United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued October 21, 2005 Decided May 2, 2006

No. 04-5350

ABIGAIL ALLIANCE FOR BETTER ACCESS TO DEVELOPMENTAL DRUGS AND WASHINGTON LEGAL FOUNDATION,
APPELLANTS

v.

ANDREW C. VON ESCHENBACH, M.D.,
IN HIS OFFICIAL CAPACITY AS ACTING COMMISSIONER,
FOOD AND DRUG ADMINISTRATION AND
MICHAEL O. LEAVITT,
IN HIS OFFICIAL CAPACITY AS SECRETARY,
U.S. DEPT. OF HEALTH AND HUMAN SERVICES,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 03cv01601)

James S. Ballenger argued the cause for appellants. With him on the briefs were *Daniel J. Popeo* and *David Price*.

Richard A. Samp entered an appearance.

Rhonda C. Fields, Assistant U.S. Attorney, argued the cause for appellee. With her on the brief were *Kenneth L. Wainstein*, U.S. Attorney, *Michael J. Ryan*, Assistant U.S. Attorney, *Eric M. Blumberg*, Deputy Chief Counsel, U.S. Department of Health and Human Services, and *Karen E. Schifter*, Associate Chief Counsel. *R. Craig Lawrence*, Assistant U.S. Attorney, entered an appearance.

Before: GINSBURG, *Chief Judge*, and ROGERS and GRIFFITH, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* ROGERS.

Dissenting opinion filed by *Circuit Judge* GRIFFITH.

ROGERS, *Circuit Judge*: The Abigail Alliance for Better Access to Developmental Drugs ("the Alliance") seeks to enjoin the Food and Drug Administration ("FDA") from continuing to enforce a policy barring the sale of new drugs that the FDA has determined, after Phase I trials on human beings, are sufficiently safe for expanded human testing (hereafter "post-Phase I investigational new drugs"). More specifically, the Alliance seeks access to potentially life-saving post-Phase I investigational new drugs on behalf of mentally competent, terminally ill adult patients who have no alternative government-approved treatment options (hereafter "terminally ill patients"). The Alliance contends that the FDA's policy violates the substantive due process rights to privacy, liberty, and life of its terminally ill members. The complaint presents the question of whether the Due Process Clause protects the right of terminally ill patients to decide, without FDA interference, whether to assume the risks of using potentially life-saving investigational new drugs that the FDA has yet to approve for commercial

marketing but that the FDA has determined, after Phase I clinical human trials, are safe enough for further testing on a substantial number of human beings.

Upon applying the Supreme Court's test for addressing substantive due process claims set forth in *Washington v. Glucksberg*, 521 U.S. 702, 710 (1997), we hold that the district court erred in dismissing the Alliance's complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. First, the right at issue, carefully described, is the 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. Second, we find, upon examining "our Nation's history, legal traditions, and practices," *Glucksberg*, 521 U.S. at 710, that the government has not blocked access to new drugs throughout the greater part of our Nation's history. Only in recent years has the government injected itself into consideration of the effectiveness of new drugs. Third, Supreme Court precedent on liberty indicates that the right claimed by the Alliance can be inferred from the Court's conclusion in *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261, 278 (1990), that an individual has a due process right to refuse life-sustaining medical treatment, *id*. at 279. Here, the claim implicates a similar right — the right to access potentially life-sustaining medication where there are no alternative government-approved treatment options. In both instances, the key is the patient's right to make the decision about her life free from government interference.

Because the question remains whether the FDA's challenged policy has violated that right, we reverse the dismissal of the Alliance's complaint and remand the case to the district court to determine whether the FDA's policy "is narrowly tailored to serve a compelling [governmental]

interest." *Glucksberg*, 521 U.S. at 721 (quoting *Reno v. Flores*, 506 U.S. 292, 302 (1993)).

In Part I, we set forth the background to this appeal. In Part II, we examine Supreme Court precedent indicating how substantive due process rights are to be discerned. So guided, we consider, in Part III, whether the Alliance's claimed right warrants protection under the Due Process Clause.

I.

A.

The Food, Drug, and Cosmetic Act ("FDCA"), Pub. L. No. 75-717, §§ 1-902, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 301 *et seq*. (2000)), prohibits drug manufacturers from introducing any "new drug" into interstate commerce until manufacturers have applied for, and received, FDA approval. 21 U.S.C. § 355(a). A "new drug" is any substance covered by the FDCA not "generally recognized, among experts . . . as safe and effective for use under the conditions prescribed . . . in the labeling." 21 U.S.C. § 321(p)(1); *see also United States v. 50 Boxes More or Less*, 909 F.2d 24 (1st Cir. 1990). Before a new drug is eligible for full approval and marketing, the Secretary of the U.S. Department of Health and Human Services must find "substantial evidence that the drug will have the effect it purports or is represented to have." 21 U.S.C. § 355(d). Exempted from this general ban are new drugs "intended solely for investigational use by experts . . . ." *Id.* § 355(i)(1).

The FDCA directs the Secretary to promulgate regulations for testing new drugs. *Id.* Pursuant to this authority, the FDA has promulgated regulations that require three phases of government testing on humans before investigational new drugs can receive FDA approval and enter the commercial marketplace. In Phase I, new drugs are tested on 20 to 80

human subjects to determine "the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness." 21 C.F.R. § 312.21(a). It takes approximately one year to conduct Phase I testing.[1] FDA counsel acknowledged at oral argument that drugs that survive this phase have been deemed "sufficiently safe for substantial human testing, but [are] not yet proven to be safe and effective to the satisfaction of the FDA [to be commercially marketed]." Oral Argument Tape of Oct. 21, 2005 at 15:57-15:59. Phase II involves targeted, controlled clinical studies of up to several hundred human subjects "to evaluate the effectiveness of the [Phase I investigational new] drug . . . and to determine the common short-term side effects and risks associated with the drug." 21 C.F.R. § 312.21(b). Phase III expanded trials, which can include several thousand human subjects, are "performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug . . . ." *Id.* § 312.21(c). With narrow exceptions, FDA regulations require informed consent to be obtained from clinical trial participants. *Id*. §§ 50.1-50.27.

B.

On January 16, 2003, the Alliance submitted a proposal to the FDA for new regulations to render post-Phase I investigational new drugs available to terminally ill patients who were not admitted to the FDA's clinical trials. The FDA rejected the proposal by letter dated April 25, 2003, outlining the FDA's policy. On June 11, 2003, Alliance filed a Citizen Petition, pursuant to 21 C.F.R. § 10.30, challenging the FDA's

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[1] *See* Alison R. McCabe, *A Precarious Balancing Act—The Role of the FDA as Protector of Public Health and Industry Wealth*, 36 SUFFOLK U. L. REV. 787, 790 n.26 (2003).

policy barring the sale of investigational new drugs that have successfully completed Phase I trials to terminally ill patients not selected for clinical trials. The FDA acknowledged receipt of the Citizen Petition but otherwise did not respond within 180 days, thereby entitling the Alliance to seek judicial review of the challenged policy. *See id*. § 10.30(e)(2).

The Alliance filed suit against the FDA Commissioner and the Secretary of the Department of Health and Human Services, seeking to enjoin the FDA from enforcing the policy barring the sale of post-Phase I investigational new drugs to terminally ill patients not in Phase II clinical trials. Noting that the FDA has administrative discretion to define several stages for human testing of new drugs after animal testing has been conducted, the complaint alleges that it takes, on average, just under seven years for investigational new drugs to complete the three phases of clinical human trials and receive FDA approval for commercial marketing and thus become eligible for purchase by persons not in FDA clinical trials. Compl. ¶ 12.[2] The complaint also alleges that non-commercial options provide relief only to a very small number of terminally ill patients as spaces in clinical trials are "very limited . . . in relation to the need." Compl. ¶ 15. The Alliance asserts that clinical human trials are limited in number and by type of patient who qualifies. Further, the FDA's "compassionate use" programs, which permit drug companies voluntarily to provide new drugs at cost during the pre-approval period, are available only to "a fraction of those in desperate need." *Id.* Although the FDA may permit "treatment use" of unapproved new drugs, *see* 21 C.F.R. § 312.34 (1999), and has allowed access for limited groups of persons with

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[2] *See also* Christopher P. Adams & Van V. Brantner, *New Drug Development: Estimating Entry from Human Clinical Trials* 9 (July 7, 2003), *available at* http://www.ftc.gov/be/workpapers/wp262.pdf.

AIDS,[3] the FDA has refused as a general matter to allow terminally ill patients to have access to investigational new drugs that have successfully completed Phase I trials. Consequently, the complaint alleges, the effect of the FDA policy, as illustrated by the examples of the deaths of four terminally ill patients, has been to deny terminally ill patients the choice to use post-Phase I investigational new drugs despite the patients' willingness "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." Compl. ¶¶ 16, 18. Prior to discovery, the FDA moved to dismiss the complaint, and, alternatively, for summary judgment. The Alliance responded by filing an opposition and its own motion for summary judgment.

The district court dismissed the complaint pursuant to Rule 12(b)(6) for failure to state a claim. The court rejected the Alliance's argument that it sought no "new" right but only recognition and enforcement of the right to life that is explicitly guaranteed by the Due Process Clause, observing that no court decision has "extended the Due Process Clause to cover a terminally ill patient's right to receive medical treatment." Mem. Op. of Aug. 30, 2004, at 18 (emphasis deleted). Although acknowledging "the Nation's longstanding legal tradition . . . to attempt to preserve life," *id*., the district court stated that in *Glucksberg*, the Supreme Court had distinguished some "personal" decisions from others, 521 U.S. at 727, and that the Alliance could not "possibl[y] claim that the specific right claimed has a long-standing tradition." Mem. Op. at 18. The district court also rejected the Alliance's argument that the Supreme Court's recognition in *Cruzan* of the right to choose

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[3] *See* Michael D. Greenberg, *AIDS, Experimental Drug Approval, and the FDA New Drug Screening Process*, 3 N.Y.U. J. LEGIS. & PUB. POL'Y 295, 315-20 (1999-2000).

death by refusing medical treatment implied a complementary right to choose life by obtaining potentially life-saving medication. In the district court's view, the Alliance sought recognition of "an entirely different sort of right [from that recognized in *Cruzan*] — not freedom from government imposition, but an affirmative right of access to medical treatment." *Id*. at 19. In the absence of due process protection for terminally ill patients seeking access to potentially life saving post-Phase I drugs, the district court concluded that the challenged FDA policy is rationally related to a legitimate governmental interest.

The Alliance appeals, and our review is *de novo*.[4] *See Cicippio-Puleo v. Islamic Republic of Iran,* 353 F.3d 1024, 1031-32 (D.C. Cir. 2004). We treat the dismissal of the complaint as occurring pursuant to Rule 12(b)(6), notwithstanding the district court's consideration of the FDA's April 23, 2003 letter because the letter's conclusion was alleged in the complaint and the FDA does not dispute its contents. *See Gryl ex rel. Shire Pharms. Group PLC v. Shire Pharms. Group PLC*, 298 F.3d 136, 140 (2d Cir. 2002); *Pryor v. Nat'l Collegiate Athletic Ass'n*, 288 F.3d 548, 560 (3d Cir. 2002) (citing 62 Fed. Proc. L. Ed. § 62:508). *Cf. Settles v. United States Parole Comm'n*, 429 F.3d 1098, 1107 (D.C. Cir. 2005).

