No. 07-444

In the Supreme Court of the United States

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

v.

ANDREW VON ESCHENBACH, COMMISSIONER, FOOD AND DRUG ADMINISTRATION, ET AL.

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

BRIEF FOR THE RESPONDENTS IN OPPOSITION

PAUL D. CLEMENT
Solicitor General
Counsel of Record
JEFFREY S. BUCHOLTZ
Acting Assistant Attorney General
JONATHAN F. COHN
Deputy Assistant Attorney General
MARK B. STERN
SCOTT R. MCINTOSH
Attorneys
Department of Justice
Washington, D.C. 20530-0001
(202) 514-2217

QUESTION PRESENTED

Whether terminally ill patients who lack alternative treatment options have a constitutional right to purchase unapproved investigational drugs that have not been shown to be safe or effective and that have not been authorized for treatment uses by the Food and Drug Administration.

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OPINIONS BELOW

The opinion of the en banc court of appeals (Pet. App. 1a-57a) is reported at 495 F.3d 695. The vacated opinion of the initial panel of the court of appeals (Pet. App. 79a-130a) is reported at 445 F.3d 470. The opinion of the district court (Pet. App. 58a-78a) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on August 7, 2007. The petition for a writ of certiorari was filed on September 28, 2007. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. a. Before a new drug may be introduced into interstate commerce, the Federal Food, Drug and Cosmetic Act (FDCA or Act), 21 U.S.C. 301 *et seq.*, requires the drug's manufacturer to obtain the approval of the Food and Drug Administration (FDA) by demonstrating that the drug is both safe and effective for each of its intended uses. 21 U.S.C. 355(a), (b), and (d); *United States* v. *Rutherford*, 442 U.S. 544, 546-548, 549-550 n.7 (1979). The FDCA has required proof of drug safety since its enactment in 1938, nearly seventy years ago, and proof of effectiveness has been a separate requirement for nearly fifty years (since 1962), and an implicit part of the safety determination since 1938. See FDCA, ch. 675, § 505, 52 Stat. 1052; Drug Amendments of 1962, Pub. L. No. 87-781, § 102, 76 Stat. 781.

Clinical testing on humans is a prerequisite for the approval of a new drug application. See 21 U.S.C. 355(d). The Act therefore authorizes the FDA to promulgate regulations that allow the distribution of unapproved drugs intended "solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs." 21 U.S.C. 355(i)(1). The FDA's regulations prescribe a three-phase process for clinical trials of investigational new drugs (INDs). 21 C.F.R. 312.21.

Phase 1 involves the initial experiments introducing the new drug into human subjects. A Phase 1 study involves a small number of subjects, typically twenty to eighty, and is "designed to determine the metabolism and pharmacologic actions of the [new] 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)(1).

Phase 2 involves a well-controlled, closely monitored evaluation of the drug in a small group of patients, usually no more than several hundred. 21 C.F.R. 312.21(b). Phase 2 trials are conducted to evaluate "the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug." *Ibid.*

Phase 3 involves the evaluation of the drug in a large clinical trial or trials, usually from several hundred to several thousand subjects. 21 C.F.R. 312.21(c). Phase 3 is intended to gather "additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling," as a predicate to approval of the drug for marketing to the general population. *Ibid.*

A decision by the FDA to permit a clinical trial to proceed from Phase 1 to subsequent phases does not represent a judgment by the FDA that the investigational drug is either safe or effective for use in treating diseases. Instead, it merely reflects a preliminary determination that the drug is safe enough for administration to a limited number of participants in a carefully monitored clinical trial. See Pet. App. 17a.

Unfortunately, preliminary expectations of safety and efficacy often prove to be unfounded, and drugs that initially appear promising are frequently found ineffective or even affirmatively dangerous to life and health. See Pet. App. 17a n.11. The risk of serious adverse health consequences, including increased mortality, is particularly acute with respect to experimental chemotherapy, because anti-cancer drugs are toxic by design,

and their toxic effects often do not discriminate well between cancerous and non-cancerous cells.[1]

Successful clinical trials are the exception, not the rule, as "the great majority of experimental drugs ultimately provide no benefit." See Pet. App. 22a n.15. Only five percent of all cancer drugs that begin clinical testing are ultimately approved for patient use, and even among cancer drugs that successfully complete Phase 1 testing, less than a third proceed from Phase 2 to Phase 3. *Ibid.*[2] Thus, when investigational drugs are fully tested by the FDA's clinical trial process, the expectations regarding safety and efficacy that led the sponsor to initiate the process commonly prove to be unfounded.

b. When other treatments are unavailing, patients may seek access to investigational drugs before the sponsor has completed the clinical trial process and the FDA has determined that the drug is safe and effective. The FDA, acting in concert with Congress, has developed a variety of mechanisms for making investigational drugs available for treatment uses during the course of ongoing clinical trials.

