenbach, in his official capacity as Commissioner of the Food and Drug Administration, and Michael O. Leavitt, in his official capacity as Secretary of the United States Department of Health and Human Services. Mark B. McClellan was originally a defendant, but was first changed to Lester M. Crawford and now to Andrew C. von Eschenbach by operation of Fed. R. App. P. 43(c)(2).

RULE 29.6 STATEMENT

Petitioner Abigail Alliance for Better Access to Developmental Drugs is a nonprofit organization based in Fredericksburg, Virginia seeking broader availability of investigational drugs on behalf of its members and terminally ill patients generally. It has no parent company and there is no company with any ownership interest. Petitioner Washington Legal Foundation is a nonprofit public interest law and policy center based in Washington, D.C., with supporters nationwide. It also has no parent company and there is no company with any ownership interest.

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OPINIONS BELOW

The *en banc* opinion of the D.C. Circuit (Pet. App. 1a–57a) is reported at 2007 U.S. App. LEXIS 18688. The panel opinion (Pet. App. 79a–130a) is reported at 445 F.3d 470. The order granting rehearing is reported at 2006 U.S. App. LEXIS 28974 (Pet. App. 145a–46a). The panel issued a separate opinion on standing, which is reported at 469 F.3d 129 (Pet. App. 131a–44a). The district court's opinion is reported at 2004 WL 3777340 (Pet. App. 58a–78a).

JURISDICTION

The D.C. Circuit issued its *en banc* opinion on August 7, 2007. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Fifth Amendment provides that "[n]o person shall ... be deprived of life, liberty, or property, without due process of law." U.S. Const. amend. V.

STATEMENT OF THE CASE

Each year tens of thousands of Americans are terminally ill and exhaust all of the FDA-approved treatment options for their condition. Frequently they are told by their physician that their best remaining hope is a drug in Phase 2 or Phase 3 clinical trials. Some patients in that position elect to forgo further treatment and seek palliative or hospice care. Others decide they want to fight for their lives on the frontiers of modern medicine, despite the necessarily uncertain odds and risks. Those patients struggle for often rare and coveted spots in the trials, and some are successful.

This case is about the patients who cannot get into the trials—because they are too young, too sick, cannot qualify for the trial protocol, cannot travel, or because the trial is simply too small. FDA policy is that those patients may seek access to the drug outside of the trial, and a willing drug company may provide it, *only* if they come to the FDA, fill out a mountain of regulatory paperwork, and convince FDA officials that the likely benefits outweigh the risks. Petitioners contend that a terminally ill patient with no

approved treatment options has a right to decide *for himself*, in consultation with his own doctor, whether to take a drug that the FDA concedes is safe and promising enough to be tested in substantial numbers of human subjects.

That right is fully consistent with the history and traditions of our Nation, including the history of drug regulation and the traditional rights to self-defense and to be free from interference with private rescue efforts. The Framers called self-preservation the "first law of nature"—the first and most self-evident of the natural rights of man. This Court has already recognized a fundamental right to defend one's own life by medical means, by holding that a woman always has a right to an abortion that is necessary to save her life or protect her health—even after viability, and even in some circumstances if the government disagrees with her doctor's judgment. This Court has also recognized a fundamental right to refuse all medical treatment, including nutrition and hydration, despite our society's deep reverence for life and historical prohibitions against suicide. It cannot be the law that a patient has a fundamental right to seek medical treatment *only* if it involves the incidental destruction of a human fetus. And if a patient has a right to refuse all treatment and die, surely she also has a right to assume some risks in a good faith attempt to save her life.

The D.C. Circuit nonetheless held that FDA regulations interfering with the medical judgment of terminally ill patients and their doctors do not implicate fundamental rights, and should be subjected to nothing but rational basis review. That is a profound and important error. This Court has rightly urged caution in substantive due process cases, but as the dissent below noted "[t]o deny the constitutional importance of the right to life and to attempt to preserve life is to move from judicial modesty to judicial abdication." Pet. App. 46–47a. The D.C. Circuit's decision abandons the textual commitment to "life" in the Due Process Clause, creates bizarre inconsistencies with this Court's cases, and denies thousands of Americans their most important rights.

Regulatory Background

The Food, Drug, and Cosmetic Act ("FDCA"), Pub. L. No. 75-717, §§ 1-902, 52 Stat. 1040 (1938), as amended by 21 U.S.C. §§ 301 *et seq.*, requires a drug manufacturer to file an application and receive FDA approval before introducing any "new drug" into commerce. 21 U.S.C. §§ 355(a), 321(p). The original 1938 version only gave the FDA the authority to review the *safety* of new drugs. The FDA was given the authority to evaluate the *effectiveness* of new drugs in 1962.

Congress authorized an exception for drug distribution "intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs." *Id.* § 355(i)(1). The investigation process generally follows three phases. "Phase 1" trials usually involve 20 to 80 subjects, and are intended to "determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness." 21 C.F.R. § 312.21(a). "Phase 2" normally involves controlled clinical studies of several hundred subjects, intended to "evaluate the effectiveness of the drug for a particular indication or indications ... and to determine the common short-term side effects and risks associated with the drug." *Id.* § 312.21(b). "Phase 3" involves expanded controlled and uncontrolled trials, often including several hundred to several thousand subjects, "performed after preliminary evidence suggesting effectiveness of the drug has been obtained." *Id.* § 312.21(c). On average, it takes about eight years for a drug to pass through all stages.

The FDA has recognized that the statutory exception for "investigational use," 21 U.S.C. § 355(i)(1), permits the treatment use of "investigational new drugs" ("IND") prior to full approval, even outside the context of a formal clinical trial. The "treatment IND" regulations allow a physician or sponsor to submit a proposal for the use of a drug in the treatment of patients not in clinical trials. 21 C.F.R. §§ 312.34, 312.35. The FDA authorizes treatment IND only if the drug is "intended to treat a serious or immediately

life-threatening disease," "[t]here is no comparable or satisfactory alternative drug or other therapy available to treat that stage of the disease," "[t]he drug is under investigation in a controlled clinical trial," and "[t]he sponsor of the controlled clinical trial is actively pursuing marketing approval." *Id.* § 312.34(b)(1)(i)–(iv). But it reserves the right to deny any request if, in its judgment, the evidence does not provide a reasonable basis for concluding that the drug "[m]ay be effective for its intended use in its intended patient population" or that it would not expose patients to "an unreasonable and significant additional risk of illness or injury." *Id.* § 312.34(b)(3)(i). FDA regulations also forbid sponsors from "charging a price larger than that necessary to recover costs of manufacture, research, development, and handling of the investigational drug." *Id.* § 312.7(d)(3).

Once a drug has been approved as safe and effective for any condition, physicians may prescribe it "off-label" in any other circumstances where the physician believes that the available scientific evidence justifies its use. Steven R. Salbu, *Off-Label Use, Prescription, and Marketing of FDA-Approved Drugs: An Assessment of Legislative and Regulatory Policy*, 51 Fla. L. Rev. 181, 188–92 (1999).

