United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued March 1, 2007 Decided August 7, 2007

No. 04-5350

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

v.

ANDREW VON ESCHENBACH,
IN HIS OFFICIAL CAPACITY AS 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)

J. Scott Ballenger argued the cause for appellants. With him on the briefs were *Daniel J. Popeo*, *David A. Price*, and *Richard A. Samp*.

Brian P. Brooks and *Arthur W.S. Duff* were on the brief for *amici curiae* John E. Calfee, et al. in support of appellants.

John J. Edmonds was on the brief for *amici curiae* Emil Freireich and Stephen Strum in support of appellants.

Jonathan F. Cohn, Deputy Assistant Attorney General, U.S. Department of Justice, argued the cause for appellees. With him on the brief were *Peter D. Keisler*, Assistant Attorney General, *Jeffrey A. Taylor*, U.S. Attorney, *Jeffrey S. Bucholtz*, Principal Deputy Assistant Attorney General, *Michael J. Ryan* and *Rhonda C. Fields*, Assistant U.S. Attorneys, *Mark B. Stern* and *Scott R. McIntosh*, Attorneys, *Daniel Meron*, General Counsel, U.S. Department of Health and Human Services, *Eric M. Blumberg*, Deputy Chief Counsel for Litigation, and *Karen E. Schifter*, Associate Chief Counsel. *R. Craig Lawrence*, Assistant U.S. Attorney, entered an appearance.

Samuel D. Turner was on the brief for *amici curiae* American Society of Clinical Oncology, et al. in support of appellees.

William B. Schultz was on the brief for *amici curiae* National Organization for Rare Disorders, et al. in support of appellees.

Before: GINSBURG, *Chief Judge*, SENTELLE, HENDERSON, RANDOLPH, ROGERS, TATEL, GARLAND, BROWN, GRIFFITH, and KAVANAUGH, *Circuit Judges*.

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

Dissenting opinion filed by *Circuit Judge* ROGERS, with whom *Chief Judge* GINSBURG joins.

GRIFFITH, *Circuit Judge*: This case presents the question whether the Constitution provides terminally ill patients a right of access to experimental drugs that have passed limited safety

trials but have not been proven safe and effective. The district court held there is no such right. A divided panel of this Court held there is. Because we conclude that there is no fundamental right "deeply rooted in this Nation's history and tradition" of access to experimental drugs for the terminally ill, *see Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997) (quoting *Moore v. East Cleveland*, 431 U.S. 494, 503 (1977) (plurality opinion)), we affirm the judgment of the district court.

I.

A.

The Abigail Alliance for Better Access to Developmental Drugs (the "Alliance") is an organization of terminally ill patients and their supporters that seeks expanded access to experimental drugs for the terminally ill. The Food, Drug, and Cosmetic Act ("FDCA" or "Act"), however, generally prohibits access to new drugs unless and until they have been approved by the Food and Drug Administration ("FDA"). *See* 21 U.S.C. § 355(a). Gaining FDA approval can be a long process. First, an experimental drug's sponsor (*e.g.*, a drug company) must submit an application for approval. *See id.* § 355(a). Because no drug may be approved without a finding of "substantial evidence that the drug will have the effect it purports or is represented to have," *id.* § 355(d)(5), an 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). Such reports rely in large measure on clinical trials with human subjects.

But before a sponsor can even begin human testing, it 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. Once the application for human testing has been approved, *see id.* § 312.20, several phases of clinical testing begin. The Alliance's amended complaint alleges that this testing process is an extremely lengthy one, requiring nearly seven years for the average experimental drug.[1] Am. Compl. ¶ 15.

Clinical testing for safety and effectiveness requires three or sometimes four phases. *See* 21 C.F.R. § 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). Although gathering data on effectiveness may be part of Phase I, its primary focus is to determine whether the drug is safe enough for continued human testing. *See id.* Phase II studies are "well controlled" and "closely monitored" clinical trials of no more than several hundred subjects, used to evaluate both the "effectiveness of the drug for a particular indication" and its "common short-term side effects and risks." *Id.* § 312.21(b).

Phase III studies are expanded clinical trials of several hundred to several thousand subjects designed to "gather . . . additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician

[1] In FDA parlance, experimental drugs that have not yet been approved for public use are deemed "investigational drug[s]." *See* 21 C.F.R. § 312.3(b).

labeling." *Id.* § 312.21(c).[2] At any time during the clinical trials, a drug sponsor is required to notify the FDA of "[a]ny adverse experience associated with the use of the drug that is both serious and unexpected," *id.* § 312.32(c)(1)(A), and the FDA may order a "clinical hold" halting the trials if it determines that safety concerns so warrant, *id.* § 312.42. To guide the clinical testing 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). These panels must include scientists from a variety of disciplines. *See id.* § 355(n)(3).[3]

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[2] In some circumstances, a Phase IV review is conducted, which "delineate[s] additional information about the drug's risks, benefits, and optimal use." 21 C.F.R. § 312.85.

[3] 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, pharmacology, pharmacoeconomics, biological and physical sciences, and other related professions;
>
> (C) a representative of consumer interests, and a

Terminally ill patients need not, however, always await the results of the clinical testing process. The FDA and Congress have created several programs designed to provide early access to promising experimental drugs when warranted. For example, under the "treatment IND" program, the FDA may approve use of an investigational drug by patients not part of the clinical trials for the treatment of "serious or immediately life-threatening disease[s]" if there exists "no comparable or satisfactory alternative drug or other therapy," 21 C.F.R. § 312.34(a), (b)(1)(i)-(ii); if "[t]he drug is under investigation in a controlled clinical trial," *id.* § 312.34(b)(1)(iii); and if the drug's sponsor "is actively pursuing marketing approval of the investigational drug with due diligence," *id.* § 312.34(b)(1)(iv). The FDA reserves the right, however, to deny any treatment IND request if (1) the agency believes there is no "reasonable basis" to conclude that the drug is effective; or (2) granting the request "[w]ould . . . expose the patient[] . . . to an unreasonable and significant additional risk of illness or injury." *Id.* § 312.34(b)(3). Sponsors may not profit from any approved treatment IND program and may only "recover costs of manufacture, research, development, and handling of the investigational drug." *Id.* § 312.7(d)(3).[4]

> representative of interests of the drug manufacturing industry not directly affected by the matter to be brought before the panel; and
>
> (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.