In 1987, the FDA amended its Investigational New Drug (IND) regulations (21 C.F.R. Pt. 312) to provide a formal framework for the agency to authorize treatment uses of investigational drugs. See 21 C.F.R. 312.34-314.36. A decade later, Congress added treatment-use

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[1] See, *e.g.*, Frank M. Balis et al., *General Principles of Chemotherapy*, in *Principles and Practice of Pediatric Oncology*, ch. 9 (Philip A. Pizzo & David G. Poplack eds. 1989) ("anticancer drugs are relatively non-selective" and "have the lowest therapeutic index (ratio of toxic dose to therapeutic dose) of any class of drugs").

[2] See Peter D. Jacobson & Wendy E. Parmet, *A New Era of Unapproved Drugs: The Case of Abigail Alliance* v. *Von Eschenbach*, 297 JAMA 205, 206 (2007).

provisions to the FDCA that were largely based on the FDA's existing regulatory framework. See 21 U.S.C. 360bbb. Most recently, the FDA issued a notice of proposed rulemaking in December 2006 regarding expanded access to investigational drugs for treatment uses. 71 Fed. Reg. 75,147 (2006). The proposed rules are intended primarily to clarify and codify, rather than to change, the agency's existing criteria and procedures for treatment uses of investigational drugs. See *id.* at 75,149, 75,157, 75,162 (describing rulemaking goals).

These mechanisms are designed to strike a balance among the competing interests and concerns that are presented when patients and physicians wish to treat serious diseases with investigational drugs. On the one hand, when existing treatments have been tried and have proven ineffective, patients who are suffering from serious diseases have an understandable interest in trying potentially effective investigational drugs, particularly when the patient's illness is life-threatening. On the other hand, allowing patients to obtain and use unproven drugs carries a host of risks and potential detriments for the public health.

An investigational drug that appears promising to a patient or his physician may in fact be wholly ineffective. Worse still, the drug may be affirmatively unsafe, and taking it may sicken the patient or even kill him. In addition, unfettered access to investigational drugs for treatment uses may harm society at large by undermining the clinical trial process itself and thereby impeding the development of the data needed for FDA to assess the safety and efficacy of the drug. See 71 Fed. Reg. at 75,150 ("a system of blindly permitting uncontrolled access to investigational drugs could make it difficult or impossible to enroll adequate numbers of patients in

clinical trials"). The risk to the clinical trial process would be compounded if the sponsor were allowed to sell unapproved investigational drugs for a profit. In that case, the sponsor's financial incentive to complete the scientifically rigorous and expensive clinical trial process is directly reduced, and the sponsor may find it more attractive to sell the unapproved drug today than to vigorously pursue years of research for regulatory approval that most investigational drugs never obtain.

When the FDA is presented with a request for access to an investigational drug for treatment uses, the agency's physicians and scientists seek to balance these interests by gauging the potential risks and benefits of the drug to the patient or patients and the possible impact of expanded access on the clinical trial and drug development process. To approve a request, the FDA must determine that:

> The patient or patients have a serious or immediately life-threatening disease or condition for which there is no comparable or satisfactory alternative therapy;
>
> The potential patient benefit justifies the potential risks of the treatment use, and those potential risks are not unreasonable in the context of the disease or condition to be treated; and
>
> Providing the drug for the requested use will not interfere with clinical trials that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access use.