Statement of Facts

Because the district court granted respondents' motion to dismiss for failure to state a claim, the allegations of petitioners' complaint must be accepted as true.

Patients with life-threatening illnesses face immense regulatory barriers to obtaining promising new medications from drug sponsors that are willing to sell or donate them during the years of clinical testing. Am. Compl. ¶¶ 16–18. Evidence of a new drug's effectiveness is often available to physicians specializing in that disease long before the FDA approves it. *Id.* But current regulations provide access only to an extremely small patient population. Spaces in clinical trials are limited and carry stringent criteria in terms of patient condition and treatment history. "Treatment IND" programs are authorized for only a small fraction of those terminally ill patients in desperate need. Those programs

are small, when they exist, in part because companies may not charge more than cost recovery. *Id.* ¶ 18. Terminally ill patients are often willing to assume risks if their physicians advise them that a treatment may save or prolong their lives and if they have no other viable options. *Id.* ¶ 19. The effect of FDA policy is to deny patients this choice.

Abigail Burroughs learned at age nineteen that she had head and neck cancer. For the next eighteen months, Abigail fought the cancer with painful chemotherapy and radiation, to no avail. Abigail was told in March of 2001 that she had run out of FDA-approved options. Her cancer cells had very high levels of a receptor called EGFR, and her renowned oncologist at Johns Hopkins believed there was a significant chance of saving her life if she could get the new EGFR cancer drug Erbitux. *Id.* ¶ 22. Early trial results presented at the May 24, 2000 meeting of the American Society of Clinical Oncology showed a remarkable response rate in patients with head and neck cancer for whom chemotherapy alone no longer worked. "All observable signs of the cancer were eliminated in 13 (87 percent) of the 15 patients who received the drug in combination with radiation therapy. In the remaining two patients, the tumors shrank but did not completely disappear."[1]

Abigail could not get into the Erbitux trials, and died on June 9, 2001, at the age of twenty-one. *Id.* Erbitux was approved in 2004. Dr. Mark Thornton, one of the FDA medical reviewers involved in that approval, has stated publicly that there was "'extremely compelling' data on Erbitux for head and neck cancer as early as 2000," and that "'it was hard to argue against providing it to patients.'"[2]

Petitioner Abigail Alliance was founded by Abigail, her father, and other patients and family members to fight for improved access to drugs currently in clinical trials. It helps patients and their families navigate the often byzantine

[1] *See Monoclonal Antibody Drug IMC-C225 Shows Wide Promise*, Am. Cancer Society News Ctr., May 24, 2000, *available at* http://tinyurl.com/y2kqcr.

[2] *Drug Reckoning*, Wall St. J., Mar. 6, 2006, at A14.

regulatory process, works with drug companies and the FDA to create and expand access programs, advocates for the approval of promising new therapies, and pushes for changes to FDA regulations that interfere with patient access or discourage drug companies from participating in expanded access programs. Although many of the Alliance's members are lost to their diseases, it represents an ongoing constituency of new patients who find themselves terminally ill and without any remaining approved treatment options.

When the FDA challenged standing after the panel opinion in this case, the Alliance submitted several affidavits from current members. It also sought leave to amend the complaint to add allegations that FDA regulations have "frustrated Abigail Alliance's efforts to assist its members and the public in accessing potentially life-saving drugs and its other activities, including counseling, referral, advocacy, and educational services," and have caused it "to divert significant time and resources from these activities toward helping its members and the public address the unduly burdensome requirements that the FDA imposes on experimental treatments." Am. Compl. ¶ 6. The panel granted leave to amend. Pet. App. 133a.

Proceedings Below

Petitioners filed this action on July 8, 2003, in the U.S. District Court for the District of Columbia. The complaint alleges that FDA regulations violate the Due Process rights of terminally ill patients with no approved treatment options, by denying them both life and the liberty to decide, in consultation with their own physicians, whether to take a drug that is currently in Phase 2 or Phase 3 trials and that the company is willing to make available. Compl. ¶¶ 1–2. It also alleges that FDA regulations prohibiting companies from earning any profit on the sale of investigational drugs violate Due Process. Compl. ¶ 15 & pp. 10-11.

The district court held that the complaint was ripe and not barred by exhaustion principles, but dismissed for failure to state a claim. It held that under the D.C. Circuit's decision in *Dronenburg v. Zech*, 741 F.2d 1388 (D.C. Cir.

1984), it lacked authority to recognize a "new" fundamental right not already recognized by this Court, and that FDA regulations have a rational basis. Pet. App. 72a–78a.

A divided panel of the D.C. Circuit reversed, holding that the right sought by appellants satisfies the restrictive *Washington v. Glucksberg*, 521 U.S. 702 (1997), test for fundamental rights because it is deeply rooted in the traditional doctrines of self-defense and interference with rescue, and because federal regulation of the effectiveness of drugs has been too recent and haphazard "to establish that the government has acquired title to this right by adverse possession." *Id.* at 99a–100a & n.24, 105a. The panel also held that that right is "implicit in the concept of ordered liberty," based in part on this Court's reasoning in *Cruzan v. Director, Mo. Dep't of Health*, 497 U.S. 261, 279 (1990). *Id.* at 100a. It remanded for the district court to determine whether FDA policies burdening that right are narrowly tailored to compelling state interests. *Id.* at 105a. The panel later issued a separate opinion unanimously concluding that Abigail Alliance has both organizational standing in its own right, and representational standing on behalf of particular terminally ill members. The court held that even though the patients originally named in the complaint have now died, the Alliance had demonstrated a "continuing interest" through the affidavits of new members. *Id.* at 139a.

The *en banc* court vacated the panel's merits opinion (but not its standing opinion) and reversed. It concluded that FDA regulation is "consistent with our historical tradition of prohibiting the sale of unsafe drugs," *id.* at 18a, citing early laws governing adulterated or contaminated drugs. It held that the "arguably limited" history of efficacy regulation prior to 1962 did not establish a fundamental right, because "Congress and the FDA have continually responded to new risks presented by an evolving technology" and have invoked Congress's "well-established power to regulate in response to scientific, mathematical, and medical advances." *Id.* It held that self-defense, the tort of interference with rescue, and this Court's "life or

health of the mother" abortion cases provide no support for a right to seek investigational drugs, because those doctrines protect only "necessary" life-saving measures and "[t]he Alliance seeks access to drugs that are experimental and have not been shown to be safe, let alone effective at (or 'necessary' for) prolonging life." *Id.* at 22–25a.

Judge Rogers and Chief Judge Ginsburg dissented, arguing that the majority "fails to come to grips with the Nation's history and traditions, which reflect deep respect and protection for the right to preserve life, a corollary to the right to life enshrined in the Constitution." *Id.* at 32a. They reviewed the historical foundations of the rights to self-defense and to be free from interference with rescue efforts, and wrote that the majority's holding that unproven drugs are not "necessary" for saving life "commits a logical error of dramatic consequence" by "confus[ing] what is necessary with what is sufficient." *Id.* at 33a, 41a. "By the court's reasoning, it is not 'necessary' for the driver of a car that is hurtling toward a cliff to press the brake because 'we cannot know until after' he has done so whether the car will stop in time." *Id.* at 41a. The dissent pointed out that this Court has recognized a fundamental right to abortion whenever "'it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother,'" and has never "intimated that the government may ban procedures that represent a patient's only chance of survival because they might not be successful." *Id.* at 42a, 44a.