A court should not dismiss a complaint pursuant to Rule 12(b)(6) for failure to state a claim "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957); *Warren v. District of Columbia*, 353 F.3d 36, 37 (D.C. Cir. 2004). In determining the sufficiency of the

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[4] The Washington Legal Foundation is also a named appellant, but conceded at oral argument that it lacked Article III standing.

complaint, this court reviews questions of law *de novo* while treating the complaint's factual allegations as true and granting the plaintiff the benefit of all reasonable inferences from the facts alleged. *See Conley,* 351 U.S. at 45-46; *Sparrow v. United Air Lines, Inc.*, 216 F.3d 1111, 1114 (D.C. Cir. 2000).

II.

The Due Process Clause of the Fifth Amendment to the United States Constitution provides that "[n]o person shall be . . . deprived of life, liberty, or property, without due process of law." U.S. CONST. AMEND. V. The Supreme Court has held that the Clause "guarantees more than fair process" and accords substantive protection to the rights it guarantees. *See Troxel v. Granville*, 530 U.S. 57, 65 (2000) (plurality opinion); *Glucksberg*, 521 U.S. at 719; *Flores*, 507 U.S. at 301-02. Substantive due process claims can present difficulties for courts. *See Michael H. v. Gerald D.*, 491 U.S. 110, 121 (1989) (plurality opinion); *Moore v. City of East Cleveland*, 431 U.S. 494, 502 (1977). In a case of first impression where fundamental rights may be at stake, determining the limits of the government's authority over an individual's freedom to make certain personal decisions unavoidably entails a careful and possibly arduous assessment of that personal decision's objective characteristics in order to determine whether it warrants protection under the Due Process Clause. *Cf. Roberts v. U.S. Jaycees*, 468 U.S. 609, 620 (1984). Nonetheless, the district court appears to have viewed its role as unduly constrained. Pointing to an advisory cautioning in *Dronenburg v. Zech*, 741 F.2d 1388, 1396 (D.C. Cir. 1984), that lower courts "should [not] freely create new constitutional rights" without "guidance from the Constitution or . . . from articulated Supreme Court principle," the district court focused on the absence of binding precedent recognizing the substantive due process right claimed by the Alliance. Since *Dronenberg,* the Supreme Court

has provided guideposts to enable a court to assess the merits of the Alliance's claim.[5]

Although the Supreme Court has never explicitly said so, and we need not decide the matter here, it appears the Supreme Court has employed two distinct approaches when faced with a claim to a fundamental right. In some cases, the Court has discerned the existence of fundamental rights by probing what "personal dignity and autonomy" demand. *See Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 851 (1992) (citations omitted). In other cases, the Court has derived fundamental rights by reference to the Nation's history and legal tradition, *see, e.g., Glucksberg*, 521 U.S. 702.[6] The line of cases beginning with *Griswold v. Connecticut*, 381 U.S. 479 (1965), and continuing through *Eisenstadt v. Baird*, 405 U.S. 438 (1972), *Roe v. Wade*, 410 U.S. 113 (1973), and *Casey*, 505 U.S. 833, follow the first approach with their heavy reliance on the concepts of individual rights to autonomy and self-determination, and in their unwillingness to countenance state intrusion into certain protected domains such as the bedroom, the clinic, and the womb. This approach is succinctly captured by *Casey*'s characterization of substantive due process rights as those that involve "the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy." *Casey*, 505 U.S. at 851.

The other approach for determining whether a claimed right

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[5] The dissent, to the extent it presupposes the only liberties protected by the Constitution are those that have been explicitly recognized by the Supreme Court, *see* Dissent at 13 & n.3, is in error.

[6] *See* Robert C. Post, *The Supreme Court, 2002 Term—Foreword: Fashioning the Legal Constitution: Culture, Courts, and Law*, 117 HARV. L. REV. 4, 89 (2003).

warrants substantive due process protection, which appears to be more restrictive,[7] has two "features." *See Glucksberg*, 521 U.S. at 720. Under *Glucksberg*, courts must inquire whether the fundamental right asserted is "objectively, 'deeply rooted in this Nation's history and tradition,'" *id*. at 721 (quoting *Moore*, 431 U.S. at 503; *Snyder v. Massachusetts*, 291 U.S. 97 (1934)),[8] and

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[7] Post, *supra* note 6, at 91-93; Laurence H. Tribe, Lawrence v. Texas: *The "Fundamental Right" That Dare Not Speak its Name*, 117 HARV. L. REV. 1893, 1921-23 (2004).

[8] The Supreme Court's mention in *Lawrence v. Texas*, 539 U.S. 558, 592 (2003), of the "emerging awareness" regarding the liberty to engage in homosexual conduct does not limit the swath of time to be surveyed in a *Glucksberg* analysis of history and tradition. The reference to "laws and tradition in the past half century" appears in support of the Court's decision to depart from stare decisis and overrule *Bowers v. Hardwick*, 478 U.S. 186 (1986). Discrediting *Bowers*'s "sweeping references" to history thus had a purpose in addition to that addressed by the *Glucksberg* analysis: it is intended to show that not only had the Court in *Bowers* misread history but that it also had ignored modern trends giving protection to conduct that had long avoided criminal proscription in the states. *See Lawrence,* 539 U.S. at 568. Reading *Lawrence* as narrowing the *Glucksberg* historical inquiry to the last half century would gut the purpose of the *Glucksberg* test, which is to prevent the creation of substantive due process rights by forcing courts to accord due process protection only to those rights with a strong foundation in tradition. Other circuits have either treated the *Glucksberg* analysis as controlling after *Lawrence, see Fields v. Palmdale School Dist*., 427 F.3d 1197 (9th Cir. 2005); *Fields v. Legacy Health System*, 413 F.3d 943 (9th Cir. 2005); *Doe v. City of Lafayette, Ind*., 377 F.3d 757, 768 (7th Cir. 2004), or viewed *Lawrence* as not, properly speaking, a substantive due process decision, *see Lofton v. Sec'y of Dep't of Children and Family Servs*., 358 F.3d 804, 815-16 (11th Cir. 2004); *Muth v. Frank*, 412 F.3d 808, 818 (7th Cir. 2005). No court has regarded *Lawrence* as cabining *Glucksberg*.

"implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if [it] were sacrificed," *Glucksberg*, 521 U.S. at 721 (quoting *Palko v. Connecticut*, 302 U.S. 319, 325-26 (1937)) (internal quotation marks omitted). Additionally, in order to ensure that courts do not multiply rights without principled boundaries, courts must provide a "careful description of the fundamental liberty interest." *Id*. at 721-23. If a court concludes that the claimed right is a fundamental right entitled to protection under the Due Process Clause, then the burden shifts to the government to show that its encroachment upon the right "is narrowly tailored to serve a compelling [governmental] interest." *Id.* at 721 (quoting *Flores*, 507 U.S. at 302).

Because we conclude, upon applying the seemingly more restrictive analysis of *Glucksberg*, that the claimed right warrants protection under the Due Process Clause, we need not decide whether the line of cases construing the concept of "personal dignity and autonomy" would also lend protection to the claimed right.

III.

The question presented by the Alliance's complaint is whether the Due Process Clause protects the right of terminally ill patients to make an informed decision that may prolong life, specifically by use of potentially life-saving new drugs that the FDA has yet to approve for commercial marketing but that the FDA has determined, after Phase I clinical human trials, are safe enough for further testing on a substantial number of human beings. The Due Process Clause, as *Glucksberg* makes clear, protects those liberties "deeply rooted in this Nation's history and tradition." 521 U.S. at 721 (citation omitted). The Supreme Court has variously referred to these rights as principles "so rooted in the traditions and conscience of our people as to be

ranked as fundamental," *Snyder*, 291 U.S. at 105, and as immunities "implicit in the concept of ordered liberty," *Palko*, 302 U.S. at 325. Thus, a court's examination of our Nation's history and tradition cannot be based on so specific a description of the claimed right as would undercut the interests protected by the Due Process Clause.

A.

One feature of the *Glucksberg* analysis requires courts to compose a "careful description" of the asserted fundamental liberty interest before extending due process protection to it. 521 U.S. at 721. The Supreme Court has not settled on how precisely formulated the right must be. Two Justices have interpreted the "careful description" requirement as indicating that courts should identify fundamental rights at the "most specific level at which a relevant tradition protecting, or denying protection to, the asserted right can be identified." *Michael H.*, 491 U.S. at 127 n.6 (1989) (Scalia, J., with Rehnquist, C.J., concurring). Two other Justices have indicated that asserted rights not expressed at "'the most specific level' [of generality] available" can nonetheless be recognized. *Id.* at 132 (O'Connor and Kennedy, JJ., concurring). The "careful description" requirement was first invoked by the Court in *Flores*, 507 U.S. at 302 (1993), which relied on *Collins v. City of Harker Heights*, 503 U.S. 115, 125 (1992), where the notion of careful description was expressed as a pleading requirement. Since *Glucksberg*, the Court has applied this requirement once without elaboration. *See Chavez v. Martinez*, 538 U.S. 760, 775-76 (2003).

In *Hutchins v. District of Columbia*, 188 F.3d 531 (D.C. Cir. 1999), the en banc court applied the careful description requirement in its substantive due process analysis. The court viewed the careful description requirement as a means of constraining the inadvertent creation of rights that could fall

within the scope of loosely worded descriptions and thus threaten the separation of powers. *See id.* at 542-45. Despite reaching different conclusions about the appropriate level of generality in describing the claimed right, *compare id.* at 538 (citing *Michael H.*, 491 U.S. at 127 n.6) (Scalia, J., with Rehnquist, C.J., concurring), *with id.* at 555-57 (Rogers, J., dissenting) (citing *Moore,* 431 U.S. at 502-03), the court concluded that the animating principle underlying the careful description requirement is that courts should proceed with care in examining substantive due process claims. *See id.* at 538.

The Alliance's complaint contains the careful description we seek, allowing this court to consider whether the challenged FDA policy impinges upon one or more of the interests protected by the Due Process Clause. The FDA characterizes the Alliance's claimed right as a broadly stated prerogative to access post-Phase I investigational new drugs and to receive treatment, but the Alliance has defined the right more narrowly. The Alliance claims neither an unfettered right of access to all new or investigational new drugs nor a right to receive treatment from the government or at government expense. The Alliance's claim also does not challenge the Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.*, or the government's authority to regulate substances deemed harmful to public health, safety, and welfare. Rather, the Alliance contends that the fundamental due process rights to privacy, liberty, and life include the right of terminally ill patients, acting on a doctor's advice, to obtain potentially life-saving medication when no alternative treatment approved by the government is available. Recognizing that the effectiveness and side effects of the investigational new drugs may still be in question after the Phase I trials have been completed, the Alliance asks only that the decision to assume these known or unknown risks be left to the terminally ill patient and not to the FDA. This description of the claimed right conforms to the demands of even the narrowest interpretation of the *Glucksberg*

"careful description" requirement.[9]

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[9] In light of the dissenting opinion, it bears emphasizing that, first, the court is presented with a constitutional challenge to a policy adopted by the FDA pursuant to a statutory delegation of authority. The dissent therefore can derive no support from its misplaced reliance on cases raising statutory challenges, especially given that these cases explicitly declined to address constitutional challenges. *Compare* Dissent at 11-12, 19 (relying on *United States v. Oakland Cannabis Buyers' Co-op.*, 532 U.S. 483 (2001) and *Gonzales v. Raich*, 125 S.Ct. 2195 (2005)), *with Oakland Cannabis Buyers' Co-op.*, 532 U.S. at 491 ("We need not decide, however, whether necessity can ever be a defense when the federal statute does not expressly provide for it."), *id*. at 494 ("Nor do we consider the underlying constitutional [substantive due process] issues today."), *and Gonzales*, 125 S.Ct. at 2215 ("[W]e do not address the question whether judicial relief is available to respondents" on their "substantive due process claim and . . . [their] medical necessity defense."). No more helpful are the other cases cited, *see* Dissent at 19-20 & n.6, because in these cases either no fundamental right was at issue, *see* Opinion at 28-29, or else the fundamental right that was asserted was far broader in scope than the right asserted here. Had these courts addressed the substantive due process claim asserted by the Alliance, they no less than this court could not ignore the Supreme Court's substantive due process precedents that discern fundamental liberty interests in long-standing common law and constitutional protections. *See* Opinion at 19 n.12.