71 Fed. Reg. at 75,166 (proposed 21 C.F.R. 312.305(a)); see 21 U.S.C. 360bbb(c); 21 C.F.R. 312.34(b).

In applying these criteria, "the showing * * * needed to demonstrate the safety and potential benefit of a proposed use varies with the size of the population to be treated and the relative seriousness of the disease or condition to be treated." 71 Fed. Reg. at 75,151. Only a modest showing is required "to support expanded access for an individual patient when the patient has an immediately life-threatening condition that is not responsive to available therapy." *Ibid.* "[O]rdinarily, completed [P]hase 1 safety testing in humans at doses similar to those to be used in the treatment use, together with preliminary evidence suggesting possible effectiveness, would be sufficient to support such a use." *Ibid.*; see *id.* at 75,153 ("little if any clinical evidence" of "potential benefit" or limited safety data may be sufficient if patient has immediately life-threatening condition). Because the FDA's standards for terminally ill patients who lack alternative treatment options are accommodating, "[m]ost"—indeed, nearly all—"of the single-patient IND requests submitted to FDA are approved." See FDA, *Patient Access to New Therapeutic Agents for Pediatric Cancer: Report to Congress* 15 (Dec. 2003) <http://www.fda.gov/cder/pediatric/BPCA-ReportDec2003.doc>. Drug manufacturers may not, however, sell the drugs for a profit. 21 C.F.R. 312.7(d)(3); 71 Fed. Reg. at 75,181 (proposing 21 C.F.R. 312.8(d)).

2. Petitioner Abigail Alliance for Better Access to Developmental Drugs is an advocacy organization that seeks to expand the availability of unapproved investigational drugs for use in treating cancer and other life-threatening illnesses. In July 2003, petitioners brought suit to enjoin the government "from enforcing the FDA's policy of barring unapproved drugs from interstate commerce, insofar as it has the effect of prohibit-

ing terminally ill patients with no other treatment options from purchasing investigational drugs." Pet. App. 60a. Petitioners asserted that terminally ill patients who lack alternative treatments have a fundamental liberty interest under the Due Process Clause of the Fifth Amendment in purchasing investigational drugs that have completed Phase 1 trials, and that drug manufacturers have a derivative right to charge whatever the market will bear for such sales.

The district court granted the government's motion to dismiss, holding that terminally ill patients do not have a fundamental liberty interest in obtaining access to unapproved investigational drugs, and that the FDA's regulations governing access to such drugs for treatment uses satisfy rational basis review. Pet. App. 58a-59a.

A divided panel of the court of appeals reversed. Pet. App. 79a. The panel majority held that substantive due process protects a fundamental "right of a mentally competent, terminally ill adult patient to access potentially life-saving post-Phase I investigational new drugs, upon a doctor's advice, even where that medication carries risks for the patient." *Id.* at 80a. Judge Griffith dissented, stating that "[b]alancing the risks and benefits found at the forefront of uncertain science and medicine has been, for good reason, the historical province of the democratic branches," and "I can find no basis in the Constitution or judicial precedents to remove that function from the elected branches." *Id.* at 107a.

The court of appeals granted en banc rehearing, affirmed the district court, and upheld the constitutionality of the FDA's treatment use regulations by a vote of 8-2. Pet. App. 1a. The court evaluated petitioners' substantive due process claim under *Washington* v.

Glucksberg, 521 U.S. 702 (1997), which requires two independent showings to establish that an asserted liberty interest is a "fundamental" right. Pet. App. 11a. First, the plaintiff must show that the interest is, "objectively, 'deeply rooted in this Nation's history and tradition.'" *Glucksburg*, 521 U.S. at 721 (citation omitted). The nation's "history, legal traditions, and practices * * * provide the crucial 'guideposts for responsible decision-making'" that "direct and restrain [the Court's] exposition of the Due Process Clause." *Ibid.* (citation omitted); see also *id.* at 722 (historical inquiry "rein[s] in the subjective elements that are necessarily present in due-process judicial review"). Second, the plaintiff must demonstrate that the asserted interest is "'implicit in the concept of ordered liberty,' such that 'neither liberty nor justice would exist if [it] were sacrificed.'" *Ibid.* (citation omitted). This inquiry demands "a 'careful description' of the asserted fundamental liberty interest" that is framed in suitably specific, rather than abstract and general, terms. *Id.* at 721-722, 724.

The en banc court held that petitioners failed to meet the first prong of the *Glucksberg* test because "there is no fundamental right 'deeply rooted in this Nation's history and tradition' of access to experimental drugs for the terminally ill." Pet. App. 1a-2a. Reviewing the history of federal and state drug regulation, the court concluded that federal law has restricted access to drugs on the basis of safety considerations since the early twentieth century, and other federal and state drug laws have even deeper historical roots. *Id.* at 14a-18a. To the extent that nineteenth century drug laws were more limited in scope than their twentieth century successors, the court added that "creating constitutional rights to be free from regulation based solely upon a prior lack of

regulation would undermine much of the modern administrative state, which, like drug regulation, has increased in scope as changing conditions have warranted." *Id.* at 20. The court further held that are no relevant common law precedents for petitioners' claimed constitutional law right of access to unapproved drugs. *Id.* at 20a-25a.