The dissenters also noted that the statutes the majority relied upon to show a supposed history of "safety" regulation "address misbranded or adulterated drugs, sales of poisons, and fraudulent curative claims," none of which "suggest[ed] that a physician could not prescribe a new medication for a terminal patient." *Id.* at 53a–54a.

The dissenters concluded that even "[s]etting aside the textual anchor of the Alliance's claim in the right to life, the claimed right also falls squarely within the realm of rights implicit in ordered liberty." *Id.* at 56a. "Denying a terminally ill patient her only chance to survive without

even a strict showing of governmental necessity presupposes a dangerous brand of paternalism" and is "directly at odds with this Nation's history and traditions." *Id.* at 57a.

REASONS FOR GRANTING THE WRIT

Substantive due process cases are often controversial, but this one should not be. All that petitioners seek is a right for terminally ill patients with no remaining treatment options to fight for their own lives, by taking a drug that their doctors have concluded is justified by the available scientific evidence and that the FDA itself would let them take if they were lucky or well-connected enough to get a spot in the trial. The FDA concedes that given the available evidence a trial involving several hundred or several thousand patients is ethical, and that patients can reasonably decide to participate and give informed consent.

A terminally ill patient's right to make that same choice is "implicit in the concept of ordered liberty" if anything is. The stakes are literally life and death, and beyond the medical consequences these decisions express the patient's basic philosophical commitments, how she chooses to face the prospect of death, and how she hopes to be remembered. These decisions are at least as central to an individual's right to define the course and meaning of her own life as the decisions about marriage, procreation, parenting, and sex that this Court has held implicate fundamental rights.

The right sought by petitioners is also firmly grounded in historical tradition, which until 1962 left decisions about the efficacy of medical treatments to patients and their doctors. That deference to private medical judgment reflected traditional views about the limits of the police power, as well as the ancient common law right to take action thought necessary for self-preservation or the rescue of others. This Court has already recognized a fundamental right to attempt to save one's life in the abortion context. This case just calls for an application of those principles in a medical context without the countervailing historical and moral considerations that make the abortion cases difficult.

The D.C. Circuit majority engaged in what the dissent rightly calls "tragic wordplay." Pet. App. 57a. It ignored the textual basis of the right to life and to self-preservation. It committed the precise error this Court warned against in *Glucksberg*, by inferring a broad historical tradition of regulating the "safety" of drugs from early laws that in fact prohibited only *adulterated* or *contaminated* drugs and left the safety and efficacy of accurately labeled substances to the judgment of patients and doctors. It misstated the traditional common law by suggesting that self-defense or rescue efforts were protected only if likely to succeed. (To the contrary, the law has always recognized a right to fight back even when resistance is obviously futile and dangerous, and interfering with rescue efforts has always been tortious even if the rescue is unlikely to succeed). And it completely failed to engage with this Court's cases holding that a woman has a right to an abortion at any stage of pregnancy if her life or health is threatened. This Court has never required proof that the procedure will *succeed* in preserving the mother's life or health as a condition of the right to try.

The D.C. Circuit's decision also leaves the rights of dying Americans as a bizarre and senseless patchwork. This Court has recognized that even fairly healthy patients have a fundamental right to refuse life-sustaining treatment (including nutrition and hydration) and die, despite our society's strong preference that they instead choose to live. The D.C. Circuit has now held that a terminally ill patient with no other options has no right to make the opposite choice: to assume some risks and possible suffering in a good faith effort to fight for his life by the only means available. Five Justices of this Court left open in *Glucksberg* that the Due Process Clause may protect a right to palliative pain treatment, even if it might shorten the patient's life. The D.C. Circuit has held that there is no right to *potentially life-saving* medical treatment, precisely because the FDA fears the treatment might instead shorten the patient's life. And, finally, a woman dying on an operating table has a settled fundamental right to have her doctor administer

medical treatment believed to be necessary to save her life but that is otherwise unlawful—if that treatment happens to be a late-term abortion. The D.C. Circuit has now held that she has no such right if the treatment is an investigational cancer vaccine that could harm no one but (possibly) herself. These contradictions turn the traditional values that the Due Process Clause is supposed to reflect upside down.

This case presents issues that have vexed and divided courts and commentators ever since the FDCA was passed, and on which this Court's most analogous precedents take "radically differing approaches ... resulting in a glaring doctrinal inconsistency."[3] It involves the most important rights of many thousands of terminally ill Americans, who deserve an answer to these life-or-death questions from this Court. And it presents an opportunity to bring some clarity to the conflicts and confusion that have arisen in the courts of appeals in the wake of *Glucksberg*.

The FDA may assert public policy objections to expanding access to drugs. These are narrow tailoring issues for remand. If the treatment decisions of terminally ill patients and their doctors must be overridden for compelling societal reasons, then so be it. But the basic dignity and humanity of these patients, and the magnitude of the stakes for their own lives and families, demands a better justification for disregarding their own choices than merely rational basis review. Certiorari should be granted.

I. REVIEW IS WARRANTED BECAUSE THE D.C. CIRCUIT DECISION IS INCONSISTENT WITH HISTORICAL TRADITION AND THIS COURT'S PRECEDENTS

This Court has explained that the Due Process Clause protects rights that are "'implicit in the concept of ordered liberty,'" and "'deeply rooted in this Nation's history and tradition.'" *Glucksberg*, 521 U.S. at 721 (citations omitted). The right of terminally ill patients with no other options to

[3] B. Jessie Hill, *The Constitutional Right to Make Medical Treatment Decisions: A Tale of Two Doctrines*, 86 Tex. L. Rev. (forthcoming 2007), *at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1016203 at p. 6.

take investigational drugs that the FDA has approved for substantial human trials satisfies both standards.

A. Allowing Individual Choice Concerning Potentially Life-Saving Drugs Is Implicit In The Concept Of Ordered Liberty

The right of a terminally ill patient, with no approved treatment options, to take some risks on an investigational treatment in an effort to save her life is "implicit in the concept of ordered liberty" under any reasonable standard.