[4] The FDA has several other regulatory programs designed to hasten research of the safety and effectiveness of drugs for terminally or severely ill patients and allow early access where scientifically and

B.

Concluding that the FDA's current process for early access to new drugs was inadequate to meet the needs of its terminally ill members, the Alliance submitted its own proposals to the FDA. Those proposals culminated in a "citizen petition" to the FDA, *see* 21 C.F.R. § 10.25, arguing that there is a "different risk-benefit tradeoff facing patients who are terminally ill and who have no other treatment options." Abigail Alliance Citizen Petition, *In re Tier 1 Initial Approval Program to Expedite the Availability of Lifesaving Drugs* 9 (June 11, 2003). 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 . . . [,] these steps may well entail a delay that is fatal" for terminally ill patients. *Id.* The Alliance contended that these patients "should have the ability to opt for a new treatment that has met a lower evidentiary hurdle with respect to safety and efficacy." *Id.* The Alliance's proposal suggested that

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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 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 FDA allow early access based upon "the risk of illness, injury, or death from the disease in the absence of the drug." *Id.* at 4. Accordingly, the Alliance requested that the FDA promulgate new regulations that would allow sponsors to market experimental drugs, under some circumstances, after the completion of Phase I trials.

The FDA never responded to the Alliance's citizen petition, but did respond to the Alliance's earlier submissions. After noting that a number of senior FDA officials had reviewed those submissions, the agency 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." Letter from Peter J. Pitts, Associate Commissioner for External Relations, Department of Health and Human Services, to Frank Burroughs, President, Abigail Alliance for Better Access to Developmental Drugs 3 (Apr. 25, 2003). The officials concluded that the early access proposed by the Alliance "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." *Id.* at 4. 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." *Id.* 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." *Id.*

Relying upon its experience exercising its scientific and medical judgment in creating its regulations for experimental drugs and, in certain circumstances, exceptions to those regulations for the terminally ill, the FDA noted 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. *Id.* For example, most experimental cancer drugs "have potentially lethal toxicity, with potentially large effects on a patient's remaining quality of life." *Id.* Accordingly, "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." *Id.* at 4-5. The FDA concluded that accepting the Alliance's proposal "would upset the appropriate balance that [it 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." *Id.* at 5.

Having thus been rejected by the FDA, the Alliance turned to the courts, arguing that the United States Constitution provides a right of access to experimental drugs for its members. In a complaint that mirrored much of its earlier submissions to the FDA, the Alliance argued that the FDA's lengthy clinical trials, combined with the "FDA's restrictions on pre-approval availability[,] amount to a death sentence for these [terminally ill] patients." Am. Compl. ¶¶ 15-17. Nor, the Alliance argues, are the FDA's exceptions to the clinical testing process sufficient to provide the terminally ill the access they need because they "are small, when they exist at all," and the ban on profits prevents many drug sponsors from participating. *Id.* ¶ 18.

"Terminally ill patients," in the Alliance's view, "are typically willing to assume risks . . . ." *Id.* ¶ 19. Before the district court, the Alliance argued that the Constitution guarantees them the right to do so. The district court rejected that argument, holding that "there is no constitutional right of access to unapproved drugs." *Abigail Alliance for Better Access to Developmental Drugs v. McClellan*, No. 03-1601, 2004 WL 3777340, at *1 (D.D.C. Aug. 30, 2004). A divided panel of this Court reversed, concluding 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." *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 486 (D.C. Cir. 2006). We vacated that decision and granted rehearing *en banc*. *See Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, No. 04-5350 (D.C. Cir. Nov. 21, 2006).

As framed by the Alliance, we now consider:

> Whether the liberty protected by the Due Process Clause embraces the right of a terminally ill patient with no remaining approved treatment options to decide, in consultation with his or her own doctor, whether to seek access to investigational medications that the [FDA] concedes are safe and promising enough for substantial human testing.

Appellants' Br. at 1.[5] That is, we must determine whether terminally ill patients have a fundamental right to experimental drugs that have passed Phase I clinical testing. If such a right exists, the Alliance argues that both 21 C.F.R. § 312.34(b)(3) (preventing access to experimental drugs for terminally ill patients where there is insufficient evidence of effectiveness or

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[5] The dissent has recast the Alliance's proposed right away from the terms used in its briefs and oral argument—a right to access investigational new drugs—into a right "to try to save one's life," which has "its textual anchor in the right to life [expressed in the Fifth Amendment]." Dissent at 2-3. Regardless of how it is described, we must examine the proposed right under *Glucksberg*, which specifically cautions against the type of broad generalization the dissent now employs. *See Glucksberg*, 521 U.S. at 721 (requiring a "'careful description' of the asserted fundamental liberty interest"). If the asserted right is so broad that it protects a person's efforts to save his life, it might subject to strict scrutiny any government action that would affect the means by which he sought to do so, no matter how remote the chance of success. The Supreme Court rejected a similar attempt to broadly define the right at issue in *Reno v. Flores* when it refused to accept the petitioner's definition as the "freedom from physical restraint" and instead cast the right as the "right of a child who has no available parent, close relative, or legal guardian, and for whom the government is responsible, to be placed in the custody of a willing-and-able private custodian rather than of a government-operated or government-selected child-care institution." *Reno v. Flores*, 507 U.S. 292, 302 (1993). The dissent suffers from the same flaw in arguing that this is about the right to save one's life, because, in the end, this case is about the right to access experimental and unproven drugs in an attempt to save one's life, which we conclude under *Glucksberg* is not deeply rooted in our Nation's history and traditions. By describing too broadly at the outset a proposed right that will cover the Alliance's more narrow claim, the dissent fails *Glucksberg*'s threshold requirement of a carefully described right. We need not pursue the arguments that follow that initial misstep.

where there is an unreasonable risk of injury) and 21 C.F.R. § 312.7 (prohibiting drug manufacturers from profiting on the sale of experimental drugs) must be subjected to strict scrutiny because they interfere with a fundamental constitutional right. We do not address the broader question of whether access to medicine might ever implicate fundamental rights.

II.

The Due Process Clause of the Fifth Amendment provides that "[n]o person shall be . . . deprived of life, liberty, or property, without due process of law." U.S. CONST. amend. V. The Supreme Court has held that the protections of the Amendment "guarantee[] more than fair process." *Glucksberg*, 521 U.S. at 719. The Court has stated that "[t]he Clause . . . provides heightened protection against government interference with certain fundamental rights and liberty interests," *id.* at 720 (citing *Reno v. Flores*, 507 U.S. 292, 301-02 (1993); *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 851 (1992)), including "the rights to marry, to have children, to direct the education and upbringing of one's children, to marital privacy, to use contraception, to bodily integrity, and to abortion," *Glucksberg*, 521 U.S. at 720 (citations omitted).