Second, contrary to the dissent's argument, *see* Dissent at 21-22, the court does not undertake scientific analysis in addressing the Alliance's claim to potentially life-saving medication. The science has been decided by the FDA, as the Alliance acknowledges. The FDA has determined, upon scientific analysis and evaluation, that certain Phase I investigational new drugs are sufficiently safe for expanded human testing in Phase II trials. The Alliance seeks only to piggyback on the FDA's scientific determination. Also, contrary to the dissent's claims, *see* Dissent at 11, 21-24, the court has engaged in no balancing of interests and has not evaluated whether the FDA's restrictions are narrowly tailored. It remains for the district court on remand to

B.

The other feature of the *Glucksberg* inquiry requires courts

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determine in the first instance whether FDA restrictions on a terminally ill patient's right of access to potentially life-saving medication that has cleared FDA Phase I trials are narrowly tailored to serve a compelling governmental interest. *See* Opinion at 30. At that time, the governmental interests will be identified by the FDA. The dissent oscillates between ignoring that this issue remains to be resolved, *see* Dissent at 9, and asserting that the issue is incapable of resolution, *see id.* at 24. Performing strict scrutiny is not a task that Article III courts have historically regarded as "impossible." *But see* Dissent at 24.

Third, the dissent suggests that the court paves the way for medicinal use of marijuana. *See* Dissent at 14, 24. There is no slippery slope from finding a right of access to potentially life-saving investigational new drugs that have cleared FDA Phase I trials for safety to finding a right of access to illegal narcotics. Marijuana is listed as a Schedule I substance under the Controlled Substances Act. A drug is included in Schedule I if it "has a high potential for abuse," "has no currently accepted medical use in treatment in the United States," and has "a lack of accepted safety for use . . . under medical supervision." 21 U.S.C. §§ 812(b)(1)(A)-(C). The investigational new drugs that have cleared FDA Phase I trials do not possess these attributes or the FDA would not be permitting their medical use in treatment, under medical supervision, by Phase II trial participants. Nothing in the court's holding supports the dissent's inference that marijuana, or any other Schedule I substance, if tested, would qualify for Phase I clearance and be potentially life-saving. By the same token, the record does not imply that a right of access exists to "federally-funded stem cell research and treatment." Dissent at 24. That issue is not before the court and the considerations that would be relevant under *Glucksberg* are not obviously similar. *See infra* n.26.

to determine whether there exists a long-standing tradition in our Nation that would protect individual access to potentially life-saving medication. Courts must focus on discerning those constitutionally protected interests whose existence can be inferred from the Due Process Clause and Supreme Court precedent construing the Clause. *See Cruzan*, 497 U.S. at 278. Although it is relevant to the substantive due process analysis that the government has never proscribed the desired conduct, this is not dispositive. The absence of regulation could be attributable to a liberty interest that is deeply rooted in this Nation's history and tradition, and therefore characterized by a history of liberty from governmental interference, but there may be another explanation. For example, a lack of regulation might indicate only that the technology of yesteryear did not warrant it.

The FDA's discussion of the merits of this question consists of a single sentence: "[The] FDA has had statutory authority to regulate drugs for almost a century, and that authority is now firmly ingrained in our understanding of the appropriate role of government." Appellee's Br. at 19.[10] We offer the following observations, mindful of the fact that the Alliance is complaining only of obstacles to post-Phase I investigational new drugs erected by the FDA and not obstacles that might be

[10] The FDA argues in its brief that the Alliance never argued in the district court that drugs were unregulated for most of our Nation's history, and thus cannot raise this argument for the first time on appeal. In fact, the Alliance argued in district court that *Glucksberg* supported its due process claim, *see* Pls.' Cross-Mot. at 8-9, and the district court relied on the *Glucksberg* analysis in dismissing the complaint. As the FDA states in its brief, whether the Alliance has asserted a fundamental right is a legal issue on which this court is fully briefed. There is no reason why the analysis cannot proceed.

erected by state consumer protection or other laws.[11]

A right of control over one's body has deep roots in the common law. The venerable commentator on the common law William Blackstone wrote that the right to "personal security" includes "a person's legal and uninterrupted enjoyment of his life, his limbs, his body, [and] his health," as well as "the preservation of a man's health from such practices as may prejudice or annoy it." WILLIAM BLACKSTONE, 1 COMMENTARIES *125, *130. This right included the right to self-defense and the right to self-preservation. "For whatever is done by a man, to save either life or member, is looked upon as done upon the highest necessity and compulsion." *Id.* at *127. As recognized throughout Anglo-American history and law, when a person is faced with death, necessity often warrants extraordinary measures not otherwise justified. Indeed the principle holds even when that action impinges upon the rights of others. *See, e.g.*, *Ploof v. Putnam*, 81 Vt. 471, 475 (1908) ("This doctrine of necessity applies with special force to the preservation of human life. . . . One may sacrifice the personal property of another to save his life or the lives of his fellows.") (internal citation omitted); *Mouse's Case*, 77 Eng. Rep. 1341, 1342 (K.B. 1609) (deciding that it is lawful to throw overboard property of another for safety of lives of passengers); RESTATEMENT (FIRST) OF TORTS § 197 (1934); *see generally* George C. Christie, *The Defense of Necessity Considered from the Legal and Moral Points of View*, 48 DUKE L. J. 975 (1996). *But see The Queen v. Dudley and Stephens*, 14 Q.B.D. 273 (1884) (holding that the defense of necessity did not justify

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[11] The FDCA does not regulate doctors in their practice of medicine; they are licensed by the states. *See Chaney v. Heckler*, 718 F.2d 1174, 1179 (D.C. Cir. 1983), *rev'd on other grounds*, *Heckler v. Chaney*, 470 U.S. 821 (1985). *See also Gonzales v. Oregon*, 126 S. Ct. 904, 922-23 (2006).

taking of innocent life). Barring a terminally ill patient from the use of a potentially life-saving treatment impinges on this right of self-preservation.

Such a bar also puts the FDA in the position of interfering with efforts that could save a terminally ill patient's life. Although the common law imposes no general duty to rescue or to preserve a life, it does create liability for interfering with such efforts. Section 326 of the Restatement (First) of Torts, first published in 1934, explained that

> [o]ne who, without a privilege to do so, intentionally prevents a third person from giving to another aid necessary to his bodily security, is liable for bodily harm caused to the other by the absence of aid which he has prevented the third person from giving.

While infrequently invoked, this common law rule is of venerable vintage. *See id.*; *see also Soldano v. O'Daniels,* 190 Cal. Rptr. 310, 313, 316-18 (Ct. App. 1983); *Miller v. Arnal Corp.*, 632 P.2d 987, 993 (Ariz. App. 1981).[12]

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[12] As the dissent notes, fundamental rights may "not [be] simply deduced from abstract concepts of personal autonomy." Dissent at 10 (quoting *Glucksber*g, 521 U.S. at 725). Were it impermissible to draw any inferences from a broader right to a narrower right, however, nearly all of the Supreme Court's substantive due process case law would be out of bounds. *See, e.g.*, *Griswold*, 381 U.S. at 484-86 (inferring specific right to use contraception from general right to be free from intrusion into "sacred precincts of marital bedrooms"); *Roe*, 410 U.S. 113 (identifying specific right to terminate a pregnancy from broader right to privacy); *Moore*, 431 U.S. at 503 (extrapolating from broader constitutional protection for "the sanctity of the family" to specific right to determine extended family living arrangements). In any event, the court's holding is not grounded in the abstract notion of personal autonomy but rather in the specific

In contrast to these ancient principles, regulation of access to new drugs has a history in this country that is of recent origin. Prior to 1906, there was essentially no drug regulation in the United States.[13] In that year Congress enacted the Pure Food and Drug Act ("1906 Act"), Pub. L. No. 59-384, 34 Stat. 768 (repealed 1938), which prohibited misbranded and adulterated foods or drugs from entering interstate commerce, 34 Stat. at 768, and prohibited false and misleading labeling, *id*. at 770.

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right to act in order to save one's own life.

[13] *See* Charles J. Walsh & Alissa Pyrich, *Rationalizing the Regulation of Prescription Drugs and Medical Devices: Perspectives on Private Certification and Tort Reform,* 48 RUTGERS L. REV. 883, 890-91 (1996); Note, *The Catch-22 for Persons with AIDS: To Have or Not To Have Easy Access to Investigational Therapies and Early Approval for New Drugs*, 69 S. CAL. L. REV. 105, 109 (1995); *see also Gonzales v. Raich,* 125 S. Ct. 2195, 2202-03 (2005). The FDA Historian Wallace F. Janssen writes that prior to 1906 was the "heyday of 'patent medicines,'" a time when "[a]nyone, no matter how ignorant or unqualified, could go into the drug manufacturing business" and when "[m]edicines . . . were sold without restriction at almost every crossroads store." Wallace F. Janssen, *Outline of the History of U.S. Drug Regulation and Labeling*, 36 FOOD DRUG COSM. L. J. 420, 422 (1981) ("*Outline of the History*"). He further recounts that in "colonial days, and long afterward, consumers . . . were their own food and drug inspectors," "there was a striking absence of statutes dealing with drugs," and, although there were food inspection laws and standards for weights and measures, *see id*. at 423, 425, "drug laws were virtually non-existent." Janssen, *America's First Food and Drug Laws,* 30 FOOD DRUG COSM. L. J. 665, 669, 671 (1975). This suggests that in this country's early history there were no restrictions on a patient's access to potentially life-saving medication, regardless of whatever restrictions may have been placed on physicians, pharmacists, apothecaries, poisons, or misbranded or adulterated substances. *See id.* at 669-72; Janssen, *Outline of the History*, at 426-28. *But cf*. Dissent at 15-17.