In *Cruzan*, this Court recognized that "[t]he principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions," and even assumed that the Due Process Clause "would grant a competent person a constitutionally protected right to refuse lifesaving hydration and nutrition," and thereby choose death, even if she was not terminally ill. 497 U.S. at 278-79. Five Justices of this Court also reserved judgment in *Glucksberg* about whether the Due Process Clause would protect a right to obtain palliative medicine sufficient to alleviate pain, even if it hastens death. *See* 521 U.S. at 736-38 (O'Connor, J., concurring); *id.* at 745 (Stevens, J., concurring); *id.* at 779-82 (Souter, J., concurring); *id.* at 791-92 (Breyer, J., concurring). If a patient has a fundamental right to starve herself to death, or perhaps to take pain medication the State would prefer to restrict, then surely she has a right to choose to fight for her life by taking a potentially life-saving drug even if it has not yet met the FDA's full approval standards. The patient's autonomy interests are the same no matter which decision she makes, and if she chooses to seek experimental treatment she is also invoking her traditional right to self-defense, discussed *infra*, and her fundamental right to *life*, which is protected along with liberty in the plain text of the Due Process Clause. This Court recognized in *Cruzan* that "[t]he choice between life and death is a deeply personal decision of obvious and overwhelming finality," and that "[i]t cannot be disputed that the Due Process Clause protects an interest in

life as well as an interest in refusing life-sustaining medical treatment." 497 U.S. at 281.

Even leaving aside the possibility of saving or extending life, FDA interference with private medical decision-making denies patients the autonomy to make what may be the last profound, self-defining choice in their lives. This Court has repeatedly held that the Constitution protects a basic right of autonomy in making critically important and private decisions. Whether that right is located in the "liberty" protected by the Due Process Clause or is implied by the more specific provisions of the Bill of Rights, *see Griswold v. Connecticut*, 381 U.S. 479, 484 (1965), it embraces the freedom for individuals to decide for themselves whom to marry, *Loving v. Virginia*, 388 U.S. 1 (1967); *Zablocki v. Redhail*, 434 U.S. 374 (1978), how their children will be raised and in what language they will be educated, *Meyer v. Nebraska*, 262 U.S. 390 (1923); *Wisconsin v. Yoder*, 406 U.S. 205 (1972), whether to possess and view pornography in the home, *Stanley v. Georgia*, 394 U.S. 557 (1969), and whether to engage in private sexual relationships, *Lawrence v. Texas*, 539 U.S. 558 (2003). It also guarantees the right to make personal medical decisions, including a right of access to contraceptive drugs the State has banned, *Griswold*, 381 U.S. 479 (1965); *Eisenstadt v. Baird*, 405 U.S. 438 (1972).

Decisions concerning the treatment of life-threatening diseases are among the most private and significant in life. Unlike even choices involved in marriage, parenting, and sexual behavior, medical decisions "are, to an extraordinary degree, intrinsically personal. It is the individual making the decision, and no one else, who lives with the pain and disease ... [and] must live with the results of that decision." *Andrews v. Ballard*, 498 F. Supp. 1038, 1047 (S.D. Tex. 1980). The personal nature of medical decisions is amplified for terminally ill patients with no approved options.

The autonomy interests of these patients cannot be reduced to an empirical disagreement between their doctors and the FDA about how likely it is that a particular drug will help them. These decisions often express the patient's

life circumstances and philosophical commitments as well as her cold assessment of the statistical response rates. Are the last days of a person's life better spent in painful struggle against nearly impossible odds, but with some hope and the conviction that she is doing everything possible? Or is it instead better or more noble to accept one's fate and spend the final days saying goodbye and hoping passively for a spontaneous remission? The patient's interest in weighing those values for herself transcends any disagreement about how to interpret the evidence from a particular clinical trial. As Justice Stevens explained in *Glucksberg*, respecting a patient's own choices "gives proper recognition to the individual's interest in choosing a final chapter that accords with her life story, rather than one that demeans her values and poisons memories of her." 521 U.S. at 746-47 (Stevens, J., concurring).

The dissent's observations about "tragic wordplay" are very apt. Pet. App. 57a. Of course it would have been easy for petitioners to frame this right in grander and more abstract terms, such as a right to medical autonomy or the preservation of life, which would have made its deep roots in other legal principles (and in the Due Process Clause's explicit textual commitment to "life") more obvious. Petitioners could then have explained that at least in this one area—terminally ill patients with no other options who want to take drugs already in Phase 2 or Phase 3 testing—restrictions on patients' freedom to decide for themselves are very unlikely to be justified under strict scrutiny. It is always possible to describe a right broadly and leave more of the hard work to narrow tailoring review, but that is not what *Glucksberg* calls for.[4] As the dissent points out, the

[4] The majority's skepticism that any fundamental right could be defined by reference to the contours of the current regulations is similarly misplaced. Petitioners refer to Phase 2 only because that is the point at which the FDA currently concedes the evidence of safety is sufficient for substantial human testing to be ethical and appropriate. The interests of both patients and society take on a different character at that point; before it, for example, restrictions might be justified by analogy to the handful of early statutes prohibiting the sale of poisons. Of course under

D.C. Circuit essentially criticized petitioners for adhering to *Glucksberg*, or for "anticipating a justification for infringing the right that might survive strict scrutiny." Pet. App. 36a. "Applying the court's reasoning today, had 'Jane Roe' been prescient enough to claim a right to abort a pre-viable fetus by a procedure that is demonstrably safer than all other alternatives, *cf. Gonzales v. Carhart*, 127 S. Ct. 1610, 1638 (2007), she would have failed to show a fundamental right to an abortion." *Id.* at 36a.

B. Allowing Terminally Ill Individuals To Select Drugs With Their Physicians Is Deeply Rooted In Historical Tradition

1. Self-Defense and Rescue

The traditions of our country and the common law have always recognized that persons in mortal peril have the right to try to save their own lives, even if the chosen means would otherwise be illegal or involve enormous risks. That commitment is reflected in several doctrines, including self-defense, necessity, and the tort of interference with rescue. The persons who framed and ratified the Constitution understood those doctrines as a core aspect of traditional Anglo-American liberty, and would have viewed the intrusion at issue here in those terms.

As Samuel Adams explained in 1772, "[a]mong the natural rights of the Colonists are these: First, a right to life; Secondly, to liberty; Thirdly, to property; together with the right to support and defend them in the best manner they can. These are evident branches of, rather than deductions from, the duty of self-preservation, commonly called the first law of nature." Samuel Adams, *The Rights of the Colonists: Report of the Committee of Correspondence to the Boston Town Meeting*, 7 Old South Leaflets 417, 417 (No. 173) (Burt Franklin 1970) (1772). The right to take action thought necessary to self-preservation was commonly understood during the colonial period as the "first law of nature." *See* 1 St. George Tucker, *Blackstone's Commentaries* app. at 300 (1803).

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a different regulatory regime that line might bear a different label.

Of course state law on self-defense has always differed on some details. But courts have recognized throughout our history that at least the core of the right to defend one's own life is constitutionally protected. "Rooted in the Anglo-American tradition is the belief that a killing in self-defense is not a crime." *Thomas v. Leeke*, 725 F.2d 246, 249 n.2 (4th Cir.) (abrogated on other grounds), *cert. denied*, 469 U.S. 870 (1984). The Sixth Circuit has held that "the right of a defendant in a criminal trial to assert self-defense" is one of the "few customs and principles 'so rooted in the traditions and conscience of our people as to be ranked as fundamental.'" *Taylor v. Withrow*, 288 F.3d 846, 851 (6th Cir.) (citations omitted), *cert. denied*, 537 U.S. 1007 (2002). A plurality opinion of this Court recognized that "the historical record may support" the proposition "that the right to have a jury consider self-defense evidence ... is fundamental." *Montana v. Egelhoff*, 518 U.S. 37, 56 (1996). Many state supreme courts have reached the same conclusion, under both the federal and state constitutions. *See* Eugene Volokh, *Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 Harv. L. Rev. 1813, 1819–20 (2007) (reviewing cases).