Having concluded that petitioners' substantive due process claim lacks the requisite grounding in history and tradition, the court of appeals found it unnecessary to reach *Glucksberg*'s second prong—whether the asserted interest is "implicit in the concept of ordered liberty, such that neither liberty nor justice would exist it [it] were sacrificed." See Pet. App. 27a n.19. Finally, applying rational basis review, the court found that the FDA's treatment use regulations readily pass constitutional muster, for even terminally ill patients can be harmed by the use of "potentially unsafe drugs with unknown therapeutic effects." *Id.* at 30a.

Judge Rogers, joined by Chief Judge Ginsburg, dissented from the en banc court's decision. Pet. App. 31a-57a.

ARGUMENT

The decision of the en banc court of appeals is correct and is consistent with a uniform body of federal precedents that have rejected constitutionally based demands for access to unapproved investigational drugs. The decision is also faithful to this Court's admonition that "[t]he doctrine of judicial self-restraint requires us to exercise the utmost care whenever we are asked to break new ground" in the realm of substantive due process, *Collins* v. *City of Harker Heights*, 503 U.S. 115, 125 (1992), because, "[b]y extending constitutional protection to an asserted right or liberty interest, we, to a

great extent, place the matter outside the arena of public debate and legislative action." *Washington* v. *Glucksberg*, 521 U.S. 702, 720 (1997). As the court of appeals recognized, striking an appropriate balance among the competing interests surrounding treatment uses of investigational drugs involves delicate judgments, but those judgments are ones of public policy, not constitutional law. That decision below does not conflict with any decision of this Court or any other court of appeals and, therefore, does not warrant this Court's review.

1. "[I]n all due process cases," courts must "begin * * * by examining our Nation's history, legal traditions, and practices." *Glucksberg*, 521 U.S. at 710. The en banc court correctly held that there is no "deeply rooted" (*id.* at 721) historical tradition of granting terminally ill patients unregulated access to unapproved drugs that have completed the first, most preliminary stage of the clinical trial process. Pet. App. 12a-20a.

a. Ever since the enactment of the FDCA in 1938, federal law has categorically prohibited the marketing and distribution of new drugs without the approval of the FDA. See 21 U.S.C. 331(d), 355(a). The requirement of FDA approval applies to all new drugs, including those intended for use in treating terminal illnesses. *United States* v. *Rutherford*, 442 U.S. 544, 551-559 (1979). Thus, for nearly seventy years, patients have required advance approval by the FDA before they can lawfully obtain drugs to treat their illness, even if they are terminally ill and even if they lack alternative treatments. As noted (pp. 6-7, *supra*), the FDA's practice has been to approve requests for access to investigational drugs when the agency finds sufficient preliminary indicia of safety and efficacy and when access would not

compromise the clinical trial process. But the agency has never abandoned the gatekeeping role assigned to it by Congress by ceding the ultimate decision about access to investigational drugs to patients or other private parties. Thus, even from the historical perspective most favorable to petitioners, federal regulation of patient access to new drugs is itself "deeply rooted in this Nation's history and tradition." *Cf. Lawrence* v. *Texas*, 539 U.S. 558, 571-572 (2003) ("our laws and traditions in the past half century are of most relevance" in evaluating historical provenance of an asserted liberty interest). Indeed, given this practice of making investigative drugs available in the circumstances identified above, petitioners' contention necessarily is, as they concede (Pet. 1-2), that they have a constitutional right to obtain an investigational drug without even having to request approval from the FDA under its established practice. In light of the regulatory history, that asserted right is especially without foundation.

Petitioners seek to abridge the relevant history by claiming that federal law did not concern itself with drug effectiveness, as distinct from safety, until 1962. Pet. 22 & n.10. That is incorrect. While the FDCA was amended in 1962 to make effectiveness an express prerequisite for new drug approval under 21 U.S.C. 355, an evaluation of effectiveness was already an integral part of the FDA's licensing standards under the 1938 Act, particularly for drugs intended to treat life-threatening diseases. See *Rutherford*, 442 U.S. at 553 n.9.[3] Simply

[3] As the Secretary of Health, Education, and Welfare explained when Congress was considering the 1962 amendments, "[i]f the drug is offered for the treatment of progressive or life-threatening diseases, such as cancer, * * * we now consider its effectiveness. In such cases the determination of safety is, in light of the purpose of the new drug

put, evaluations of effectiveness have been an integral part of the regulatory process for determining access to potentially life-saving drugs for nearly seventy years.