As such rights are not set forth in the language of the Constitution, the Supreme Court has cautioned against expanding the substantive rights protected by the Due Process Clause "because guideposts for responsible decisionmaking in this unchartered area are scarce and open-ended." *Collins v. Harker Heights*, 503 U.S. 115, 125 (1992) (citing *Regents of Univ. of Mich. v. Ewing*, 474 U.S. 214, 225-26 (1985)). There is an additional and substantial concern that courts must also consider: "By extending constitutional protection to an asserted right or liberty interest, we, to a great extent, place the matter outside the arena of public debate and legislative action."

Glucksberg, 521 U.S. at 720. Thus, the Supreme Court has directed courts to "exercise the utmost care whenever we are asked to break new ground in this field, lest the liberty protected by the Due Process Clause be subtly transformed into the policy preferences of the [courts' members]." *Id.* (quotation marks and citations omitted); *see Moore*, 431 U.S. at 502 ("As the history of the *Lochner* era demonstrates, there is reason for concern lest the only limits to such judicial intervention become the predilections of those who happen at the time to be Members of this Court.") (footnote omitted).

In *Glucksberg*, the Supreme Court described its "established method of substantive-due-process analysis" as having "two primary features." *Glucksberg*, 521 U.S. at 720.

> First, we have regularly observed that the Due Process Clause specially protects those fundamental rights and liberties which are, objectively, deeply rooted in this Nation's history and tradition and implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if they were sacrificed. Second, we have required in substantive-due-process cases a careful description of the asserted fundamental liberty interest.

Id. at 720-21 (quotation marks and citations omitted).

We will assume *arguendo* that the Alliance's description of its asserted right would satisfy *Glucksberg*'s "careful

description" requirement.[6] Looking to whether the Alliance has demonstrated that its right is deeply rooted in this Nation's history, tradition, and practices, the Alliance's claim for constitutional protection rests on two arguments: (1) that "common law and historical American practices have traditionally trusted individual doctors and their patients with almost complete autonomy to evaluate the efficacy of medical treatments"; and (2) that FDA policy is "inconsistent with the way that our legal tradition treats persons in all other life-threatening situations." Appellants' Br. at 31. More specifically, the Alliance argues that the concepts of self-defense, necessity, and interference with rescue are broad enough to demonstrate the existence of the fundamental right they seek—a right for "persons in mortal peril" to "try to save their own lives, even if the chosen means would otherwise be illegal or involve enormous risks." *Id.* at 32.

A.

"We begin, as we do in all due process cases, by examining our Nation's history, legal traditions, and practices."

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[6] We nonetheless have serious doubt about whether the Alliance's *description* of its proposed constitutional right could ever pass constitutional muster. The Alliance's claimed right depends on a regulatory determination that the drug is safe for testing, prompting an obvious question: How can a constitutional right be defined by an administrative regulation that is subject to change? Would an FDA decision requiring increased testing for safety and efficacy before the commencement of human clinical trials affect the Alliance's constitutional right? Moreover, we find it difficult to imagine how a right inextricably entangled with the details of shifting administrative regulations could be "deeply rooted in this Nation's history and tradition and implicit in the concept of ordered liberty." *Glucksberg*, 521 U.S. at 721 (quotation marks and citations omitted).

Glucksberg, 521 U.S. at 710. The Alliance argues that its right can be found in our history and legal traditions because "the government never interfered with the judgment of individual doctors about the medical *efficacy* of particular drugs until 1962," *i.e.*, when major amendments were made to the Food, Drug, and Cosmetic Act. Appellants' Br. at 44 (emphasis added); *see id.* at 23 ("[T]he common law consistently left judgments about the *efficacy* of medical treatments in the hands of individual doctors and their patients. Governmental review of the effectiveness of drugs did not exist in this country at all until 1962 . . . .") (emphasis added).

The Alliance has little to say, however, about our Nation's history of regulating the *safety* of drugs. The Alliance's effort to focus on efficacy regulation ignores one simple fact: it is unlawful for the Alliance to procure experimental drugs not only because they have not been proven effective, but because they have not been proven safe. Although the Alliance contends that it only wants drugs that "are safe and promising enough for substantial human testing," *id.* at 1, *i.e.*, drugs that have passed Phase I testing, current law bans access to an experimental drug on safety grounds until it has successfully completed all phases of testing. *See* 21 C.F.R. § 312.21(b) (requiring that Phase II studies examine "*common short-term side effects and risks*" of new drugs) (emphasis added); *id.* § 312.21(c) (requiring Phase III studies to "gather . . . additional information about effectiveness and *safety* that is needed to evaluate the overall benefit-risk relationship of the drug") (emphasis added). Thus, to succeed on its claim of a fundamental right of access for the terminally ill to experimental drugs, the Alliance must show not only that there is a tradition of access to drugs that have not yet been proven effective, but also a tradition of access to drugs that have not yet been proven safe.

Examining, as we are required to do under *Glucksberg*, our Nation's history, legal traditions, and practice with respect to the regulation of drugs for efficacy and safety, we conclude that our Nation has long expressed interest in drug regulation, calibrating its response in terms of the capabilities to determine the risks associated with both drug safety and efficacy.