For a small number of particularly dangerous drugs, the 1906 Act required the labels to identify the drug's ingredients and quantities. *Id.* The statute also authorized the Bureau of Chemistry, a predecessor of the FDA, to seize nonconforming goods and to recommend federal prosecution of those who violated the 1906 Act. *Id*. at 769 § 4. The 1906 Act did not, however, limit individual access to new drugs or regulate therapeutic claims by drug manufacturers. *Cf. United States v. Johnson*, 221 U.S. 488 (1911). It thus appears that a patient still could obtain access to any new drug for medicinal use, even if the drug had no therapeutic benefit, albeit subject to the controls placed on narcotics in 1914 by the Harrison Narcotic Act. Act of Dec. 17, 1914, 38 Stat. 785.[14]

In 1938, Congress enacted the FDCA in response to the deaths of more than one hundred people, many of them children, from ingesting Elixir Sulfanilamide, which had been marketed as an antibiotic. *See* Report of the Secretary of Agriculture on Deaths Due to Elixir Sulfanilamide, S. Doc. No. 124, 75th Cong., 2d Sess. 1, 1-3 (1937) ("1937 Report").[15] For the first time, Congress required that drug manufacturers test, and the FDA review, all new drugs for safety prior to their commercial distribution. Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301 *et seq.*); 1937 Report at 1-3. Under the 1938 Act, a new drug could be commercially

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[14] *See generally* James L. Zelenay, Jr., *The Prescription Drug User Fee Act: Is a Faster Food and Drug Administration Always a Better Food and Drug Administration?*, 60 FOOD & DRUG L.J. 261, 263-64 (2005); Steven R. Salbu, *Regulation of Drug Treatments for HIV and AIDS: A Contractarian Model of Access,* 11 YALE J. ON REG. 401, 406-09 (1994); *cf. State of Minnesota ex rel. Whipple v. Martinson*, 256 U.S. 41, 45 (1921).

[15] *See* Salbu, *supra* note 14, at 407.

marketed only after the manufacturer filed a New Drug Application ("NDA") with the FDA that set forth medical and scientific information attesting to the drug's safety. The 1938 Act did not, however, require drug manufacturers to receive affirmative FDA approval before marketing the drug.[16] Rather, an NDA became automatically effective within a time frame set by the FDA unless the FDA determined that the drug was unsafe and barred its commercial distribution.[17] It was not until 1951, in the Durham-Humphrey Amendment, that Congress created the category of prescription drugs, i.e., drugs that are unsafe for self-medication but which can be used while under a doctor's supervision. *See* Act of Oct. 25, 1951, 65 Stat. 648 (1951) (codified at 21 U.S.C. § 353(b)).

Only in 1962 did Congress require drug manufacturers to provide empirical evidence of the effectiveness of a drug as opposed to merely the drug's safety.[18] The Kefauver-Harris Amendments, Pub. L. No. 87-781, 76 Stat. 780 (1960) (codified in scattered sections of 21 U.S.C. §§ 301-81 (1982 & Supp. IV 1986)), were enacted in response to the rash of birth defects discovered in babies whose mothers had taken Thalidomide to ease morning sickness caused by pregnancy.[19] The Kefauver-Harris Amendments transformed drug regulation and the approval process in several respects. First, the Amendments required the FDA to review a new drug for both safety and effectiveness and specified that to demonstrate effectiveness

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[16] *See* Zelenay, *supra* note 14, at 264-65.

[17] *Id*.

[18] *See* Greenberg, *supra* note 3, at 295, 300 & n.23.

[19] *See* Salbu, *supra* note 14, at 408 n.41; *see generally* HARVEY TEFF & COLIN R. MUNRO, THALIDOMIDE: THE LEGAL AFTERMATH 1-10 (1976); Janssen, *Outline of the History*, at 438.

manufacturers were required to submit data from "adequate and well-controlled investigations." 21 U.S.C. § 355(d). Second, the Amendments authorized the FDA to approve human clinical trials, regulate drug advertising, inspect drug-manufacturing facilities, and promulgate good manufacturing practices. The Amendments also required drug manufacturers to disclose to the FDA any information they received regarding the adverse consequences of approved drugs.[20] This legislation set the framework for the system of drug regulation currently in place.

Despite the increased federal scrutiny of new drugs, important aspects of patient access to drugs are unregulated by the government and appear always to have been unregulated. "The FDA's regulatory authority extends to manufacturers of drugs but not to the physicians who dispense them."[21] Thus, a doctor may prescribe a drug to a patient for a purpose other than that for which the FDA has approved the use of the drug. Such "off-label" use may occur even if the drug is not deemed safe or effective for that use. Further, it appears that the FDA has never prohibited either off-label prescription or off-label use of drugs.[22] In recent years, the FDA has been moving to permit drug manufacturers to promote the use of their drugs for off-label purposes in limited circumstances.[23] *See* Food and Drug Administration Modernization Act of 1997, Pub. L. No.

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[20] *See* Walsh & Pyrich, *supra* note 13, at 901; *see also* Zelenay, *supra* note 14, at 266.

[21] Steven R. Salbu, *Off-Use, Prescription, and Marketing of FDA-Approved Drugs: An Assessment of Legislative and Regulatory Policy*, 51 FLA. L. REV. 181, 189-92 (1999). *See Chaney*, 718 F.2d at 1180.

[22] *See* Salbu, *supra* note 21, at 189-92.

[23] *See id.* at 211.

105-115, 111 Stat. 2296 (codified in scattered sections of 21 U.S.C. §§ 301-81).

For over half of our Nation's history, then, until the enactment of the 1906 Act, a person could obtain access to any new drug without any government interference whatsoever. Even after enactment of the FDCA in 1938, Congress imposed no limitation on the commercial marketing of new drugs based upon the drugs' effectiveness. Rather, at that time, the FDA could only interrupt the sale of new drugs based on its determination that a new drug was unsafe. Government regulation of drugs premised on concern over a new drug's efficacy, as opposed to its safety, is of recent origin. And even today, a patient may use a drug for unapproved purposes even where the drug may be unsafe or ineffective for the off-label purpose. Despite the FDA's claims to the contrary, therefore, it cannot be said that government control of access to potentially life-saving medication "is now firmly ingrained in our understanding of the appropriate role of government," Appellee's Br. at 19, so as to overturn the long-standing tradition of the right of self-preservation.[24]

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[24] The court does not, as the dissent suggests, "infer[] a constitutional right to be free from regulation" from "the lack of federal regulation" in this area prior to the recent past. *See* Dissent at 14. Rather, the court infers the right from the Due Process Clause and Supreme Court precedents construing the Due Process Clause. *See supra* n. 12. The fundamental right to take action, even risky action, free from government interference, in order to save one's own life undergirds the court's decision. Our point is that the relatively short-lived history of drug regulation, particularly as regards the effectiveness of a new drug, is not, as the dissent suggests, sufficient to establish that the government has acquired title to this right by adverse possession. The same logic plainly would not serve to establish a right to recreational drugs merely because, in the grand sweep of the Nation's history, these regulations are of relatively recent

C.

The Alliance's claim also falls squarely within the realm of rights the Supreme Court has held are "implicit in the concept of ordered liberty." *Palko*, 302 U.S. at 325. Specifically, the claimed right is implied by the Court's conclusion in *Cruzan* that due process protects a person's right to refuse life-sustaining treatment. *See Cruzan*, 497 U.S. at 279. Writing for the Court, Chief Justice Rehnquist noted in examining the origins of the doctrine of informed consent that the Court had observed early on that "[n]o right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law." *Id*. at 269 (quoting *Union Pacific R. Co. v. Botsford*, 141 U.S. 250, 251 (1891)). The Court reasoned that "[t]he logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, to refuse treatment." *Id*. at 270. Confronting for the first time what it described as a "perplexing question with unusually strong moral and ethical overtones," *id*. at 277, the Court turned to the language of the Fourteenth Amendment and its precedent to determine whether "the United States Constitution grants what is in common parlance referred to as a 'right to die,'" *id*. The Court reasoned 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." *Id.* Without qualification, the Court stated: "It cannot be disputed that the Due Process Clause protects an interest in life as well as an interest in refusing life-sustaining medical treatment." *Id.* at 281.

A similar analysis leads to the conclusion that the Due

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vintage.

Process Clause protects the liberty interest claimed by the Alliance for its terminally ill members. *See supra* Part III.A. The text of the Due Process Clause refers to protecting "liberty" and "life." Although there is no similarly clear textual basis for a "right to die" or refusing life-sustaining medical treatment, the Supreme Court in *Cruzan* recognized, in light of the common law and constitutionally protected liberty interests based on the inviolability of one's body, that an individual has a due process right to make an informed decision to engage in conduct, by withdrawing treatment, that will cause one's death.[25] The logical corollary is that an individual must also be free to decide for herself whether to assume any known or unknown risks of taking a medication that might prolong her life.

Like the right claimed in *Cruzan*, the right claimed by the Alliance to be free of FDA imposition does not involve treatment by the government or a government subsidy. Rather, much as the guardians of the comatose patient in *Cruzan* did, the Alliance seeks to have the government step aside by changing its policy so the individual right of self-determination is not violated. The Alliance claims that there is a protected right of terminally ill patients to choose to use potentially life-saving investigational new drugs that have successfully cleared Phase I. If there is a protected liberty interest in self-determination that includes a right to refuse life-sustaining treatment, even though this will hasten death, then the same liberty interest must

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[25] It was only in the course of balancing an individual's liberty interest against the relevant government interests that the Court indicated "the dramatic consequences involved in the refusal of [life-sustaining] treatment would inform the inquiry as to whether the deprivation of that interest is constitutionally permissible." *Cruzan*, 497 U.S. at 279. The Court's holding allowed the government to protect the autonomous exercise of the right to refuse life-sustaining treatment; it did not undermine the right.

include the complementary right of access to potentially life-sustaining medication, in light of the explicit protection accorded "life."[26] Our reasoning is not unlike that of the Supreme Court in *Eisenstadt*, 405 U.S. 438, where the Court held that the right to be free from unwanted government intrusion into the fundamental decision whether to have children establishes a right of access to contraception.

Contrary to the FDA's position, nothing in this court's precedent or that of the other circuit courts of appeal conflicts with our analysis. Although the district court concluded, in reliance upon our decision in *Dronenberg*, 741 F.2d at 1396, that lower courts may not consider claims to new substantive due process rights and principles not previously identified by the

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[26] The dissent fails to see how the court can reason from a right to refuse life-saving treatment to a right of access to life-saving treatment, *see* Dissent at 17-18, but the two go hand in hand. In either instance — refusal or access — the key is the patient's right to make her own decision free from government interference. Moreover, the right of access to investigational new drugs that have cleared Phase I trials is different from and does not imply a general right to receive life-saving treatment, as the dissent, Dissent at 24, and the district court presumed. Nor does the court reach the question whether there is such a right for that is not the Alliance's claim.

Finally, the dissent mistakenly suggests the court offends the "concept of ordered liberty" because the court's decision is "contrary to the expressed will of Congress and the Executive and to the deference courts owe to the democratic branches on such controversial matters." Dissent at 22-23. Although the term "ordered liberty" necessarily remains somewhat unclear, it cannot stand for a broad principle of deference to the political branches whenever "unknown questions of science" are involved. *See id*. Otherwise, it would establish a zone in which the political branches would be free to regulate persons unconstrained by the individual liberties preserved in the Constitution.