Threatened persons may use any means they choose, not simply the best or least harmful, to protect themselves.[5] A person is entitled to defend himself against animals, children, and the insane, and is even blameless if he inadvertently kills an innocent bystander. Volokh, *supra*, at 1817. There is no moral or legal difference between attack by an animal and attack by mutated cancer cells. And this situation does not raise any of the borderline issues in self-defense that are outside the protected core. *Id* at 1829–32.

The D.C. Circuit rejected any analogy to self-defense on

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[5] *See Gross v. Commonwealth*, 186 S.W.2d 190, 193 (Ky. 1945) ("'[D]efendant was justified in using any means at hand to protect himself, his body and life against harm ....'") (quoting jury charge approvingly); *State v. Jordan*, 5 S.E.2d 156, 157 (N.C. 1939) ("'any means at his command'") (same); *Hall v. State*, 60 S.W. 769, 770 (Tex. Crim. App. 1901) ("any means within his power").

the ground that petitioners want to take risks "in pursuit of *potentially* life-saving drugs ... with no proven therapeutic effect." Pet. App. 24a. But the law has never required proof that self-defense measures are certain or even likely to succeed. A person has a right to defend himself even in circumstances or ways that government officials might consider futile, imprudent and excessively dangerous. A woman threatened with rape is entitled to resist by any means at hand, even if they stand essentially no chance of success and will substantially increase the risk that she will be killed. Safety guidelines counsel persons being mugged to turn over their possessions and flee, and the conventional wisdom is that attempted self-defense by firearm is often counterproductive. Fighting back may dramatically increase the risk, but remains within the victim's rights.

Efforts to save the lives of others are also traditionally protected. The common law tort of interference with rescue imposes liability upon anyone who intentionally prevents a third person from giving another aid necessary to prevent physical harm. *See* Restatement (Second) of Torts § 326. "[P]reventing the third person from using a chattel" in order to effect a rescue is also tortious. *Id.* cmt. a. Government interference with private rescue attempts have been held to violate due process. *E.g., Ross v. United States*, 910 F.2d 1422, 1433-34 (7th Cir. 1990) (officer liable for preventing private dive rescue until arrival of on-duty personnel).

The D.C. Circuit reasoned (as with self-defense) that the Restatement defines the tort as interference with rescue efforts "*necessary* to ... bodily security," and that petitioners seek access to drugs that "have not been shown to be safe, let alone effective at (or 'necessary' for) prolonging life." Pet. App. 39a, 40a (emphasis added). Thus, in its view, "[i]t is difficult to see how a tort addressing interference with providing 'necessary' aid would guarantee a constitutional right to override the collective judgment of the scientific and medical communities expressed through the FDA's clinical testing process." *Id.* at 23a.

Describing FDA's interim decisions as "the collective

judgment of the scientific and medical communities" is absurd.[6] *Id.* And petitioners do not propose to "override" any "judgment[s]" produced by the FDA's testing process; they seek access to drugs about which the FDA is still agnostic, not drugs it has tested and rejected. Regardless, the law has never required proof that rescue efforts would be certain or even likely to succeed; it is interference with the *chance* of rescue that is tortious. (Futility may be relevant to causation and damages, but that is a different issue). In *Ross*, the Seventh Circuit held that a sheriff violated due process by interfering with a private dive team that wanted to try to rescue a boy who had already been underwater as long as ten minutes. 910 F.2d at 1424. As the dissent below observed, the majority "confuses what is necessary with what is sufficient." Pet. App. 40a.[7]

The application of traditional self-defense and rescue principles in the medical context can be seen most clearly by

[6] As the dissent points out, that assertion is inconsistent with the allegations that must be taken as true. Pet. App. 45a. It is also obviously incorrect. FDA frequently makes decisions that large numbers (and sometimes most) of the relevant specialists disagree with. Its long delay in approving the abortion pill RU-486 had little if any medical support. And it recently denied approval of a cancer vaccine called Provenge for technical statistical reasons, despite the vote of its own scientific advisory committee that Provenge is safe and effective. Over its history Abigail Alliance has pushed for earlier access to several drugs , and every one has later been approved by the FDA—which shows that doctors outside the FDA often can make good decisions about how to treat a particular patient well before the FDA is ready to approve the drug. The FDA "attaches inordinate weight to the visible adverse consequences of bad drugs and puts aside the less visible costs that result when sick people suffer and die because they are denied access." Richard A. Epstein, *Overdose: How Excessive Government Regulation Stifles Pharmaceutical Innovation* 10–11 (Yale Univ. Press 2006).

[7] The D.C. Circuit also discussed an analogy to the separate doctrine of necessity, which further supports petitioners' point that persons in life-threatening circumstances have always been exempted from ordinary legal requirements. In part because necessity cases often involved injury to the rights of non-threatening third-parties, however, the precedents are more fractured and yield fewer clear principles. *See, e.g.*, Volokh, *supra*, at 1826 n.65. Petitioners believe necessity is relevant, but that self-defense and interference with rescue cases are better analogies.

looking at the one medical procedure sometimes banned at common law: abortion. In *Roe*, this Court recognized a controversial new right to abortion during the first two trimesters as a requirement of constitutional privacy. But it also recognized another, entirely separate right to abortion: a woman's right to abort a fetus *at any stage of a pregnancy* if doing so "is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother." *Roe v. Wade*, 410 U.S. 113, 165 (1973); *see also Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 879 (1992).

This second right to abortion was always firmly entrenched in historical tradition. *Roe*, 410 U.S. at 130–41. It is also based on self-defense rather than privacy. *See, e.g.*, Volokh, *supra*, at 1824; *Steinberg v. Brown*, 321 F. Supp. 741, 747 (N.D. Ohio 1970) (approving statute providing that "abortion is noncriminal when it is necessary, or declared by two physicians to be necessary, to preserve the life of the mother" because "throughout the development of our law, self-defense has always been recognized as a justification for homicide"); *see also McRae v. Califano*, 491 F. Supp. 630, 695 (E.D.N.Y. 1980) (relying on testimony that "[t]he exception allowing abortion in the case in which the mother's life is threatened was in the nature of a justifiable homicide, the equivalent to killing in self-defense"). That right has never depended on proof that an abortion would be *successful* in preserving the mother's life or health. It exists whenever a therapeutic abortion is *necessary*, in the exercise of "appropriate medical judgment."