Drug regulation in the United States[7] began with the Colonies and States when the Colony of Virginia's legislature passed an act in 1736 that addressed the dispensing of more drugs than was "necessary or useful" because that practice had

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[7] Drug regulation also has a long history in England, beginning no later than Henry VI's royal decree in 1447 that gave grocers the power to inspect "anis, wormseed, rhubarb, scammony, spikenard, senna and all sort of drugs belonging to medicine, so as not, in the buying of these to be hurt in their bodily health." EDWARD KREMERS, KREMERS AND URDANG'S HISTORY OF PHARMACY 111 (4th ed. 1976). The Pharmacy Wares Drugs and Stuffs Act in 1540 allowed inspectors to search apothecaries' [*i.e.*, pharmacists'] shops for drugs that were "defective, corrupted and not meet nor convenient to be ministered in any medicines for the health of man's body." John P. Griffin, *Venetian Treacle and the Foundation of Medicines Regulation*, 58 BRIT. J. OF CLINICAL PHARMACOLOGY 317, 319 (2004); *see also* John P. Griffin & Rashmi R. Shah, *History of Drug Regulation in the United Kingdom*, *in* THE TEXTBOOK OF PHARMACEUTICAL MEDICINE 457 (John P. Griffin & John O'Grady eds., 2006). "[W]hen the Society of Apothecaries 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." KREMERS, *supra*, at 111. "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.

become "dangerous and intolerable." EDWARD KREMERS, KREMERS AND URDANG'S HISTORY OF PHARMACY 158 (4th ed. 1976).[8] The Territory of Orleans (Louisiana) passed an act in 1808 requiring a diploma and an examination before permitting pharmacists to dispense drugs; 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 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 regulating adulteration (impure drugs), and a few others had laws addressing poisons. *Id.* at 216. In the early history of our Nation, we observe not a tradition of protecting a right of access to drugs, but rather governments responding to the risks of new compounds as they become aware of and able to address those risks. *See* Cowen, *supra*, at 56 ("The history of state laws pertaining to pharmacy obviously reflect[s] the development of pharmacy scientifically, professionally, and economically.").

Nor were the States the only regulators of access to drugs. Although early federal regulation was not extensive, perhaps

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[8] Although not an example of legislative or regulatory intervention, in 1630 Nicholas Knopp of Massachusetts was "fined five pounds, or was whipped, for vending as a cure for scurvy 'a water of no worth nor value,' which he 'solde att a very deare rate.'" JAMES HARVEY YOUNG, THE TOADSTOOL MILLIONAIRES: A SOCIAL HISTORY OF PATENT MEDICINES IN AMERICA BEFORE FEDERAL REGULATION 16 (1961) (quoting *Records of the Governor and Company of the Massachusetts Bay in New England* (Boston, 1853), I, 83).

because "[n]ot until interstate commerce began its great expansion after the Civil War did the need for Federal rule-making become widely realized," Wallace F. Janssen, *Outline of the History of U.S. Drug Regulation and Labeling*, 36 FOOD DRUG COSM. L.J. 420, 425 (1981), there are early examples of federal government intervention. In 1848, the Import Drug Act, ch. 70, 9 Stat. 237 (1848), banned "imported adulterated drugs" after a Congressional committee concluded that "this country had become the grand mart and receptacle of all the refuse [drug] merchandise . . . , not only from the European warehouses, but from the whole Eastern world." Wesley J. Heath, *America's First Drug Regulation Regime: The Rise and Fall of the Import Drug Act of 1848*, 59 FOOD & DRUG L.J. 169, 175 (2004) (footnote omitted). Congress acted again when it passed the Biologics Controls Act of 1902, ch. 1378, 32 Stat. 728 (1902), in response to a series of deadly reactions to a tainted diphtheria vaccine that killed children in New Jersey and Missouri. Sue McGrath, *Only A Matter Of Time: Lessons Unlearned at the Food and Drug Administration Keep Americans at Risk*, 60 FOOD & DRUG L.J. 603, 604 (2005). This Act "secure[d] licensing control over both biological drug laboratories and their products." Janssen, *supra*, at 425. Congress followed with the Pure Food and Drugs Act of 1906, which prohibited the manufacture of any drug that was "adulterated or misbranded." The Pure Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768 (1906).[9]

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[9] As the Alliance notes, "the Supreme Court held that the 1906 Act did not prohibit a drug manufacturer from marketing an ineffective cancer remedy with false therapeutic claims, so long as it was not adulterated." Appellants' Br. at 45 (citing *United States v. Johnson*, 221 U.S. 488 (1911)). But *Johnson* was merely a question of statutory interpretation, and the Court specifically noted that it would "say nothing as to the limits of constitutional power." *Johnson*, 221 U.S. at 498. *Johnson* therefore cannot be read to support the

The current regime of federal drug regulation began to take shape with the Food, Drug, and Cosmetic Act of 1938. *See* Federal Food, Drug, and Cosmetic Act of 1938, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 301 *et seq.*). The Act required that drug manufacturers provide proof that their products were safe before they could be marketed. *See id.* The new Act also prohibited false therapeutic claims. *Id.* Notably, the drug industry "strenuously objected" to the 1938 Act "ostensibly on the ground that it would deprive the American people of the right to self-medication," HARRY A. TOULMIN, JR., LAW OF FOODS, DRUGS AND COSMETICS 8-9 (2d ed. 1963)—an argument not unlike the Alliance's position of today.

We end our historical analysis where the Alliance would prefer it begin—with the 1962 Amendments to the FDCA. Undoubtedly, as the Alliance argues at length, Congress amended the FDCA in 1962 to explicitly require that the FDA only approve drugs deemed effective for public use. *See* Drug Amendments of 1962, Pub. L. No. 87-781, § 102, 76 Stat. 780, 781 (1962). Thus, the Alliance argues that, prior to 1962, patients were free to make their own decisions whether a drug might be effective.[10] But even assuming *arguendo* that efficacy

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recognition of a constitutional right to access experimental drugs or consume any drugs regardless of the risks.

[10] Looking to *Lawrence v. Texas*, the FDA argues that "[t]he history of the FDCA over the past seventy years is entitled to particular weight in the substantive due process calculus," Appellees' Br. at 31, because, in determining the constitutionality of a Texas statute prohibiting certain intimate sexual conduct between members of the same sex, the Supreme Court looked to the Nation's "laws and traditions *in the past half century*" as having the "most relevance" to the constitutional dispute in that case. *Lawrence v. Texas*, 539 U.S.

regulation began in 1962, the Alliance's argument ignores our Nation's history of drug safety regulation described above. Nor can the Alliance override current FDA regulations simply by insisting that drugs which have completed Phase I testing are safe enough for terminally ill patients. Current law bars public access to drugs undergoing clinical testing on safety grounds. The fact that a drug has emerged from Phase I with a determination that it is safe for limited clinical testing in a controlled and closely-monitored environment after detailed scrutiny of each trial participant does not mean that a drug is safe for use beyond supervised trials.[11] FDA regulation of post-Phase I drugs is entirely consistent with our historical tradition of prohibiting the sale of unsafe drugs.

558, 571-72 (2003) (emphasis added). We need not determine today whether recent history is particularly relevant in measuring the scope of rights under the Due Process Clause. In this case, there is no evidence of a deeply rooted right of terminally ill patients to gain access to experimental drugs—either throughout our Nation's history or during the past half century.