Supreme Court, *see supra* page 9, this court has addressed substantive due process claims on a number of occasions. *See, e.g.*, *N.Y. State Opthalmological Soc'y v. Bowen*, 854 F.2d 1379 (D.C. Cir. 1988). Most pertinently, in *Butera v. District of Columbia*, 235 F.3d 637 (D.C. Cir. 2001), the court confronted, in the context of a qualified immunity defense, the claim of a substantive due process right to life, personal security, and bodily integrity. *Butera* involved a suit under 42 U.S.C. § 1983 brought by the mother of a man who was shot while working undercover for the police department. The court in *Butera* did not suggest that the advisory admonition in *Dronenberg*, 741 F.2d at 1396, precluded either the substantive due process inquiry or the conclusion that a fundamental right was implicated.

The decisions in the other circuits on which the FDA relies likewise fail to support its position that there is no substantive due process right of access to potentially life-saving treatment. *United States v. Burzynksi Cancer Research Institute*, 819 F.2d 1301 (5th Cir. 1987), which held that the doctor and patient had not stated a constitutional tort based on the allegedly improper seizure of the doctor's patient records and thus that they did not overcome the defendant's claim of qualified immunity, *id.* at 1310-11, bears no legal or factual relevance to the question before this court. The statement in *Carnohan v. United States,* 616 F.2d 1120, 1122 (9th Cir. 1980), that "[c]onstitutional rights of privacy and personal liberty do not give individuals the right to obtain [the cancer drug] laetrile free of the lawful exercise of government police power," was dictum; the Ninth Circuit never reached the merits of the claimed fundamental right of access as the complaint was dismissed for failure to exhaust administrative remedies.

Further, as the Alliance pointed out in its brief, the terminally ill patients in *Rutherford v. United States*, 616 F.2d

455 (10th Cir. 1980), like those in *Carnohan*, sought access to laetrile, a new cancer drug that had not cleared FDA's Phase I safety hurdle and thus had not been approved for expanded testing on humans in ongoing clinical trials, *see id.* at 456-57. The Tenth Circuit rejected a right to laetrile, reasoning that the choice of a particular treatment or medication is "within the area of governmental interest in protecting public health." *Id.* at 457. Of course, the government's interest in regulating has no bearing upon the identification of a fundamental right. Rather, its interest is to be considered only if, and after, a court recognizes a fundamental right; at that point, the burden shifts to the government to demonstrate a narrowly tailored "compelling interest" in burdening that right. Because the FDA had neither eliminated the possibility that laetrile was a poison nor approved the drug for basic human testing in Phase I trials, the government's interest in *Rutherford* might well have been sufficiently compelling to warrant restricting access to the drug. In this case, the government's interest may prove to be weaker because the Alliance seeks only access to investigational new drugs that the FDA, after Phase I human trials, has deemed sufficiently safe for human testing on a substantial number of human beings. In other words, the Alliance seeks for its members the same right of access enjoyed by those terminally ill patients lucky enough to secure a spot in Phase II trials.

Accordingly, we hold that the district court erred in dismissing the Alliance's complaint pursuant to Rule 12(b)(6) for failure to state a claim. We conclude, upon applying the *Glucksberg* analysis and heeding the protected liberty interests articulated by the Supreme Court, that where there are no alternative government-approved treatment options, a terminally ill, mentally competent adult patient's informed access to potentially life-saving investigational new drugs determined by the FDA after Phase I trials to be sufficiently safe for expanded human trials, warrants protection under the Due Process Clause.

The prerogative asserted by the FDA — to prevent a terminally ill patient from using potentially life-saving medication to which those in Phase II clinical trials have access — thus impinges upon an individual liberty deeply rooted in our Nation's history and tradition of self-preservation. *See Glucksberg*, 521 U.S. at 721; *Flores*, 506 U.S. at 302. The district court never reached the question of whether the challenged FDA policy violates this protected liberty interest, and we therefore remand the case to the district court to determine whether the FDA's policy barring access to post-Phase I investigational new drugs by terminally ill patients is narrowly tailored to serve a compelling governmental interest.

GRIFFITH, *Circuit Judge*, dissenting: Experimental drugs present a variety of potential risks and benefits to patients. Some drugs may harm patients; others may help. Acting at the direction of Congress, the Food and Drug Administration ("FDA") determines and balances those risks and benefits during the testing process for new drugs with input from the scientific and medical communities. Sometimes initial scientific conclusions support providing seriously ill patients early access to experimental drugs or hastening the testing process. Sometimes they do not. The FDA examines the science behind each new drug and makes a judgment about what level of access will provide patients with an effective drug that carries an acceptable level of risk. One group of terminally ill patients believes the FDA is too cautious. The Abigail Alliance for Better Access to Developmental Drugs (the "Alliance") favors a different balance that would allow terminally ill patients access to all experimental drugs after the first phase of FDA testing is complete. The Alliance argues that the Constitution guarantees them this access.

Courts must, of course, be cautious about acceding to a litigant's claim of a newly-discovered constitutional right. To succeed here, the Alliance must show that the access to experimental drugs it seeks for terminally ill patients is a "fundamental right[] and libert[y] which [is], objectively, 'deeply rooted in this Nation's history and tradition,'" *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997) (quoting *Moore v. East Cleveland*, 431 U.S. 494, 503 (1977) (plurality opinion)), and "'implicit in the concept of ordered liberty,' such that 'neither liberty nor justice would exist if [it] w[as] sacrificed,'" 521 U.S. at 721 (quoting *Palko v. Connecticut*, 302 U.S. 319, 325-26 (1937)). Although others previously have argued for the creation of a similar right, until today, no circuit court has assented to such a claim. The majority creates a fundamental right by making a series of inferences prohibited by *Glucksberg*. From the fact that the Government has not always regulated drugs, the majority infers

a constitutional right to be free from such regulation. From the common law defense of necessity and the tradition prohibiting battery and forced medication, the majority infers a fundamental right of access to medication. From the fact that drugs in the first phase of FDA testing have undergone some testing, the majority infers that those drugs will probably have a medical benefit with sufficiently minimal risk. But there is no evidence in this Nation's history and traditions of a right to access experimental drugs. Balancing 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. Because I can find no basis in the Constitution or judicial precedents to remove that function from the elected branches, I respectfully dissent.

I.

People of good will wish for scientists to develop effective, safe cures for terminally ill patients as quickly as possible. The Alliance could have taken its argument to Congress and attempted to convince our Nation's lawmakers that the current balance between safety and risk is scientifically or morally misguided and that terminally ill patients should have the early access to experimental drugs that the Alliance seeks. Congress could have held hearings on the subject and heard the viewpoints of scientists, doctors, patients, advocacy groups (like the Alliance), moralists, ethicists, and citizens. Congress could then exercise its lawmaking function by striking a new balance between early availability and the need for sufficient understanding of the toxicity and potential benefits of experimental drugs. The Alliance could also work with the FDA, as the agency suggested in a letter to the Alliance, to "help expand patient access to promising new treatments [by] work[ing] with sponsors and with [the] FDA to better understand the reasons sponsors choose not to create these [early

access] programs [already existing under the FDA's regulations] and to identify additional incentives for participation." Just as the Supreme Court reminded litigants who argued last term in *Gonzales v. Raich* that substantive due process allowed them to use marijuana for medicinal purposes, "perhaps even more important than these legal avenues is the democratic process, in which the voices of voters allied with these respondents may one day be heard in the halls of Congress." 125 S.Ct. 2195, 2215, __ U.S. __, __ (2005). Of course, changing the present level of access to experimental drugs through the democratic branches would involve intense and complicated scientific and moral debates about how best to regulate new drugs.

Instead of allowing the elected branches to resolve these debates, the Alliance argues that the Constitution mandates its desired outcome, regardless of the particular balance already struck by Congress and the Executive. In the Alliance's view, the Due Process Clause of the Constitution guarantees terminally ill patients a fundamental "right of access to drugs that have cleared Phase I trials" because those drugs are "safe enough to be tested in humans" and "simply ha[ve] not yet met FDA's standards." Based upon that argument, the majority creates a fundamental right and concludes that, under the Constitution, "a terminally ill, mentally competent adult patient's informed access to potentially life-saving investigational new drugs determined by the FDA after Phase I trials to be sufficiently safe for expanded human trials warrants protection under the Due Process Clause." Maj. Op. at 29.

The Alliance's proposed new constitutional right would exempt terminally ill patients from much of the legislative and regulatory approval process created by Congress and the FDA for new experimental drugs. Section 505(a) of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(a), bars the introduction of new drugs into interstate commerce until the

FDA has approved a sponsor's application. A new drug application must contain "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use." *Id.* § 355(b)(1)(A). Before testing a new drug on humans for safety and effectiveness, a sponsor must submit for the FDA's approval an investigational new drug application ("IND"), *see id.* § 355(i)(1); *see also* 21 C.F.R. pt. 312, containing detailed information establishing that human testing is appropriate, *see* 21 C.F.R. § 312.23.

Testing a new drug for safety and effectiveness in treating humans generally requires three or sometimes four phases. *See id.* § 312.21. Phase I involves the initial introduction of a new drug into human subjects. A Phase I study usually consists of twenty to eighty subjects 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." *Id.* § 312.21(a)(1). The majority and I differ in our understanding of the importance of the testing that occurs after Phase I. The majority implies that the FDA is primarily concerned with effectiveness after Phase I and that the right argued for by the Alliance would only override FDA regulation for effectiveness.[1]

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[1] *See* Maj. Op at 14 ("The Alliance's claim also does not challenge . . . the government's authority to regulate substances deemed harmful to public health, safety, and welfare."); *id.* (suggesting that only the "*side effects* of the investigational new drugs *may* still be in question after the Phase I trials have been completed," and not addressing the fact that later studies address risks, safety, and the overall benefit-risk relationship of a new drug) (emphasis added); *id.* at 22 ("Only in 1962 did Congress require drug manufacturers to provide empirical evidence of the effectiveness of a drug as opposed to merely the drug's safety."); *id.* at 24 ("Government regulation of drugs premised on concern over a new drug's efficacy, as opposed to

Contrary to the majority's suggestion, all phases of the FDA's testing process for new drugs involve testing for safety. In addition to addressing the effectiveness of a new drug, Phase II studies are used "to determine the common short-term side effects and risks associated with the drug." *Id.* § 312.21(b). Phase III studies "gather . . . additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug." *Id.* § 312.21(c). The FDA further requires some drugs to go through Phase IV studies, which "delineate additional information about the drug's risks, benefits, and optimal use." *Id.* § 312.85.

To guide this process, Congress has directed the FDA to establish "[s]cientific advisory panels" to "provid[e] expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug." 21 U.S.C. § 355(n)(1). Quite specifically, Congress has mandated that the FDA include on these panels scientists from a variety of disciplines. *See id.* § 355(n)(3).[2]

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its safety, is of recent origin.").

[2] Section 355(n)(3) of Title 21, United States Code, provides:

> The Secretary shall make appointments to each panel . . . so that each panel shall consist of—
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> (A) members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in the development, manufacture, or utilization of such drugs;
>
> (B) members with diverse expertise in such fields as clinical and administrative medicine, pharmacy,

Thus, at issue today is whether terminally ill patients have a fundamental right to procure and use an experimental drug before the FDA and the scientific community have evaluated its scientific and medical risks and corresponding benefits as called for in the FDCA and its accompanying regulations.