This Court reaffirmed the right to abortion necessary to protect the mother's life or health, and the "appropriate medical judgment" standard, *unanimously* just last Term. *Ayotte v. Planned Parenthood of N. N.E.*, 546 U.S. 320, 327 (2006). New Hampshire argued in *Ayotte* that its abortion statute did not need a health exception because it was supplied by the State's general "competing harms" defense—basically a codification of common law self-defense and necessity principles. *See Planned Parenthood of N. N.E. v. Heed*, 390 F.3d 53, 61 (1st Cir. 2004). This Court did

not think the defense clear enough, but the argument illustrates the self-defense roots of these exceptions.

That right to try to save one's own life by medical means is illustrated most dramatically by *Stenberg v. Carhart*, 530 U.S. 914 (2000), in which the State of Nebraska, backed by various medical groups, contended that partial birth abortion should be banned even when necessary to protect the *health* of the mother (threats to her life were excepted) because the procedure "may create special risks" to the mother not posed by other procedures, and because "there are no medical studies 'establishing the safety of the partial-birth abortion/D&X procedure.'" *Id.* at 933 (citation omitted). This Court acknowledged the "division of opinion among some medical experts ... [and] absence of controlled medical studies that would help answer these medical questions." *Id.* at 936-37. It nonetheless held that since "[d]octors often differ in their estimation of comparative health risks and appropriate treatment," the state must "tolerate responsible differences of medical opinion—differences of a sort that the American Medical Association and American College of Obstetricians and Gynecologists' statements together indicate are present here." *Id.* at 937. In other words, no abortion statute can interfere with the responsible medical judgment of a woman and her doctor—even if other doctors believe the procedure unsafe and no scientific evidence resolves that dispute.

Of course this Court was divided in *Stenberg*, and placed substantial limits on that decision last Term in *Gonzales v. Carhart*, 127 S. Ct. 1610 (2007). But the point that divided the Court in *Stenberg* and ultimately produced *Gonzales* was a legislative determination that the banned procedure is medically unnecessary because there are always other safe alternatives. Congress made a finding that partial-birth abortion "'is a gruesome and inhumane procedure that is never medically necessary.'" *Id.* at 1624 (citation omitted). This Court held that "[a]lternatives are available to the prohibited procedure," and that "[p]hysicians are not entitled to ignore regulations that direct them to use

reasonable alternative procedures." *Id.* at 1637, 1636. But this Court *unanimously* agreed that under *Ayotte* and *Casey* a restriction on medical practice "would be unconstitutional ... if it 'subject[ed] [women] to significant health risks.'" *Id.* at 1635 (citation omitted) (alterations in original); *see also id.* at 1641–42 (Ginsburg, J., dissenting). Accordingly this Court held out the possibility of "as applied" challenges if, in a particular case, a woman could show that the alternative procedures would be inadequate to protect her health. *Id.* at 1638–39. (It also bears noting that the statutes at issue in *Stenberg* and *Gonzales* did not even apply when the woman's *life* is threatened.)

The FDA has not made any finding that "reasonable alternative [treatments]" are available to petitioners, or that the drugs they seek are unsafe, ineffective, or unnecessary. Petitioners have *no* medical alternatives, the FDA has made an expert judgment that these drugs are safe enough for substantial human testing, and it has made no findings on efficacy either way.[8] And because these patients are terminally ill, denying them access to the only therapies that have any hope of helping certainly "subject[s] [them] to significant health risks." This case is thus far easier and more compelling than the "as applied" challenges authorized by *Gonzales*—which would require a court to override Congress's express finding that partial-birth abortion is never medically necessary.[9] The problem of judicial deference to legislative fact-finding that made *Stenberg* and *Gonzales* so difficult is not present here. Petitioners are not questioning any scientific or medical factual finding by the FDA for which judicial second-guessing might be ill-suited.

[8] The D.C. Circuit suggested that "safe for limited clinical testing in a controlled and closely-monitored environment ... does not mean ... safe for use beyond supervised trials." Pet. App. 17a. Petitioners are claiming a right to take these drugs *under medical supervision*, and would not object if the FDA imposed narrowly tailored monitoring requirements.

[9] Petitioners also contend that FDA regulations are unconstitutional only *as applied* to a narrow class of patients. This case is procedurally identical to *Glucksberg*, which held that such cases are "'atypical but not uncommon.'" 521 U.S. at 709 n.6 (citations omitted); *id.* at 735 n.24.

They challenge the FDA's *values judgment* that, in the face of acknowledged scientific uncertainty, paternalistic caution is more important than autonomy—and avoiding false hope or any risk of harm is more important than the chance of saving life. Those are precisely the sorts of judgments that constitutional law is well-equipped to test.

2. The History of Drug Regulation

There is no real dispute about the history. Early drug regulation was directed at adulterated or mislabeled drugs so that patients and doctors could be sure about what they had. Edward Kremers & George Urdang, *History of Pharmacy: A Guide and a Survey* (J.B. Lippincott Co. 1940). There were also a handful of statutes restricting the sale of poisons in states with large slave populations. Public concern about *contaminated* food and drugs eventually led to the 1906 Food and Drugs Act. Federal Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (repealed 1938). But that Act still just mandated that the contents be correctly and fully described. In *United States v. Johnson*, 221 U.S. 488 (1911), this Court held that the 1906 Act did not prohibit a company from marketing an ineffective cancer remedy with false therapeutic claims, so long as it was not adulterated. In 1938 Congress enacted the FDCA, which authorized the FDA to review the safety of new drugs. But it was not until 1962 that Congress first authorized review of whether new drugs were *effective*. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780. And even after 1962, the FDA has always permitted doctors to exercise their own judgment about "off-label" uses, where, by definition, the clinical proof of effectiveness is not sufficient to satisfy the FDA. Many current treatments are "off-label," such as the widespread use of Thalidomide to treat cancer when, until recently, it was approved only for leprosy.

The majority tried to recast the history of regulation for contamination or mislabeling as regulation for "safety."[10]

[10] The majority's offhand suggestion that *efficacy* regulation existed before 1962 is unexplained and incorrect. There was common law liability for making false therapeutic claims, but that is irrelevant. Petitioners do

But that regulation was always directed at ensuring that doctors and patients knew what they had. The government never interfered on "safety" grounds with doctors' judgments about whether to administer an *accurately labeled* substance. The specific historical tradition is thus fully consistent with the right claimed here. In *Cruzan* and *Glucksberg* this Court rebuked the plaintiffs for inferring a "right to die" from vague characterizations of common law principles, when the specific tradition directly on point was to criminalize suicide. The D.C. Circuit has committed the same error in reverse. (It errs in more dramatic form when it invokes Congress's supposedly "well-established power to regulate in response to scientific, mathematical, and medical advances." Pet. App 18a. If the history is described at that level of generality, Congress can do anything at all.) In the end, the majority framed the issue correctly by insisting that "the Alliance must show ... a tradition of access to drugs that have not yet been proven safe." Pet. App. 13a. Its own review of the history proves exactly that tradition.