[11] In fact, the FDA cites numerous examples in which drugs have been pulled from the market post-Phase I due to safety concerns. *See, e.g.*, Alex Berenson, *End of Drug Trial Is a Big Loss for Pfizer and Heart Patients*, N.Y. TIMES, Dec. 4, 2006, at A1 (highlighting Pfizer's decision to pull torcetrapib from a clinical trial of more than 15,000 patients because those taking the drug were dying at a greater rate than those taking a placebo); Milton Packer et al., *Effect of Oral Milrinone on Mortality in Severe Chronic Heart Failure*, 325 NEW ENG. J. MED. 1468 (1991) (concluding after expanded clinical trials that milrinone therapy was "associated with a 28 percent increase in mortality"); Debra S. Echt et al., *Mortality and Morbidity in Patients Receiving Encainide, Flecainide, or Placebo*, 324 NEW ENG. J. MED. 781 (1991) (concluding after expanded clinical trials that "[t]here was an excess of deaths . . . in patients treated with encainide or flecainide").

But even setting the safety issue to one side, the Alliance's argument that effectiveness was not required before 1962 also fails under closer scrutiny. First, as a matter of history, at least some drug regulation prior to 1962 addressed efficacy. More importantly, an arguably limited history of efficacy regulation prior to 1962 does not establish a fundamental right of access to unproven drugs. The amendments made to the FDCA by Congress throughout the twentieth century demonstrate that Congress and the FDA have continually responded to new risks presented by an evolving technology. Recent government efficacy regulation has reflected Congress's exercise of its well-established power to regulate in response to scientific, mathematical, and medical advances.[12]

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[12] In exercising the caution the Supreme Court demands when analyzing claims of fundamental rights, *see Glucksberg*, 521 U.S. at 720, we note a more plausible explanation for the limited efficacy regulation—the government was not previously able to systematically regulate effectively for efficacy: "The history of the effectiveness requirement in drug regulation is inextricably linked to the advent of the randomized, controlled clinical trial as the cornerstone of medical research . . . , [which] would not become widely recognized until the twentieth century." Jennifer Kulynych, *Will FDA Relinquish the "Gold Standard" for New Drug Approval? Redefining "Substantial Evidence" in the FDA Modernization Act of 1997*, 54 FOOD & DRUG L.J. 127, 131 (1999) (footnotes omitted). In fact, "World War II ushered in the era of the modern clinical trial, when the U.S. military undertook large-scale, systematic testing of tuberculosis remedies and antimalarial agents on groups of enlisted soldiers." *Id.* Ironically, the Alliance would use the recent development of tools such as modern clinical trials to bolster its claim of exemption from regulation made possible by these very tools.

It was not just advances in statistics and clinical trials, however, that improved governments' ability to regulate access to drugs. The ability of scientists to "detect, identify, and understand" the components of various drugs has contributed to "new regulatory

True, a lack of government interference throughout history might be some evidence that a right is deeply rooted. But standing alone, it cannot be enough. If it were, it would be easy to employ such a premise to support sweeping claims of fundamental rights. For example, one might argue that, because Congress did not significantly regulate marijuana until 1937, relatively late in the constitutional day, *see Gonzales v. Raich*, 545 U.S. 1, 11 (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. Or because speed limits are a recent innovation, we have a fundamental right to drive as fast as we deem fit. But this is most certainly 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. But the lack of prior governmental regulation of an activity tells us little about whether the activity merits constitutional protection: "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 nonexistent powers can be prescripted by an unchallenged exercise." *See United States*

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approaches [that] would not have been feasible and could never have occurred" without these scientific advances. Peter Barton Hutt, *The Importance of Analytical Chemistry to Food and Drug Regulation*, 38 VAND. L. REV. 479, 487 (1985). Further, the need for efficacy regulation became more pressing "[a]fter World War II [as] the number of drugs available, the range of diseases and conditions amenable to drug therapy, and the power of drugs all increased dramatically." PETER TEMIN, TAKING YOUR MEDICINE: DRUG REGULATION IN THE UNITED STATES 5 (1980).

v. Morton Salt Co., 338 U.S. 632, 647 (1950). Indeed, creating constitutional rights to be free from regulation based solely upon a prior lack of regulation would undermine much of the modern administrative state, which, like drug regulation, has increased in scope as changing conditions have warranted.

B.

The Alliance next turns to several common law doctrines, arguing that barring access to experimental drugs for terminally ill patients is "inconsistent with the way that our legal tradition treats persons in all other life-threatening situations." Appellants' Br. at 31. Specifically, the Alliance argues that three doctrines—(1) the doctrine of necessity; (2) the tort of intentional interference with rescue; and (3) the right to self-defense—each support the recognition of a right to self-preservation. Such a right to self-preservation, the Alliance believes, would permit "persons in mortal peril . . . to try to save their own lives, even if the chosen means would otherwise be illegal or involve enormous risks." *Id.* at 32. Specifically, in this case, the Alliance believes that a right to self-preservation would give the terminally ill a constitutionally protected right of access to experimental drugs.[13]

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[13] The Supreme Court in *Glucksberg* specifically disapproved of recognizing new fundamental rights solely based upon "abstract concepts of personal autonomy." *Glucksberg*, 521 U.S. at 725. The FDA argues that the Alliance's effort to create a new fundamental right based upon these three doctrines amounts to precisely this type of reasoning forbidden by *Glucksberg*, that is, amounts to the creation of a right based solely upon abstract concepts of liberty. The Alliance insists that "reasoning by analogy, and a search for broader principles, are the only available tools" in cases where there is a "tradition of non-regulation." Reply Br. at 3. In those circumstances, the Alliance argues, "there often will be no common law cases precisely on point

Looking first to the Alliance's necessity argument, the Alliance invokes the common law doctrine, which "'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)). The Alliance offers, however, little detail about how necessity would apply to its case. *See* Appellants' Br. at 37. (*E.g.*, would terminally ill patients have a right to force drug companies to provide them with experimental drugs?) Nonetheless, the Supreme Court's analysis of the common law doctrine of necessity in *Oakland* leaves little room for the Alliance's argument that common law necessity could justify overriding the Food, Drug, and Cosmetic Act.