The FDA has several regulatory programs in place to hasten research of the safety and effectiveness of drugs for terminally or severely ill patients and allow early access where scientifically and medically warranted. For example, under its "Fast Track" program, the agency has "established procedures designed to expedite the development, evaluation, and marketing of new therapies intended to treat persons with life-threatening and severely-debilitating illnesses, especially where no satisfactory alternative therapy exists." 21 C.F.R. § 312.80. Fast Track allows the FDA to waive its IND application requirement if it is "unnecessary or cannot be achieved," *id.* § 312.10, and even allows a waiver request to be made "[i]n an emergency . . . by telephone or other rapid communication," *id.* The Accelerated Approval program provides a truncated approval process for "certain new drug products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide

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> pharmacology, pharmacoeconomics, biological and physical sciences, and other related professions;
>
> (C) a representative of consumer interests, and a representative of interests of the drug manufacturing industry not directly affected by the matter to be brought before the panel; and
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> (D) two or more members who are specialists or have other expertise in the particular disease or condition for which the drug under review is proposed to be indicated.

meaningful therapeutic benefit to patients over existing treatments." *Id.* § 314.500. The FDA categorizes some new drugs, including nearly all cancer drugs, as "priority drugs" and seeks to accelerate their availability.

The Alliance contends that Congress and the FDA have not struck the right balance between early access and safety. In its view, these carefully constructed programs, refined over the years by experience, do not sufficiently allow its members access to the experimental drugs they need. Accordingly, the Alliance developed and submitted to the FDA a comprehensive proposal that argued there is a "different risk-benefit tradeoff facing patients who are terminally ill and who have no other treatment options." Although the Alliance agreed that "[e]xtensive marshalling of evidence regarding drug interactions, dose optimization, and the like" is "appropriate for new drugs to treat patients with other alternatives," the Alliance suggested that "these steps may well entail a delay that is fatal" for terminal patients. Accordingly, the Alliance contended that terminally ill patients "should have the ability to opt for a new treatment that has met a lower evidentiary hurdle with respect to safety and efficacy." The Alliance's proposal suggested, among other things, that the FDA allow early access based upon "the risk of illness, injury, or death from the disease in the absence of the drug." The FDA should have promulgated a new regulation, the Alliance contended, that would allow sponsors to market experimental drugs, under some circumstances, after the completion of Phase I trials.

Several senior FDA officials reviewed the Alliance's proposed regulation. The officials concluded that the Alliance "raised several important questions about expanded access that we believe deserve further consideration," but questioned whether the specific proposal put forward by the Alliance "would have the intended desirable effects for patients." The

officials concluded that the Alliance's "suggestion points to an area of significant range of opinion within the patient and provider communities about the standards that should be met before a drug is marketed." Although "some members of the cancer community have suggested that [the] FDA needs to maintain a strong clinical trial system as the basis of the approval of cancer drugs, . . . others, like [the Alliance], have criticized [the FDA] for relying too heavily on completing certain trials before approval." The FDA noted that "[i]n the realm of reviewing medical products to treat serious and life-threatening diseases, there is inevitable tension between early availability of products to patients, especially patients with refractory disease, and the need to obtain sufficient data to provide a reasonable expectation of benefit and lack of excessive harm."

Having previously exercised its scientific and medical judgment to "strike the appropriate balance between these two competing goals," the FDA noted its conclusion that "a reasonably precise estimate of response rate" and "enough experience to detect serious adverse effects" are "critical" in determining when experimental drugs should be made available. Most experimental cancer drugs "have potentially lethal toxicity, with potentially large effects on a patient's remaining quality of life." Accordingly, in the FDA's judgment, "it does not serve patients well to make drugs too widely available before there is a reasonable assessment of such risks to guide patient decisions, and experience in managing them." Accepting the Alliance's proposal "would upset the appropriate balance that the FDA is seeking to maintain, by giving almost total weight to the goal of early availability and giving little recognition to the importance of marketing drugs with reasonable knowledge for patients and physicians of their likely clinical benefit and their toxicity." With its proposal rejected by the FDA, the Alliance turned to the courts rather than the Congress and now asks us to create a new

constitutional right that will provide the level of access to experimental drugs they seek.

To understand the constitutional dispute in this case, it is critical to understand what this case is not about. Neither the Constitution nor Congress has authorized this Court to determine which of these two litigants has a more scientifically and medically sound view. FDA scientists, physicians, and officials, acting pursuant to express statutory authority, have determined that blanket access to experimental drugs for terminal patients would present unacceptable scientific and medical risks. Contrary to the FDA's scientific and medical views, the Alliance believes that, at least for terminally ill patients, the benefits of an experimental drug will usually outweigh its risks after the FDA completes Phase I trials. The only issue this case presents is a narrow one: whether the Due Process Clause of the Constitution mandates access to experimental drugs that have cleared Phase I of FDA testing, such that Congress cannot protect terminally ill patients from the risks experimental drugs present unless it uses a means narrowly tailored toward achieving a compelling interest in limiting access.

II.

In *Glucksberg*, the Supreme Court set forth a two-part test for determining whether an asserted right is fundamental under the Constitution. "[T]he Due Process Clause specially protects those fundamental rights and liberties which are, objectively, 'deeply rooted in this Nation's history and tradition . . . .'" *Glucksberg*, 521 U.S. at 720-21 (quoting *Moore*, 431 U.S. at 503). A right must also be "'implicit in the concept of ordered liberty,' such that 'neither liberty nor justice would exist if [it] w[as] sacrificed.'" 521 U.S. at 721 (quoting *Palko*, 302 U.S. at 325). The majority properly states the *Glucksberg* test, but

makes several critical errors in its application.

The majority structures its analysis around the first *Glucksberg* inquiry—whether the claimed right is "deeply rooted"—and gives short shrift to the second part—whether it is part of "ordered liberty." The majority relies upon three common law concepts, none of which is advanced by the Alliance, as evidence of a fundamental, deeply rooted right to procure and use experimental drugs: (1) the common law defense of necessity; (2) an individual's common law interest in being free from battery; and (3) common law liability for interference with a rescue. The majority does not discuss, however, evidence of a fundamental right to procure and use experimental drugs—because none exists. In the absence of such a tradition, the majority is left to argue for the creation of a fundamental right from a series of inferences. *Glucksberg*, mindful of the danger in courts minting new rights from an amalgam of interests, prohibits us from creating new substantive due process rights by inference.

Fundamental rights may "not [be] simply deduced from abstract concepts of personal autonomy." *Glucksberg*, 521 U.S. at 725. Instead, to be fundamental, there must be evidence that the "*asserted* right has any place in our Nation's traditions." *Id.* at 723 (emphasis added). Quite simply, the majority has provided no evidence of a right, deeply rooted in our Nation's history and traditions, to procure and use experimental drugs. To the contrary, the majority concedes that new drugs have been regulated since the early part of the last century. *See* Maj. Op. at 20. But even where other "decision[s] . . . may be just as personal and profound as the decision to refuse unwanted medical treatment," these other decisions are not protected as fundamental rights if they "ha[ve] never enjoyed similar legal protection." *Glucksberg*, 521 U.S. at 725.

Nor is a common law interest alone sufficient to establish a fundamental right under the Constitution. *See Glucksberg*, 521 U.S. at 725 (inquiring whether a right is consistent with "this Nation's history and *constitutional* traditions") (emphasis added); *Ingraham v. Wright*, 430 U.S. 651, 673 (1977) (looking to "'those privileges long recognized at common law as *essential* to the orderly pursuit of happiness by free men'") (emphasis added) (quoting *Meyer v. Nebraska*, 262 U.S. 390, 399 (1923)). I cannot agree that the common law concepts discussed by the majority demonstrate a fundamental right under *Glucksberg*. At common law, "[a] necessity defense 'traditionally covered the situation where physical forces beyond the actor's control rendered illegal conduct the lesser of two evils.'" *United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483, 490 (2001) (quoting *United States v. Bailey*, 444 U.S. 394, 410 (1980)). Putting aside the difference between a common law defense and a constitutional right, I have serious doubt about how a court can know, as a matter of constitutional law, that the lesser of two evils will be achieved by providing all terminally ill patients access to all Phase I experimental drugs, given the risks these drugs present. In any event, the Supreme Court's guidance in *Oakland* indicates that the common law doctrine of necessity is not deeply rooted in this Nation's history and traditions.

In *Oakland*, a group of patients seeking access to marijuana for medicinal purposes argued that "because necessity was a defense at common law, medical necessity should be read into the Controlled Substances Act." *Id.* at 490. As an initial matter, the Court noted that "it is an open question whether federal courts *ever* have authority to recognize a necessity defense not provided by statute." *Id.* (emphasis added). "Even at common law, the defense of necessity was somewhat controversial. And under our constitutional system, in which federal crimes are defined by statute rather than by common law, it is especially

so." *Id.* (internal citations omitted). The Court did "not decide, however, whether necessity can ever be a defense when the federal statute does not expressly provide for it," *id.* at 491, because "[u]nder any conception of legal necessity, one principle is clear: The defense cannot succeed when the legislature itself has made a determination of values," *id.* (quotation marks omitted). The structure of the FDCA does just that: Congress has prohibited general access to experimental drugs, *see* 21 U.S.C. § 355(a), and has prescribed in detail how experimental drugs may be studied and used by the scientific and medical communities, *see id.* § 355(i). Given the Supreme Court's conclusion that the common law defense of necessity remains controversial and cannot override a value judgment already determined by the legislature, I cannot see how the majority's proposed right is supported by the common law doctrine of necessity.

The Supreme Court has "required in substantive-due-process cases a careful description of the asserted fundamental liberty interest." *Glucksberg*, 521 U.S. at 721 (quotation marks omitted). The right at issue in this case, and the right that the majority concludes has been carefully described by the Alliance, is a right of terminally ill patients to access potentially life-saving drugs when no alternative treatment is available. *See* Maj. Op. Part III(A). The Alliance has narrowly described its asserted right. *Cf. Glucksberg*, 521 U.S. at 723 (carefully-described asserted right was "a right to commit suicide which itself includes a right to assistance in doing so"). The majority never provides evidence, however, that the Alliance's *asserted* right is deeply rooted and implicit in ordered liberty. Instead, the majority infers its new right from several broad principles, none of which would meet *Glucksberg*'s careful description requirement. *See* Maj. Op. Part III(B), at 18 (the "right of control over one's body"), *id.* (the "right to self-defense"), *id.* ("the right to self-preservation"), 19-

20 n.12 ("the specific right to act in order to save one's own life"), 24 n.24 (the "fundamental right to take action, even risky action, free from government interference, in order to save one's own life"); Part III(C), at 26 (the right to "be free to decide . . . whether to assume any known or unknown risks of taking a medication that might prolong . . . life"), 27 n.26 (the "right of access to life-saving treatment" with "the key [being] the patient's right to make her own decision free from government interference").