Moreover, as the en banc court explained, petitioners' "focus on efficacy regulation ignores one simple fact: it is unlawful * * * to procure experimental drugs not only because they have not been proven effective, but because they have not been proven safe." Pet. 12a. The federal ban on distributing drugs that have not been proven safe has existed since the New Deal, and federal regulation of drug safety started even before the 1938 enactment of the FDCA. Pet. App. 15a-16a. While petitioners contend that earlier federal drug laws were confined to ensuring that patients and doctors were not misled about the contents of drugs through misbranding or adulteration, the court of appeals correctly recognized that the difference between prohibiting the sale of adulterated drugs (as in the Pure Food and Drug Act of 1906) and prohibiting the sale of unsafe drugs more generally (as in the FDCA) is a difference in degree, not a difference in kind. Moreover, as early as 1902, the Biologics Control Act established a federal licensing scheme to ensure the safety and purity of vaccines, serums, and similar products by requiring their manufacturers to obtain licenses from a federal review board; empowered the board to suspend or revoke licenses; and prohibited the unlicensed sale of such products. Act of July 1, 1902, ch. 1378, 32 Stat. 728-729. The history of conditioning access to drugs on federal approval thus reaches back more than a century and, and, as the en

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provisions, inseparable from consideration of the drug's effectiveness." *Drug Industry Antitrust Act: Hearings on S. 1552 Before the Subcomm. on Antitrust and Monopoly of the Senate Comm. on the Judiciary*, 87th Cong., 1st Sess. 2588 (1961).

banc court noted (Pet. App. 14a-15a), state regulation has an even older provenance.

Faced with a century of federal drug regulation, petitioners rely on a nineteenth-century treatise for the proposition that "the police power of the State can *never* be exercised in favor of or against any system of medicine," and that "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." Pet. 24 (emphasis added) (quoting Christopher G. Tiedeman, *A Treatise on the Limitations of Police Power in the United States* 205 (1886)). This quintessential expression of a *Lochner*-type substantive due process doctrine clearly illustrates that petitioners' "historical" substantive due process claim is ultimately *Lochner* reformulated. See, *e.g.*, Pet. 29 (criticizing federal courts for deferring to "the paternalistic excesses of the nanny state"). To take *Lochner*-era views regarding the legitimate scope of government regulation as the touchstone for identifying fundamental liberty interests would be to revive a brand of judicial intervention that this Court foreswore long ago. As the court of appeals noted, inferring "constitutional rights to be free from regulation" from the relative absence of social and economic regulation in the nineteenth century "would undermine much of the modern administrative state, which, like drug regulation, has increased in scope as changing conditions have warranted." Pet. App. 20a.

b. Petitioners go further afield in seeking analogies between their asserted right of access to unapproved drugs and two common law doctrines: the defense of self-defense and the "infrequently invoked" (Pet. App. 95a) tort of intentional interference with lifesaving efforts. Pet. 15-18. As the court of appeals explained,

neither doctrine is implicated by federal regulation of access to unapproved new drugs. Pet. App. 20a-25a.[4]

The common law defense of self defense addresses how an individual may respond to violence by an assailant—not, as here, how an individual may treat his own physical ailments, much less an asserted affirmative right to purchase drugs from others. See, *e.g.*, 2 Wayne R. LaFave, *Substantive Criminal Law* § 10.4, at 142 (2d ed. 2003) (LaFave) (self-defense doctrine permits victim of attack to "us[e] a reasonable amount of force against his adversary when he reasonably believes (a) that he is in immediate danger of unlawful bodily harm from his adversary and (b) that the use of such force is necessary to avoid this danger"). As the court of appeals recognized, "terminally ill patients cannot fairly be characterized as using reasonable force to defend themselves when they take unproven and possibly unsafe drugs." Pet. App. 24a-25a.[5] Moreover, the right that petitioners are asserting is not simply the right to "defend" oneself by using drugs already in hand, but rather the right to

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[4] Petitioners relied on the common law defense of necessity in the court of appeals, which found their argument foreclosed by *United States* v. *Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001). See Pet. App. 21a & n.14. Petitioners have now essentially abandoned that theory. Pet. App. 18 n.7.