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." *Oakland*, 532 U.S. at 490.[14]

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simply because the common law never confronted the precise problem." *Id.* We need not address this FDA argument because none of the common law doctrines upon which the Alliance relies supports its proposed right.

[14] As an initial matter, the *Oakland* 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," *Oakland*, 532 U.S. at 491, because, as in this case, the federal statute at issue in *Oakland*

The Supreme Court rejected that argument 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.* at 491 (quotation marks omitted). Although the Court limited its analysis to the statutory issue and did not address the defendant's constitutional arguments, *see id.* at 494, the learning of *Oakland* is clear. Congress may limit or even eliminate a necessity defense that might otherwise be available. That is precisely what the FDCA has done. 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, the common law doctrine of necessity provides little support to the Alliance's proposed right.

The Alliance next invokes the tort of intentional interference with lifesaving efforts, which the Restatement of Torts defines as "intentionally prevent[ing] a third person from giving to another aid *necessary* to his bodily security." RESTATEMENT (FIRST) OF TORTS § 326 (emphasis added). But that is not this case. The Alliance seeks access to drugs that are experimental and have not been shown to be safe, let alone effective at (or "necessary" for) prolonging life.[15] Indeed, the

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had specifically reached the value judgment the proponents of an implied necessity defense sought to override.

[15] The lynchpin of the dissent's argument that preventing access to experimental drugs implicates a right to preserve one's own life is that we have confused "what is necessary with what is sufficient." Dissent at 3, 9. Because terminally ill patients have no other approved treatment options, so the argument goes, any drug

Alliance concedes that taking experimental drugs can "involve enormous risks." Appellants' Br. at 32. In essence, the Alliance insists on a constitutional right to assume any level of risk. It is difficult to see how a tort addressing interference with providing "necessary" aid would guarantee a constitutional right to override the collective judgment of the scientific and medical communities expressed through the FDA's clinical testing process. Thus, we cannot agree that the tort of intentional interference with rescue evidences a right of access to experimental drugs.

Finally, the Alliance looks to traditional self-defense principles to support its proposed constitutional right. The common law doctrine of self-defense provides that "[o]ne who is not the aggressor . . . is justified in using a reasonable amount

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having passed Phase I, no matter the remaining unexplored risk, is "necessary" for prolonging a patient's life. But the dissent ignores the fact that when these treatment decisions are being made, the safety and efficacy records of experimental drugs are not fully known. We thus cannot know until after the clinical testing process has been completed that these drugs are in fact necessary. This argument also defies reality as the great majority of experimental drugs ultimately provide no benefit, and we fail to see how an ineffective and unsafe drug can be classified as necessary. *See, e.g.*, Peter D. Jacobson & Wendy E. Parmet, *A New Era of Unapproved Drugs: The Case of Abigail Alliance v. von Eschenbach*, 297 JAMA 205, 206 (2007) (noting that only five percent of all cancer drugs beginning clinical trials are ultimately approved for use and that less than a third that pass Phase I advance from Phase II to Phase III). The dissent's position is further compromised by the fact that the Supreme Court rejected a similar argument in a statutory challenge to the FDCA because "[f]or 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." *United States v. Rutherford*, 442 U.S. 544, 555-56 (1979).

of force against his adversary when he reasonably believes (a) that he is in immediate danger of unlawful bodily harm from his adversary and (b) that the use of such force is necessary to avoid this danger." 2 WAYNE R. LAFAVE, SUBSTANTIVE CRIMINAL LAW § 10.4 (2d ed. 2003). Self-defense typically arises when a victim is being attacked by an aggressor and uses reasonable force to overcome immediate danger. The Alliance argues that self-defense permits victims to assume two types of risk: (1) the risk that the victim will kill the attacker; and (2) the risk that "[f]ighting back may dramatically increase the . . . harm" to the victim. Appellants' Br. at 35-36. So, the argument goes, if victims of crimes are allowed to assume these risks in defending their lives, terminally ill patients should also be allowed to assume the risk that an experimental drug may hasten their deaths.

That self-defense principles should be applied in the medical context is evidenced, the Alliance argues, by the Supreme Court's abortion jurisprudence. The Alliance does not look to the "right of personal privacy" addressed in *Roe v. Wade*, 410 U.S. 113, 152 (1973). Instead, the Alliance argues that *Roe* "recognized another, entirely separate right to abortion: a woman's right to abort a fetus *at any stage of a pregnancy* if doing so is necessary to preserve her life or health." Appellants' Br. at 39 (emphasis in original).[16] "That right," the Alliance argues, "is grounded in traditional self-defense principles rather than privacy . . . ." *Id.* Applying that concept here, the Alliance argues that because its terminally ill members are in immediate danger of harm from cancer, they can use whatever medical

[16] *See also Casey*, 505 U.S. at 879 (reaffirming exception); *Roe*, 410 U.S. at 173 (Rehnquist, J., dissenting) ("If the Texas statute were to prohibit an abortion even where the mother's life is in jeopardy, I have little doubt that such a statute would lack a rational relation to a valid state objective . . . .").

means are necessary to defend themselves. Thus, they argue, even if a medical treatment might otherwise be prohibited by law, the doctrine of self-defense justifies access to that treatment, just as self-defense justifies an assault victim using physical force otherwise prohibited by law.

This analogy also fails because this case is not about using reasonable force to defend oneself (as in most cases involving self-defense), nor is it about access to life-saving medical treatment. This case is about whether there is a constitutional right to assume, in the Alliance's own words, "enormous risks," Appellants' Br. at 32, in pursuit of *potentially* life-saving drugs. Unlike the cases in which the doctrine of self-defense might properly be invoked, this case involves risk from drugs with no proven therapeutic effect, which at a minimum separates this example from the abortion "life of the mother" exception. Because terminally ill patients cannot fairly be characterized as using reasonable force to defend themselves when they take unproven and possibly unsafe drugs, the Alliance's desire that the terminally ill be free to assume the risk of experimental drugs cannot draw support from the doctrine of self-defense.[17]

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[17] To be sure, we do not suggest that the law can never strike the balance between access to experimental drugs and risk that the Alliance suggests. We limit our analysis to whether the Constitution *demands* the balance they desire. The Alliance can, of course, advocate its position vigorously before Congress and the FDA, and convince our Nation's democratic branches that the values the Alliance favors should be protected. In fact, within the last year, the political branches have responded to the concerns of the Alliance and others. The FDA recently issued a notice of proposed rulemaking that:

> propos[ed] to amend its regulations on access to investigational new drugs for the treatment of

III.