The majority concludes that these principles are deeply rooted based upon a passage from Blackstone describing an individual's interest in being free from battery at common law, *see* WILLIAM BLACKSTONE, 1 COMMENTARIES *129, *134, and a provision of the Restatement discussing when one person will be liable under the common law for preventing aid from reaching another, *see* RESTATEMENT (FIRST) OF TORTS § 326 (1934). The majority infers from these principles a liberty interest in procuring and using experimental drugs. But *Glucksberg* does not authorize courts to create substantive due process rights by inference. These principles are precisely the type of "abstract concepts of personal autonomy" that do not constitute evidence of a fundamental right. *Glucksberg*, 521 U.S. at 725. They are indeterminate concepts that cannot meet *Glucksberg*'s careful description requirement. The majority has provided no evidence that the Alliance's "*asserted* right has any place in our Nation's traditions." *Glucksberg*, 521 U.S. at 723 (emphasis added). Simply put, under *Glucksberg*, the Alliance's asserted right fails because it is not deeply rooted and implicit in ordered liberty, and the various principles described by the majority fail because they are not carefully described.[3]

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[3] In an effort to support its inferences from common law interests, the majority briefly turns to several privacy cases, *see* Maj. Op. at 19 n.12, 27, cases that the majority earlier concludes are not

The remainder of the majority's analysis sets out to prove an unremarkable proposition: the federal government has only regulated drugs for approximately 100 years. From the lack of federal regulation prior to 1906, the majority infers a constitutional right to be free from regulation. It is not difficult to see the sweeping claims of fundamental rights that such an analysis would support. Because Congress did not significantly regulate marijuana until relatively late in the constitutional day (*i.e.*, 1937), *see Gonzales v. Raich,* 125 S.Ct. 2195, 2202, __ U.S. __, __ (2005), there must be a tradition of protecting marijuana use. Because Congress did not regulate narcotics until 1866 when it heavily taxed opium, a drug created long before our Nation's founding, *see United States v. Moore*, 486 F.2d 1139, 1215-16, 1218 n.50 (D.C. Cir. 1973) (Wright, J., dissenting), it must be that individuals have a right to acquire and use narcotics free from regulation. But this is not the law. A prior lack of regulation suggests that we must exercise care in evaluating the untested assertion of a constitutional right to be free from new regulation. Indeed, in considering an asserted fundamental right, *Glucksberg* directs us to "'exercise the utmost care whenever we are asked to break new ground in this field.'" 521 U.S. at 720 (quoting *Collins v. Harker Heights*, 503 U.S. 115, 125 (1992)). But the fact that the Government has not always regulated a concern tells us little about whether an individual has a constitutional right to pursue that concern. *See United States v. Morton Salt Co.*, 338 U.S. 632, 647 (1950) ("The fact that powers long have been unexercised well may call for close scrutiny as to whether they exist; but if granted, they are not lost by being allowed to lie dormant, any more than

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necessary to support its holding, *see id.* at 12. The majority misses the critical distinction this case presents. The Supreme Court has never suggested that an individual has a right to override the government's regulation of drug safety and to take drugs with, at best, unknown risks and, at worst, fatal consequences.

nonexistent powers can be prescripted by an unchallenged exercise.").

The majority devotes a great deal of analysis to the history of the FDCA, setting out to show that, "[i]n contrast to these ancient principles" evidenced in Blackstone and the Restatement, "regulation of access to new drugs has a history in this country that is of recent origin." Maj. Op. at 20. But the majority concedes in a footnote that it only analyzes the history of the FDCA to "establish that the Government has [not] acquired title to this right by adverse possession." *Id.* at 24 n.24. Thus, the majority appears to agree that the history of the FDCA provides no evidence, under *Glucksberg*, that would help the Alliance meet its burden. That is, the history of the FDCA does not demonstrate a tradition protecting an individual's right to procure and use experimental drugs; it only establishes that the federal government has not always regulated experimental drugs.

The majority also fails to recognize that drug regulation did not begin with the FDCA. In England, "when the Society of Apothecaries [*i.e.*, pharmacists] was chartered independently ([in] 1617), its master and wardens were empowered to inspect any pharmacy and to burn before the offender's door all drugs and preparations they deemed corrupt or unwholesome." EDWARD KREMERS, KREMERS AND URDANG'S HISTORY OF PHARMACY 111 (4th ed. 1976). "In the 18th century, power to examine the shops of apothecaries, chemists and druggists was given to the College of Physicians ([in] 1723), and cases involving questionable drugs were judged by a court composed partly of physicians and partly of apothecaries ([in] 1730)." *Id.* at 111-12.

In this Nation, the Colony of Virginia passed an act in 1736 addressing the dispensing of more drugs than was "necessary or

useful" because that practice had become "dangerous and intolerable." *Id.* at 158.[4] The Territory of Orleans (Louisiana) passed an act in 1808 requiring a diploma and an examination in order for pharmacists to dispense drugs and thus grant access to the public; Louisiana also prohibited the sale of deteriorated drugs and restricted the sale of poisons. *Id.* at 182-84, 214; *see* David L. Cowen, *The Development of State Pharmaceutical Law*, PHARMACY IN HISTORY, Vol. 37 No. 2, 1995, at 49, 54 (noting that the 1808 act prohibited the sale of drugs that were "injured, moulded, discomposed, or sophisticated" and placed restrictions on the sale of "any suspicious or dangerous remedy"). South Carolina enacted legislation in 1817 requiring pharmacists to obtain licenses, *Kremers*, *supra*, at 184, 214, followed by Georgia in 1825 and Alabama in 1852, *id.* at 214. By 1870, at least twenty-five states or territories had statutes

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[4] Specifically, Virginia's act regulated "the Practice of Physic[] in this Colony." *Id.* The Act noted that physic (the art or practice of healing disease, by, among other things, dispensing drugs) "is most commonly taken up and followed, by Surgeons, Apothecaries, or such as have only served Apprenticeships to those Trades, who often prove very unskillful in the Art of a Physician" and sought to address the concern that

> too often, for the Sake of making up long and expensive Bills, [surgeons, apothecaries, and their apprentices] load their Patients with greater Quantities thereof, than are *necessary or useful*, concealing all their Compositions, as well to prevent the Discovery of their Practice, as of the true Value of what they administer; which is become a *Grievance, dangerous and intolerable*, as well to the poorer Sort of People, as others.

Id. (emphasis added).

regulating adulteration, and a few others had laws addressing poisons. *Id.* at 216. The history of drug regulation in this country does not evidence a tradition of protecting a right of access to drugs; instead, it evidences government responding to new risks as they are presented. *See* Cowen, *supra*, at 56 ("The history of state laws pertaining to pharmacy obviously reflect[s] the development of pharmacy scientifically, professionally, and economically."). The majority's historical analysis of the FDCA demonstrates that Congress has expressed a keen interest in regulating drugs as science has progressed. Congress has responded to evolving medical technology with evolving regulation. But, unlike the majority, I do not see how the decision by Congress to regulate an area of concern in the early part of the twentieth century demonstrates a fundamental right to be free from regulation today.

Nor does the majority's analogy to *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990), and forced medication at common law explain why there is a fundamental, deeply rooted right to "self-preservation," Maj. Op. at 30, protecting a "terminally ill, mentally competent adult patient's informed access to potentially life-saving investigational new drugs determined by the FDA after Phase I trials to be sufficiently safe for expanded human trials," *id.* at 29. In *Cruzan*, the Supreme Court "assume[d] that the United States Constitution would grant a competent person a constitutionally protected right to refuse lifesaving hydration and nutrition," although the Court indicated that "the dramatic consequences involved in [a particular] refusal of [life-sustaining] treatment would inform the inquiry as to whether the deprivation of that interest is constitutionally permissible." 497 U.S. at 279. The Court's assumption that there is a right to refuse lifesaving treatment in some circumstances was predicated upon "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 (discussing *Cruzan*); *see Cruzan*, 497 U.S. at 269. But a tradition protecting individual *freedom* from life-saving, but forced, medical treatment does not evidence a constitutional tradition of providing affirmative *access* to a potentially harmful, and even fatal, commercial good.[5]

In light of *Cruzan*'s discussion of the "right of a *competent* individual to refuse medical treatment," *see* 497 U.S. at 277 (emphasis added), the majority attempts to limit its new right to a patient who is "mentally competent" and has "informed access" to experimental drugs. Maj. Op. at 29. The majority never explains what mental competence, in this context, would require. As the FDA noted in response to the Alliance's proposal, "with so little data available, it is hard to understand how a patient could be truly informed about the risks—or potential benefits—associated with the drug." By injecting patients into an early stage of the FDA's process for testing experimental drugs, the majority's approach allows terminally ill patients to take experimental drugs unknowingly—that is, without anyone having knowledge of potential risks and benefits. I fail to see how such a right is supported by *Cruzan*. *Cruzan* rejected an argument that an incompetent person has a

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[5] The majority argues that "*Cruzan* recognized . . . that an individual has a due process right to make an informed decision to *engage in conduct*, by withdrawing treatment, that will cause one's death." Maj. Op. at 26 (emphasis added). As *Glucksberg* specifically noted, however, in rejecting the argument that there is a fundamental right to commit suicide and receive assistance in doing so (*i.e.*, engage in conduct that will cause one's death), "although *Cruzan* is often described as a 'right to die' case, [the Supreme Court] w[as], in fact, more precise: [the Court] assumed that the Constitution granted competent persons a 'constitutionally protected right to *refuse* lifesaving hydration and nutrition.'" *Glucksberg*, 521 U.S. at 722-23 (quoting *Cruzan*, 497 U.S. at 279) (emphasis added).

right to withdraw treatment absent intent expressed while competent and, instead, upheld a state's requirement of clear and convincing prior evidence regarding an incompetent person's wishes to withdraw treatment. 497 U.S. at 279-80. As the Court explained, "[t]he difficulty with petitioners' claim is that in a sense it begs the question: An incompetent person is not able to make an informed and voluntary choice to exercise a hypothetical right to refuse treatment or any other right." *Id.* at 280. Under the majority's decision, terminally ill patients seem to have a right to make an uninformed and involuntary choice.