[5] Petitioners erroneously assert (without citation) that "[a] person has a right to defend himself even in circumstances or ways that government officials might consider futile, imprudent and excessively dangerous." Pet. 17. The reasonableness of the defendant's actions is a critical prerequisite for the defense of self-defense: the defendant may use only "a *reasonable* amount of force," and he must "*reasonably* believe" that, *inter alia*, "the use of such force is necessary to avoid th[e] danger." LaFave § 10.4, at 142 (emphasis added); see also *id.* § 10.4(c), at 147 ("one who honestly though unreasonably believes in the necessity of using force in self-protection loses the defense").

engage in an unregulated commercial transaction to acquire drugs that the patient and his physician do not otherwise possess. We know of no case, and petitioners have identified none, in which the common law of self-defense has been construed to create an affirmative right to *purchase* means of self-defense from third parties free from government regulation and control.

Petitioners argue that this Court's abortion decisions reflect a constitutional self-defense doctrine because they hold that the government may not constitutionally prohibit an abortion necessary to preserve the life or health of the mother. See Pet. 19-22 (citing, *e.g.*, *Stenberg* v. *Carhart*, 530 U.S. 914, 912 (2000); *Ayotte* v. *Planned Parenthood of N. New England*, 546 U.S. 320, 327 (2006)); cf. *Roe* v. *Wade*, 410 U.S. 113, 130-141 (1973). But the protection of the life or health of the mother is simply an aspect of the Court's substantive abortion jurisprudence, not the product of a general constitutional right of medical "self-defense." See *Stenberg*, 530 U.S. at 920 ("We again consider the right to an abortion."). If *Stenberg* and *Roe* did rest on some kind of broader constitutional right to self-defense, petitioner's theory would sweep much farther here than even they are prepared to go. While petitioners have disclaimed any fundamental right of access to investigational drugs by patients who are not terminally ill, *Stenberg* recognizes the necessity of an exception to protect not just the mother's life, but her health. *Id.* at 921. Under petitioner's theory, then, the entire regulatory regime embodied in the FDCA would be placed under direct and broad constitutional assault.

The tort of intentional interference with lifesaving efforts is equally inapposite. The few cases that rely on that theory bear no resemblance to the drug safety reg-

ulations here. They instead deal with such scenarios as a bartender who refuses to allow the bar's phone to be used to call for police assistance, or a ski lodge operator who refuses to allow his facilities to be used to rescue stranded hikers. See *Soldano* v. *O'Daniels*, 190 Cal. Rptr. 310 (App. 1983); *Miller* v. *Arnal Corp.*, 632 P.2d 987 (Ariz. App. 1981). In such cases, the effectiveness of the proffered assistance is not in question, and the willful obstruction of that assistance has no possible justification. Here, in contrast, petitioners are asserting a right to obtain investigational drugs whose efficacy is entirely unproven, and the FDA is regulating access to such drugs because, *inter alia*, they may actually turn out to impair the patient's health and quality and length of life—detrimental outcomes even for patients who are terminally ill. Such regulatory action is utterly different from the kinds of private misconduct that may come within the ambit of the tort.[6]

2. a. A plaintiff who succeeds in demonstrating that an asserted liberty interest is deeply rooted in the Nation's history and traditions, must further show that the interest is "'implicit in the concept of ordered liberty,' such that 'neither liberty nor justice would exist if [it] were sacrificed.'" *Glucksburg*, 521 U.S. at 721 (internal quotation marks omitted). The en banc court of appeals never reached that second question, however, because petitioners' interest in unregulated access to unap-

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[6] Petitioners' invocation of *Ross* v. *United States*, 910 F.2d 1422 (7th Cir. 1990), is unavailing. The *Ross* court found a due process violation where a police officer, in reckless disregard for the life of a drowning child, prohibited rescuers from assisting the child. *Id.* at 1431-1433. The suggestion that requiring patients to obtain permission to use potentially unsafe and ineffective investigational drugs is analogous to prohibiting the rescue of a drowning child is patently meritless.

proved investigational drugs failed the first prong of *Glucksburg*'s inquiry. See Pet. App. 27a n.19.