Although it has not addressed the precise constitutional argument urged by the Alliance, we find it highly significant that the Supreme Court has rejected several similar challenges to the FDCA and related laws brought on statutory grounds. *See, e.g.*, *Raich*, 545 U.S. at 28 ("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). And other courts have rejected arguments that the

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> patients. The proposed rule would clarify existing regulations and add new types of expanded access for treatment use. Under the proposal, expanded access to investigational drugs for treatment use would be available to individual patients, including in emergencies; intermediate-size patient populations; and larger populations under a treatment protocol or treatment investigational new drug application (IND). The proposed rule is intended to improve access to investigational drugs for patients with serious or immediately life-threatening diseases or conditions, who lack other therapeutic options and who may benefit from such therapies.

Expanded Access to Investigational Drugs, 71 Fed. Reg. 75,147-01, 75,147 (Dec. 14, 2006).

Constitution provides an affirmative right of access to particular medical treatments reasonably prohibited by the Government.[18]

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[18] 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. Exam'rs*, 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

In keeping with those decisions, we conclude that the Alliance has not provided evidence of a right to procure and use experimental drugs that is deeply rooted in our Nation's history and traditions. To the contrary, our Nation's history evidences increasing regulation of drugs as both the ability of government to address these risks has increased and the risks associated with drugs have become apparent. Similarly, our legal traditions of allowing a necessity defense, prohibiting intentional interference with rescue, and recognizing a right of self-defense cannot justify creating a constitutional right to assume any level of risk without regard to the scientific and medical judgment expressed through the clinical testing process.[19]

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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, 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.").

[19] As there exists no deeply rooted right, we need not examine whether a right of access to experimental drugs is "'implicit in the concept of ordered liberty,' such that 'neither liberty nor justice would exist if they were sacrificed.'" *Glucksberg*, 521 U.S. at 720-21 (quoting *Palko v. Connecticut*, 302 U.S. 319, 325, 326 (1937)). While we need not and do not address all of the Alliance's arguments regarding whether their proposed right is implicit in our Nation's system of ordered liberty, we note a crucial difference between this case and one of the cases relied upon by the Alliance in making that

IV.

Because the Alliance's claimed right is not fundamental, the Alliance's claim of a right of access to experimental drugs is subject only to rational basis scrutiny. *See Glucksberg*, 521 U.S. at 722 (noting that "a challenged state action [must] implicate a fundamental right" to avoid rational basis review). The rational basis test requires that the Alliance prove that the government's restrictions bear no rational relationship to a legitimate state interest. *See, e.g.*, *Harrah Indep. Sch. Dist. v. Martin*, 440 U.S. 194, 198 (1979); *Glucksberg*, 521 U.S. at 735. The challenged policy "need not be in every respect logically consistent with its aims to be constitutional. It is enough that there is an evil at hand for correction, and that it might be

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argument, *Cruzan v. Director, Mo. Dep't of Health*, 497 U.S. 261 (1990). 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." *Id.* at 279. Looking to *Cruzan*, the Alliance argues that "[i]f a patient has a fundamental right to medical self-determination that gives them the right to starve themselves to death, then surely they have a right to choose to fight for their lives even if that means taking a drug that has not yet met the FDA's full approval standards." Appellants' Br. at 27. *Cruzan*'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 also 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.

thought that the particular legislative measure was a rational way to correct it." *Williamson v. Lee Optical of Okla., Inc.*, 348 U.S. 483, 487-88 (1955).[20]

The Alliance acknowledges the risk inherent in taking experimental drugs. *See* Am. Compl. ¶ 19 ("Terminally ill patients are typically willing to assume risks . . . ."). The Alliance would rather that individual patients make decisions about this risk than have the FDA decide which drugs are safe enough for limited access to the terminally ill. The FDA counters that "[w]ithout a requirement of FDA approval, patients could be exposed to unreasonable risks from investigational drugs that may be neither safe nor effective." Appellees' Br. at 55-56.

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[20] We are mindful of the fact that this case is before us pursuant to the FDA's motion to dismiss, brought under Federal Rule of Civil Procedure 12(b)(6). The Seventh Circuit has noted some tension between the Rule 12(b)(6) standard and rational basis review. *See Wroblewski v. City of Washburn*, 965 F.2d 452, 459 (7th Cir. 1992) ("The rational basis standard requires the government to win if any set of facts reasonably may be conceived to justify its classification; the Rule 12(b)(6) standard requires the plaintiff to prevail if relief could be granted under any set of facts that could be proved consistent with the allegations. The rational basis standard, of course, cannot defeat the plaintiff's benefit of the broad Rule 12(b)(6) standard.") (quotation marks and citations omitted). In this case, however, we need not worry about the outer realm of Rule 12(b)(6) protection because, as we explain below, the Alliance's pleadings themselves make our rational basis determination straightforward. *Cf. Trudeau v. FTC*, 456 F.3d 178, 193 (D.C. Cir. 2006) (noting that it "is possible for a plaintiff to plead too much: that is, to plead himself out of court by alleging facts that render success on the merits impossible" (quoting *Sparrow v. United Air Lines, Inc.*, 216 F.3d 1111, 1116 (D.C. Cir. 2000))).

Applying the rational basis standard to the Alliance's complaint, we cannot say that the government's interest does not bear a rational relation to a legitimate state interest. That conclusion is compelled by the Supreme Court's decision in *United States v. Rutherford*, 442 U.S. 544 (1979). In that case, terminally ill patients sought to prevent the FDA from prohibiting access to the drug laetrile, even though the drug had not been approved for public use. In rejecting a challenge by terminally ill patients claiming that the FDCA's safety requirement did not apply to them, the Supreme Court held that "[f]or 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." *Id.* at 555-56; *see also id.* at 558 (noting that history has demonstrated that numerous "resourceful entrepreneurs" might try to take advantage of an unregulated market, which "suggest[s] why Congress could reasonably have determined to protect the terminally ill, no less than other patients, from the vast range of self-styled panaceas that inventive minds can devise").

Although terminally ill patients desperately need curative treatments, as *Rutherford* holds, their deaths can certainly be hastened by the use of a potentially toxic drug with no proven therapeutic benefit. Thus, we must conclude that, 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. We therefore hold that the FDA's policy of limiting access to investigational drugs is rationally related to the legitimate state interest of protecting patients, including the terminally ill, from potentially unsafe drugs with unknown therapeutic effects.