It does not help the majority's cause that the Supreme Court has rejected several similar challenges to the FDCA and related laws brought on statutory grounds. *See, e.g., Raich*, 125 S.Ct. at 2212, __U.S. at __ ("the dispensing of new drugs, even when doctors approve their use, must await federal approval"); *United States v. Rutherford*, 442 U.S. 544, 552 (1979) ("we are persuaded by the legislative history and consistent administrative interpretation of the [FDCA] that no implicit exemption for drugs used by the terminally ill is necessary to attain congressional objectives"); *cf. Oakland*, 532 U.S. at 490 (with respect to whether there is an implied "medical necessity" exemption to prosecution for marijuana use under the Controlled Substances Act, generally speaking, "[w]hether, as a policy matter, an exemption should be created is a question for legislative judgment, not judicial inference") (quotation marks omitted). To be sure, the Supreme Court has not addressed the constitutional argument raised by the Alliance. But contrary to the tradition asserted by the majority, there is a tradition of courts rejecting arguments that the Constitution provides an affirmative right of access to particular medical treatments reasonably prohibited by the Government.[6]

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[6] No circuit court has acceded to an affirmative access claim. *See, e.g.*, *Mitchell v. Clayton*, 995 F.2d 772, 775 (7th Cir. 1993)

("most federal courts have held that 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"); *N.Y. State Ophthalmological Soc'y v. Bowen*, 854 F.2d 1379, 1389 (D.C. Cir. 1988) ("We disagree that the constitutional right to privacy comprehensively protects all choices made by patients and their physicians or subjects to 'strict scrutiny' all government interference with choice of medical treatment. There is no basis under current privacy case law for extending such stringent protection to every decision bearing, however indirectly, on a person's health and physical well-being."), *cert. denied*, 490 U.S. 1098 (1989); *Carnohan v. United States*, 616 F.2d 1120, 1122 (9th Cir. 1980) ("Constitutional rights of privacy and personal liberty do not give individuals the right to obtain [the cancer drug] laetrile free of the lawful exercise of government police power."); *Rutherford v. United States*, 616 F.2d 455, 457 (10th Cir. 1980) ("[T]he patient['s] . . . selection of a particular treatment, or at least a medication, is within the area of governmental interest in protecting public health. The premarketing requirement of the [FDCA], 21 U.S.C. § 355, is an exercise of Congressional authority to limit the patient's choice of medication. This is clear under the [Supreme Court's] decisions . . . ."), *on remand from* 442 U.S. 544 (1979), *cert. denied*, 449 U.S. 937 (1980); *see also Sammon v. N.J. Bd. of Med. Examiners*, 66 F.3d 639, 645 n.10 (3d Cir. 1995); *United States v. Burzynski Cancer Research Inst.*, 819 F.2d 1301, 1313-14 (5th Cir. 1987); *cf. Lambert v. Yellowley*, 272 U.S. 581, 588, 590, 596-97 (1926) (where Congress determined, in implementing Prohibition, that "practicing physicians differ about the value of malt, vinous, and spirituous liquors for medicinal purposes, [and] that the preponderating opinion is against their use for such purposes," the Court rejected a physician's claim of a constitutional right to "use . . . such medicines and medical treatment as in his opinion are best calculated to effect [his patients'] cure and establish their health," holding that "there is no right to practice medicine which is not subordinate . . . to the power of Congress to make laws necessary and proper . . . . High medical authority being in conflict as to the medicinal value of spirituous and vinous liquors taken as a beverage,

The decision to procure and use experimental drugs has never enjoyed *legal protection*, let alone risen to the level of a "fundamental right[] and libert[y] which [is], objectively, deeply rooted in this Nation's history and tradition." *Glucksberg*, 521 U.S. at 720-21 (quotation marks omitted). The amendments made to the FDCA by Congress throughout the twentieth century, *see* Maj. Op. 20-24, show that Congress, and the FDA, have responded continuously to new risks presented by an evolving technology. Indeed, because the risks and benefits presented by new experimental drugs are different with each new drug, the majority is not even sure what level of access its constitutional right will provide. The majority suggests that terminally ill patients have a right to "potentially life-saving treatment," *id.* at 19, although the majority appears to exempt the Controlled Substances Act and state regulation from its constitutional right, *id.* at 14, 18 & n.11. The majority's vague allusion to potentially life-saving drugs demonstrates its difficulty in explaining what drugs its constitutional right protects. That difficulty arises because at issue here is a novel and unfamiliar area of science. The Alliance contends that patients would be better served by allowing them to assume unknown risks regardless of whether any benefit of an experimental drug remains uncertain. The FDA disagrees and concludes that terminally ill patients will be best served by receiving experimental drugs only when there is "reasonable knowledge for patients and physicians of their likely clinical

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it would, indeed, be strange if Congress lacked the power to determine that the necessities of the liquor problem require a limitation of permissible prescriptions . . . ."); *Watson v. Maryland*, 218 U.S. 173, 176 (1910) ("It is too well settled to require discussion at this day that the police power of the states extends to the regulation of certain trades and callings, particularly those which closely concern the public health. There is perhaps no profession more properly open to such regulation than that which embraces the practitioners of medicine.").

benefit and their toxicity." But "[t]he only certain thing that can be said about the present state of knowledge and therapy . . . is that science has not reached finality of judgment . . . . Certainly, denial of constitutional power . . . to Congress in dealing with a situation like this ought not to rest on dogmatic adherence to one view or another on controversial psychiatric issues." *Greenwood v. United States*, 350 U.S. 366, 375-76 (1956). *Greenwood* addressed an issue of psychiatry, but the same principle applies to the disputed scientific and medical issues in this case. In my view, the majority has made its own judgment about the medical benefits and risks of providing experimental drugs to terminally ill patients. That is a role Congress has rightly occupied and has, through the exercise of its Article I powers, delegated to the FDA for enforcement.

Our Nation's "'concept of ordered liberty,'" *Glucksberg*, 521 U.S. at 721 (quoting *Palko*, 302 U.S. at 325-26), does not contemplate that judges should resolve the scientific uncertainties presented by experimental drugs. The Supreme Court has "recognized repeatedly the 'uncertainty of diagnosis in this field and the tentativeness of professional judgment.'" *Jones v. United States*, 463 U.S. 354, 365 n.13 (1983) (quoting *Greenwood*, 350 U.S. at 375) (rejecting an argument that Congress could not constitutionally provide for commitment of the mentally ill based upon a prior criminal act because, a litigant argued, his proffered psychiatric research showed that prior dangerous acts do not predict future dangerousness). "The lesson [the Court] ha[s] drawn is not that government may not act in the face of this uncertainty, but rather that courts should pay particular deference to reasonable legislative judgments." *Jones*, 463 U.S. at 365 n.13. In my view, the majority's approach injects courts into unknown questions of science and medicine and does so contrary to the expressed will of Congress and the Executive and to the deference courts owe the democratic branches on such controversial matters.

"These disagreements" over scientific and medical issues "do not tie the [Government's] hands in setting the bounds of its . . . laws. In fact, it is precisely where such disagreement exists that legislatures have been afforded the widest latitude in drafting such statutes." *Kansas v. Hendricks*, 521 U.S. 346, 356-60 & n.3 (1997) (state's civil commitment statute comported with substantive due process in requiring commitment of a pedophile where "psychiatric professionals [were] not in complete harmony in casting pedophilia . . . as 'mental illnesses;'" although other states would not have required civil commitment, legislature was due wide latitude in light of medical disagreement). The majority suggests that drugs which have completed Phase I testing bear a sufficiently small medical risk. The majority confidently makes that scientific judgment, but I cannot. These drugs are experimental by their very nature. Unlike the FDA, *see* 21 U.S.C. § 355(n), we do not have Congressionally-provided scientific advisory panels at our disposal. "When Congress undertakes to act in areas fraught with medical and scientific uncertainties, legislative options must be especially broad and courts should be cautious not to rewrite legislation, even assuming, *arguendo*, that judges with more direct exposure to the problem might make wiser choices." *Marshall v. United States*, 414 U.S. 417, 427 (1974).

Our Nation's history and traditions contemplate that the democratic branches will achieve balances between the uncertain risks and benefits of medical technology. *See Jacobson v. Massachusetts*, 197 U.S. 11, 30 (1905) ("We must assume that, when the statute in question was passed, the legislature . . . was not unaware of these opposing theories, and was compelled, of necessity, to choose between them. It was not compelled to commit a matter involving the public health and safety to the final decision of a court or jury. It is no part of the function of a court or a jury to determine which one of two

modes was likely to be the most effective for the protection of the public against disease."). Our Nation's concept of ordered liberty, along with our traditions and history, do not call for courts to usurp the judgment of the scientific and medical communities, expressed through Congress and the Executive Branch, that science does not warrant allowing the early access to experimental drugs the Alliance demands.

III.

The majority's new right to procure and use experimental drugs raises a number of vexing questions that are now constitutional issues, potentially insulated from the tug and pull of the political process. If a terminally ill patient has such a right, are patients with serious medical conditions entitled to the benefit of the same logic and corresponding access? If an indigent cannot afford potentially life-saving treatment, would the Constitution mandate access to such care under the right recognized by the majority? Can a patient access any drug (*i.e.*, marijuana for medicinal purposes, *see Raich*, 125 S.Ct at 2215, __ U.S. at __) if she believes, in consultation with a physician, it is potentially life-saving? Would the majority's right guarantee access to federally-funded stem cell research and treatment? Perhaps most significantly, what potential must a treatment have in order for the Constitution to mandate access?

Because the majority does not answer this last question, the District Court faces an impossible task on remand. The majority concludes that the District Court must "determine whether the FDA's policy barring access to post-Phase I investigational new drugs by terminally ill patients is narrowly tailored to serve a compelling governmental interest." Maj. Op at 30. As a preliminary matter, the majority never explains why the District Court must determine that the FDA has a compelling, narrowly tailored interest in preventing access to *all* drugs that have

passed or will pass Phase I. Just this term, the Supreme Court reminded the Court of Appeals that "when confronting a constitutional flaw in a statute, we try to limit the solution to the problem. We prefer, for example, to enjoin only the unconstitutional applications of a statute while leaving other applications in force . . . ." *Ayotte v. Planned Parenthood of N. New England*, 126 S.Ct. 961, 967, __ U.S. __, __ (2006) (citing *United States v. Raines*, 362 U.S. 17, 20-22 (1960)). Rather than requiring the District Court to determine whether all terminally ill patients should have access to all experimental drugs after Phase I testing, it remains unclear why the District Court should not undertake the more restrained inquiry of whether the majority's right guarantees access to the specific drugs sought by individual members of the Alliance.

Under the majority's facial approach, the District Court must examine every drug undergoing FDA testing and every drug that may ever undergo FDA testing. It must then evaluate whether the FDCA's prohibition on access to unapproved drugs and corresponding exemptions for limited access serve a compelling interest and are narrowly tailored in light of all of the different potential risks and benefits of all experimental drugs and the needs of all terminally ill patients. Although the Government most likely will show that it has a compelling interest in regulating access to drugs with unknown toxicity and the potential to hasten death, the unknown risks and benefits of these experimental drugs will make nearly impossible a judicial examination of whether some level of access short of a prohibition would be more narrowly tailored to protect the majority's constitutional right of access.

Moreover, the level of benefit a patient will have to show, in order to demonstrate that under the majority's right a drug is potentially life-saving, remains an enigma. Whatever the majority means by "potentially," its use of that term suggests

that some drugs will not demonstrate enough potential benefit, while simultaneously presenting extraordinary risks. Considering the potential benefits of an experimental drug in light of its risks will require the District Court to step into the role of the FDA. Before today, scientists and physicians at the FDA, in consultation with the greater scientific and medical communities through scientific advisory panels, applied limited and often disputed scientific knowledge about an experimental drug in determining what level of access should be given to terminally ill patients and what medical circumstances warrant such access. Under the majority's approach, the United States District Court for the District of Columbia must now evaluate limited scientific knowledge about a Phase I drug and determine whether that drug is potentially life-saving enough to require constitutional protection.

Because the Alliance has failed to present objective evidence establishing a deeply rooted right to procure and use experimental drugs, I would apply rational basis review to its due process challenge. *See Glucksberg*, 521 U.S. at 728. As the Supreme Court held in rejecting a challenge by terminally ill patients claiming that the FDCA's safety requirement did not apply to them, "the [FDA] generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use. For the terminally ill, as for anyone else, a drug is unsafe if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit." *Rutherford*, 442 U.S. at 555-56. Although terminally ill patients desperately need curative treatments, their death can certainly be hastened by the use of a toxic drug. Prior to distribution of a drug outside of controlled studies, the Government has a rational basis for ensuring that there is a scientifically and medically acceptable level of knowledge about the risks and benefits of such a drug. I would affirm the decision of the District Court.