While petitioners' leading argument (Pet. 12-15) presses the merits of that unresolved, second issue, the fact that the court of appeals never reached it reinforces the conclusion that review is unwarranted here. If certiorari were granted, this Court would either decide a novel substantive due process question not addressed by the court below or confine its own review to the first prong of *Glucksberg* and leave the second prong unresolved. The first option would deny the Court the benefit of having issues properly ventilated by the lower courts, while the second would lead to piecemeal constitutional adjudication. The more prudent course would be to defer any review until the courts of appeals have evaluated the FDA's treatment use regulations under both prongs of the *Glucksberg* inquiry in order to permit the Court to address the constitutional claim in a comprehensive and fully informed manner.

b. Because the court of appeals had no occasion to reach the second prong of the *Glucksberg* inquiry, petitioners' contentions regarding the second issue need not be addressed in detail. A few basic shortcomings in their arguments are noted briefly below.

First, petitioners erroneously contend (Pet. 12) that *Cruzan* v. *Director, Missouri Department of Health*, 497 U.S. 261 (1990), "recognized" a fundamental right to refuse life-saving treatment and that a terminally ill patient must likewise have a fundamental right to use investigational drugs because individuals' "autonomy interests" are equally implicated in both cases. *Cruzan* merely "assume[d]"—and did not hold—that "a competent person [has] a constitutionally protected right to refuse lifesaving hydration and nutrition" "for purposes

of th[at] case." *Id.* at 279. Moreover, "the right assumed in *Cruzan* * * * was not simply deduced from abstract concepts of personal autonomy;" rather, it depended on "the common-law rule that forced medication was a battery, and the long legal tradition protecting the decision to refuse unwanted medical treatment." *Glucksberg*, 521 U.S. at 725; see *Cruzan*, 497 U.S. at 269 ("[a]t common law, even the touching of one person by another without consent and without legal justification was a battery"); *id.* at 287 (O'Connor, J., concurring). Here, no such concern for bodily integrity and no claim of battery are arguably present.

Second, petitioners suggest (Pet. 12) that their case is stronger than *Cruzan* because terminally ill patients wish to save their lives, and "the plain text of the Due Process Clause" protects "life" as well as liberty from government deprivation. Yet to show that the FDA's regulations amount to a "deprivation" of life, petitioners would have to show that the FDA actually intended to cause patients' death, or, at the very least, acted with deliberate and reckless indifference to the impact of its actions on patients' lives. See generally *Daniels* v. *Williams*, 474 U.S. 327 (1986); *Davidson* v. *Cannon*, 474 U.S. 344 (1986). No such showing is possible: the FDA's carefully balanced regulations are designed to *save* lives, and the agency's solicitude for the requests of individual patients (see pp. 6-7, *supra*) is the antithesis of deliberate indifference.

Finally, petitioners argue more generally (Pet. 13) that this Court's decisions recognize "a basic right of autonomy in making critically important and private decisions." The Court, however, has made clear that the fundamental character of a particular asserted interest cannot "simply [be] deduced from abstract concepts of

personal autonomy." *Glucksberg*, 521 U.S. at 725. To the contrary, the fact "[t]hat many of the rights and liberties protected by the Due Process Clause sound in personal autonomy does *not* warrant the sweeping conclusion that any and all important, intimate, and personal decisions are so protected." *Id.* at 727 (emphasis added). Petitioners thus cannot establish that the unregulated use of investigational drugs by terminally ill patients is implicit in the concept of ordered liberty simply by arguing that it reflects an important exercise of personal autonomy, or by comparing it to other rights and arguing that it is just as significant. Indeed, such open-ended appeals to personal autonomy are antithetical to the need to use "utmost care" whenever a litigant seeks "to break new ground" in the realm of substantive due process. *Collins*, 503 U.S. at 125.

3. This Court's review is also unwarranted because the decision the en banc court of appeals is consistent with the decisions of the other federal courts regarding access to unapproved investigational drugs for treatment uses. The courts of appeals have repeatedly rejected claims by patients, including those suffering from terminal illnesses, that they are constitutionally entitled to use unapproved drugs to treat their diseases. See *Rutherford* v. *United States*, 616 F.2d 455, 457 (10th Cir.) (rejecting claim that terminally ill cancer patients have constitutional right of access to laetrile; holding that "selection of a particular treatment, or at least a medication, is within the area of governmental interest in protecting public health"), cert. denied, 449 U.S. 937 (1980); *Carnohan* v. *United States*, 616 F.2d 1120, 1122 (9th Cir. 1980) (per curiam) ("Constitutional rights of privacy and personal liberty do not give individuals the right to obtain laetrile free of the lawful exercise of gov-