The D.C. Circuit also accused petitioners of trying to infer a right merely from a history of non-regulation, and suggested that the paucity of early regulation might just reflect legislative apathy or the limited science of the day. That ignored petitioners' primary reliance on the affirmative rights to life and self-preservation. Advancing technology often provides the impetus and means for new invasions of individual liberty, but that does not establish that the prior absence of regulation was solely the result of technological incapacity. *See, e.g., Kyllo v. United States*, 533 U.S. 27 (2001) (thermal imaging is a search). Indeed, the majority severely undermined its own argument by noting that "the drug industry 'strenuously objected' to the 1938 Act 'ostensibly on the ground that it would deprive the American people of the right to self-medication.'" Pet. App. 16a (citation omitted). Litigants, judges, and scholars began questioning the constitutionality of denying terminally ill

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not claim a right for companies to make false claims about their products.

patients access to unproven drugs immediately after the FDCA was passed, and have never stopped.[11] This case is the latest upwelling of a current of constitutional discontent that refuses to go away precisely because it *is* deeply rooted in the traditions and conscience of our people.

There also is plenty of evidence that the historical absence of regulation was motivated in part by individual rights concerns. Thomas Jefferson likened interference with medicine to meddling in religion, arguing that "[w]as the government to prescribe to us our medicine and diet, our bodies would be in such keeping as our souls are now." Thomas Jefferson, *Writings: Notes on the State of Virginia*, 285 (Merrill D. Peterson ed., Library of Am. 1984). As a leading 19th century treatise on the police power explained :

> [T]he police power of the State can never be exercised in favor of or against any system of medicine. The police power can be brought to bear upon quacks and disreputable practitioners, to whichever school they may belong, but when reputable and intelligent members of the profession differ in theories of practice, the State has no power to determine which of them, if either, is wrong.

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[11] There have been dozens of cases seeking access to particular drugs, most of which failed because the patients were forgoing conventional treatment options, or because they sought access to drugs that were not in trials (i.e., that the government did not concede were safe enough for human testing), that had already been tested and rejected, or that were prohibited by the Controlled Substances Act. A federal court struck down the FDCA as applied to terminally ill patients, on substantive due process grounds, as early as 1977. *See Rutherford v. United States*, 438 F. Supp. 1287, 1299-301 (W.D. Okla. 1977). That decision was eventually reversed by this Court, but by that point it had become a purely statutory case and this Court did not address the constitutional issues. *See United States v. Rutherford*, 442 U.S. 544, 559 n.18 (1979). (This Court rejected the claim in large part because the patients had approved treatment options that they were proposing to forego.) There is a rich scholarly literature arguing both for and against a Due Process right to defend one's life by medical means. *See, e.g.*, Volokh, *supra* ; Hill, *supra*; Michael E. Horwin, *"War On Cancer:" Why Does The FDA Deny Access To Alternative Cancer Treatments?*, 13 Alb. L.J. Sci. & Tech. 681 (2003).

Christopher G. Tiedeman, *A Treatise on the Limitations of Police Power in the United States* 205 (1886). Obviously that is very similar to the "appropriate medical judgment" standard routinely applied by this Court in abortion cases. *See, e.g., England v. La. State Bd. of Med. Examiners*, 259 F.2d 626, 627 (5th Cir. 1958) ("[T]he State cannot deny to any individual the right to exercise a reasonable choice in the method of treatment of his ills ...."). Of course petitioners do not believe the Due Process Clause freezes into stone the broadest implications of pronouncements like Tiedeman's. As this Court noted in *Gonzales*, legislatures can and do resolve uncertain medical issues. But it is simply inaccurate to pretend that government deference to private medical decisions in the 18th and 19th centuries reflected nothing more than the limited science of the day.

II. THIS CASE PRESENTS ISSUES OF GREAT NATIONAL IMPORTANCE, AND AN OPPORTUNITY TO RESOLVE SIGNIFICANT CONFLICTS AND DISARRAY

Petitioners respectfully submit that this Court's review would be warranted solely on the basis of the importance of this issue to terminally ill patients and their families. Approximately half a million Americans will die this year of cancer alone, and a substantial proportion will find themselves at some point without any remaining treatment alternatives. Clinical trials currently accommodate only a few thousand patients a year, and the FDA has admitted at earlier stages of this litigation that fewer than 80 people each year manage to navigate its single-patient "treatment IND" process and gain access to investigational drugs outside of the trials. If the original panel opinion in this case was correct—and surely there is enough room for good faith disagreement here to justify a hard look—then countless thousands of Americans will die in the near future under circumstances that violate their constitutional rights to life and liberty. This Court has not required lengthy percolation or direct circuit conflicts before reviewing fundamental rights issues of no greater importance than this one, such as

Glucksberg and *Cruzan*. The issues are well-developed, and further delay is not justified in light of the potential costs.

Certiorari is also warranted because of tensions within this Court's own case law that the lower courts have been unable to reconcile. In *Roe* and its progeny, *Cruzan*, and perhaps in the opinions about palliative care in *Glucksberg*, this Court "has already recognized a substantive due process right to make medical treatment decisions without unwarranted government interference." Hill, *supra*, at 58. "And it can't be that a woman has a constitutional right to protect her life using medical procedures, but only when those procedures kill a viable fetus." Volokh, *supra*, at 1816. Both the majority and dissenting opinions in *Gonzales* agreed that access to necessary medical treatment is a fundamental right—and that Congress does not get the last word as to what is necessary. But the lower courts also find support in this Court's cases for the idea that government decisions about medicine get almost total deference (so long as the treatment is not abortion). Commentators have noted the "glaring doctrinal inconsistency." Hill, *supra*, at 6.

This case also presents this Court with an opportunity to address broader conflicts and disarray that have developed in the circuits in the wake of *Glucksberg* and *Lawrence*.

First, this case presents an opportunity to provide needed guidance about *Glucksberg*'s "careful description" requirement. Careful description is supposed to ensure that a court looks to the historical record at the most specific *available* level of generality. But that methodology can be abused, if courts use narrow descriptions of the factual context of a particular case to cut meritorious claims off from genuine historical support that exists at a higher level of generality or in a different but analogous context.

In this case, for example, there obviously is no pre-FDCA history specifically dealing with access for terminally ill patients to investigational drugs in clinical trials. Clinical trials did not even exist for the most part, and drugs were almost entirely unregulated, so the only available historical traditions were framed in more general terms. As the

dissent pointed out, however, the D.C. Circuit assumed that *Glucksberg*'s historical tradition test "can be satisfied only by historical evidence involving the exact situation that the Alliance presented to us today," even though the plurality opinion in *Michael H. v. Gerald D.*, 491 U.S. 110, 122 n.2 (1989), "said the opposite." Pet. App. 47a. Even footnote 6 of Justice Scalia's opinion in *Michael H.*, which articulated a stricter approach to tradition than this Court was willing to endorse, suggested that courts "refer to the most specific level at which a relevant tradition protecting, or denying protection to, the asserted right can be identified," and acknowledged that if there is no specific tradition on point then courts must look to broader ones. 491 U.S. at 127 n.6.