ernment police power"); *United States* v. *Burzynski Cancer Research Inst.*, 819 F.2d 1301, 1313-1314 (5th Cir. 1987) (cancer patients have no constitutional right to use unapproved drugs, notwithstanding "the unavailability of any other treatment that would be effective in treating their cancer"); see also *Mitchell* v. *Clayton*, 995 F.2d 772, 775 (7th Cir. 1993) ("a patient does not have a constitutional right to obtain a particular type of treatment or to obtain treatment from a particular provider if the government has reasonably prohibited that type of treatment or provider").[7] The absence of a conflict of authority counsels strongly against granting review, particularly where, as noted, the court of appeals in this case never reached or decided the question whether peti-

[7] Petitioners incorrectly suggest (Pet. 24 n.11) that the cases cited in the text are distinguishable because the patients had alternative treatment options. Pet. 24 n.11. The plaintiff class in *Rutherford* consisted of "all "terminally ill cancer patients," specifically including patients whom "further orthodox treatment would not reasonably be expected to benefit." *Rutherford* v. *United States*, 429 F. Supp. 506, 509, 513 (W.D. Okla. 1977). The Tenth Circuit thus did not purport to, and could not, confine its holding to plaintiffs who had recognized treatment options. The Ninth Circuit's opinion in *Carnohan* is similarly unqualified, and *Burzynski* expressly acknowledged "the unavailability of any other treatment that would be effective," 819 F.2d at 1314. Petitioners' alternative suggestion (Pet. 24 n.11) that the drugs being sought in those cases "were not in trials" or "had already been tested and rejected" is likewise incorrect. Laetrile, the unapproved drug at issue in *Rutherford* and *Carnohan*, underwent a Phase 1 trial sponsored by the National Cancer Institute, and the trial eventually proceeded from Phase 1 to Phase 2, thereby bringing laetrile squarely within the scope of petitioners' claimed liberty interest. See National Cancer Inst., U.S. National Insts. of Health, *Cancer Topics: Laetrile/Amygdalin* (last modified Dec. 4, 2007) <http://www.cancer.gov/ cancertopics/pdq/cam/ laetrile/HealthProfessional/page5> (describing history of laetrile clinical trials).

tioners' asserted liberty interest is "implicit in the concept of ordered liberty."

Contrary to petitioners' suggestion (Pet. 25-26), nothing about this Court's decisions to grant review in *Cruzan* and *Glucksberg* supports review here. Pet. 25-26. In *Cruzan*, the asserted constitutional right to refuse life-sustaining medical treatment had already been the subject of judicial decisions in sixteen States by the time the Missouri Supreme Court decided the issue, and the Missouri court's decision was in self-acknowledged conflict with the great majority of those decisions. See *Cruzan by Cruzan* v. *Harmon*, 760 S.W.2d 408, 412-413 & n.4 (Mo. 1988) (explaining that decisions in other States had "[n]early unanimously * * * found a way to allow persons wishing to die, or those who seek the death of a ward, to meet the end sought"). And in *Glucksberg*, the decision under review relied on an unprecedented substantive due process theory to invalidate, rather than sustain, a longstanding statutory ban on assisted suicide. Neither case provides any precedent for reviewing the decision here, which accords with the decisions of other courts of appeals and which leaves a well-established regulatory regime intact rather than invalidating it.[8]

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[8] Petitioners suggest that certiorari is also appropriate to resolve supposed uncertainty about the degree of specificity with which an asserted fundamental liberty interest must be framed under *Glucksberg*. Pet. 26-28. But this case presents no occasion for addressing that question, since the court of appeals did not demand more (or less) specificity than petitioners themselves have chosen to employ. See Pet. App. 11a ("We will assume *arguendo* that the Alliance's description of its asserted right would satisfy *Glucksberg*'s 'careful description' requirement."). Nor does this case present a vehicle for resolving a supposed circuit split over whether "the past half-century" (Pet. 28) is the most important time frame for assessing the historical roots of a

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

PAUL D. CLEMENT
Solicitor General

JEFFREY S. BUCHOLTZ
Acting Assistant Attorney General

JONATHAN F. COHN
Deputy Assistant Attorney General

MARK B. STERN
SCOTT R. MCINTOSH
Attorneys

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claimed fundamental right. See Pet. App. 17a n.10 ("We need not determine today whether recent history is particularly relevant in measuring the scope of rights under th Due Process Clause.").