The circuit decisions evince considerable confusion about how the "careful description" requirement affects the analysis of history and precedent. For example, in *Johnson v. City of Cincinnati*, 310 F.3d 484 (6th Cir. 2002), *cert. denied*, 539 U.S. 915 (2003), the Sixth Circuit analyzed a statute excluding persons arrested for drug crimes from certain high-crime neighborhoods. It framed the potential right implicated as "a right to travel locally through public spaces and roadways," and noted that it would "draw from historical sources discussing a freedom of movement" more broadly, and "find their authority instructive." 310 F.3d at 495. The Sixth Circuit did not condemn the plaintiffs for failing to identify historical sources protecting a right to be free from exclusion from high-crime neighborhoods after an arrest, since the history did not exist at that level of specificity. And in *Kallstrom v. City of Columbus*, 136 F.3d 1055, 1062 (6th Cir. 1997), it analyzed a claim by undercover officers whose identity was disclosed in terms of a "fundamental liberty interest" in "preserving their lives and the lives of their family members, as well as preserving their personal security and bodily integrity." The Sixth Circuit would have analyzed this case in a similar fashion.

In *Hawkins v. Freeman*, 195 F.3d 732 (4th Cir. 1999), by contrast, the Fourth Circuit described the "precise right asserted" as a right "of a prisoner to remain free on

erroneously granted parole so long as he did not contribute to or know of the error and has for an appreciable time remained on good behavior to the point that his expectations for continued freedom from incarceration have 'crystallized.'" 195 F.3d at 747. "When its narrow compass and special circumstances are considered," the Fourth Circuit reasoned, that right compared unfavorably "with the relatively few, more generally shared, unenumerated rights that over time have been found by the Supreme Court (and not without difficulty) to have that 'fundamental' quality," such as the rights "to marry; to have children; to direct one's children's upbringing; [etc.]." *Id.* at 747–48 (citations omitted). But the fact that the right was so "narrow," limited to "special circumstances," and not "more generally shared" was largely a creature of the Fourth Circuit's own narrow description. There, as here, the right would have felt more "fundamental" if described with less specificity.

The acknowledged split between the Second and D.C. Circuits over juvenile curfews illustrates the same tension. The plurality opinion in *Hutchins v. District of Columbia*, 188 F.3d 531 (D.C. Cir. 1999) (*en banc*), rejected a challenge to a curfew statute on the ground that juveniles have no fundamental right "to be on the streets at night without adult supervision." 188 F.3d at 538. In *Ramos v. Town of Vernon*, 353 F.3d 171, 177 (2d Cir. 2003), the Second Circuit held that the D.C. Circuit plurality "define[d] the interest too narrowly at the outset" because "daylight and darkness are not related to whether a constitutional right *exists*" and "the presence or absence of supervision is relevant to the government's interest in protecting minors from danger, but the right to free movement itself does not magically appear and disappear with an adult's presence."[12]

Second, there is a circuit split over whether *Lawrence* modified the *Glucksberg* analysis such that the past half-century is now the most important in determining whether a right is deeply rooted in historical tradition. Following an

[12] *Ramos* is a fundamental rights *equal protection* decision, but the problem of how to describe the scope of a fundamental right is the same.

observation in this Court's opinion in *Lawrence*, the Ninth Circuit has held that the recent "emerging awareness" is more important to the *Glucksberg* analysis than the older history it supplants. *See Raich v. Gonzales*, No. 03-15481, 2007 WL 754759, at *11-12 (9th Cir. Mar. 14, 2007). The Seventh and Eleventh Circuits have explicitly rejected any suggestion that *Lawrence* modified the *Glucksberg* analysis, or that due process analysis should focus on the "emerging trend" rather than older traditions. *See Muth v. Frank*, 412 F.3d 808, 817-18 (7th Cir.), *cert. denied*, 546 U.S. 988 (2005); *Lofton v. Sec'y of Dep't of Children & Family Servs.*, 358 F.3d 804, 815-17 (11th Cir. 2004), *cert. denied*, 543 U.S. 1081 (2005); *Williams v. A.G. of Ala.* 378 F.3d 1232, 1243 (11th Cir. 2004), *cert. denied*, 543 U.S. 1152 (2005).

Judge Griffith cited the Ninth Circuit's decision in *Raich* approvingly in his dissent from the panel opinion in this case. Pet. App. 118a–19a. His subsequent opinion for the *en banc* court is more circumspect, *id.* at 17a n.10, but in the end the D.C. Circuit obviously held here that the modern history of restrictive drug regulation trumps the older history of non-interference, because "evolving technology" has rendered traditional conceptions of the limits of state power inappropriate. *Id.* at 18a. In the course of evaluating those claims, this Court could resolve the circuit split.

Finally, that conflict also points to deeper confusion about the *Glucksberg* methodology. This Court has tried to discipline the interpretation of the Due Process Clause by tethering it to history, but the D.C. Circuit and other lower courts obviously believe that our Nation's pre-20th century history has been discredited by changing conditions or the constitutional compromises of the New Deal—and have responded to *Glucksberg* with nearly total deference to the paternalistic excesses of the nanny state, even when they threaten traditional rights like life and self-defense. (The D.C. Circuit warned ominously, as if it were a justification for overriding fundamental rights, that petitioners' arguments could "undermine much of the modern administrative state, which, like drug regulation, has

increased in scope as changing conditions have warranted." Pet. App. 20a.). The Ninth Circuit's historical analysis in *Raich* displays a similar indifference to any history predating the 1930s. *See Raich*, 2007 WL 754759, at *11-12. (The Ninth Circuit's ultimate conclusion may nonetheless be justified because Congress has made a finding in the Controlled Substances Act that marijuana has no legitimate medical use, which is akin to the finding in *Gonzales* that partial-birth abortion is never medically necessary.)

This judicial disdain for pre-New Deal history guts the promise of the *Glucksberg* test. If the older (libertarian) history is disregarded because of changing conditions or the shadow of *Lochner*, then the administrative state cannot violate fundamental rights under *Glucksberg*—and the only substantive liberty protected by the Due Process Clause will be whatever freedoms are recognized under cases like *Roe* and *Lawrence*, which do not rely on history in the same way. The ironic result is that traditional liberties now receive *less* protection than the emerging innovations of modern sexual morality. As the dissent noted:

> it is startling that the oft-limited rights to marry, to fornicate, to have children, to control the education and upbringing of children, to perform varied sexual acts in private, and to control one's own body even if it results in one's own death or the death of a fetus have all been deemed fundamental rights covered, although not always protected, by the Due Process Clause, but the right to try to save one's life is left out in the cold despite its textual anchor in the right to life.

Pet. App. 33a. The lower courts need to be reminded that it is not necessary to butcher the historical record in order to reject inappropriately expansive claims under the *Glucksberg* test. The "implicit in the concept of ordered liberty" requirement can sort the truly fundamental wheat from the general chaff of 19th century laissez-faire.

CONCLUSION

The petition for certiorari should be granted.

Respectfully submitted,

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