Although in the Alliance's view the FDA has unjustly erred on the side of safety in balancing the risks and benefits of

experimental drugs, this is not to say that the FDA's balance can never be changed. The Alliance's arguments about morality, quality of life, and acceptable levels of medical risk are certainly ones that can be aired in the democratic branches, without injecting the courts into unknown questions of science and medicine. Our Nation's history and traditions have consistently demonstrated that the democratic branches are better suited to decide the proper balance between the uncertain risks and benefits of medical technology, and are entitled to deference in doing so. As the Supreme Court has held:

> 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.

Jacobson v. Massachusetts, 197 U.S. 11, 30 (1905); *see also Gonzales v. Carhart*, 127 S. Ct. 1610, 1636 (2007) ("The Court has given state and federal legislatures wide discretion to pass legislation in areas where there is medical and scientific uncertainty."); *cf. Greenwood v. United States*, 350 U.S. 366, 375-76 (1956) ("The 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."). Consistent with that precedent, our holding today ensures that this debate among the Alliance, the FDA, the scientific and medical communities,

and the public may continue through the democratic process. *See Glucksberg*, 521 U.S. at 735.

V.

For the foregoing reasons, the judgment of the district court is affirmed.

So ordered.

ROGERS, *Circuit Judge*, with whom *Chief Judge* GINSBURG joins, dissenting: Today, the court rejects the claim that terminally ill patients who have exhausted all government-approved treatment options have a fundamental right to access investigational new drugs. The court's opinion reflects a flawed conception of the right claimed by the Abigail Alliance for Better Access to Developmental Drugs and a stunning misunderstanding of the stakes. The court shifts the inquiry required by *Washington v. Glucksberg*, 521 U.S. 702 (1997), by changing the nature of the right, by conflating the right with the deprivation, and by prematurely advancing countervailing government interests. The court fails to come to grips with the Nation's history and traditions, which reflect deep respect and protection for the right to preserve life, a corollary to the right to life enshrined in the Constitution. The court confuses this liberty interest with the manner in which the Alliance alleges that the liberty has been deprived, namely by denying terminally ill patients access to investigational medications under the narrow conditions described by the Alliance. The court conflates the inquiry as to whether a fundamental right exists at all with whether the government has demonstrated a compelling interest, when strictly scrutinized, rendering its restrictive policy constitutional.

These missteps lead the court to rely upon how rights and liberties have been limited and restricted — addressing regulations to prevent fraud in the sale of misbranded and adulterated medications or safety restrictions applicable to all medicines for any palliative purpose — which says little about the historic importance of the underlying right of a person to save her own life. Likewise, in its treatment of the common law doctrines of necessity, interference with rescue, and self defense, the court points to evolved limitations on those doctrines while ignoring the core concerns that animate them, namely the special importance of life and attempts to preserve it. That the ultimate protection of such varying attempts to save life is cabined by the

precedents — regarding what constitutes "necessity," the related "necessity" of any aid being given to a third party, and the "reasonable" and "necessary" limitations on any force used in self-defense — does not suggest the absence of an underlying right to attempt to protect life, but rather the recognition of competing governmental interests that in various circumstances justify the deprivation of or a limitation upon the right.

The common law doctrines remain good evidence of a history and tradition of protecting life and attempts to preserve life as a deep-seated personal right. That the right may be and has been denied in the face of compelling governmental interests is no reason for conflating the two stages of the analysis and looking only to the results of past cases in order to avoid the analysis prescribed by the Supreme Court in *Glucksberg*, 521 U.S. at 720-21. Contrary to today's view of the court and the Federal Drug Administration ("FDA"), nothing in the prior opinion of the court would give "total weight" to the interests of the terminal patients or deny the FDA the ability to put its competing governmental interests into the balance. The court was explicit on this point, requiring precisely such weighing and proof of the proposed government concerns, rather than merely accepting, under the rubric of rational basis scrutiny, any assertions the FDA chooses to offer. *See Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 486 (D.C. Cir. 2006) ("*Abigail Alliance I*") (vacated upon grant of rehearing en banc).

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

in the cold despite its textual anchor in the right to life. This alone is reason the court should pause about refusing to put the FDA to its proof when it denies terminal patients with no alternative therapy the only option they have left, regardless of whether that option may be a long-shot with high risks. The court is on even weaker footing when it relies upon the risks entailed in medical procedures to wrest life-and-death decisions that once were vested in patients and their physicians. The court commits a logical error of dramatic consequence by concluding that the investigational drugs are somehow not "necessary." Op. at 25 & n.15; *accord id.* at 26. While the potential cures may not prove *sufficient* to save the life of a terminally ill patient, they are surely *necessary* if there is to be any possibility of preserving her life.

It bears outlining the history and common law basis for the Alliance's claim in order to demonstrate, once again, that the history and traditions of this Nation support the right of a terminal patient, and not the government, to make this fundamentally personal choice involving her own life. Because judicial precedents and the historical record require strict scrutiny before upsetting rights of this magnitude, the FDA must demonstrate a compelling governmental interest before its policy restricting access can survive. Accordingly, I would remand the case to the district court to make the initial determination as to whether FDA has met its burden, and I respectfully dissent.

I.

The Fifth Amendment of the Constitution proscribes the "depriv[ation] of life, liberty, or property." U.S. CONST. amend. V. The Alliance claims a corollary to the right to life itself, namely the right to attempt to preserve it. As alleged by the Alliance, this right is deprived without due process of law when

the FDA makes it practically impossible for Alliance members for whom conventional treatments have failed to access investigational new drugs that have been approved for substantial human testing. Under *Glucksberg*, 521 U.S. at 720-21, a substantive due process right qualifies as fundamental if it is both "'deeply rooted in this Nation's history and tradition,'" *id*. at 721 (quoting *Moore v. City of E. Cleveland*, 431 U.S. 494, 503 (1977) (plurality opinion)), and "'implicit in the concept of ordered liberty,'" *id.* (quoting *Palko v. Connecticut*, 302 U.S. 319, 325 (1937)).[1] If the Alliance has correctly alleged a fundamental right, then the FDA policy can survive only upon proof of a compelling government interest that overcomes the liberty interest.

A.

The *Glucksberg* analysis begins with a "'careful description' of the asserted fundamental liberty interest." 521 U.S. at 721-23. As the court's opinion in this case demonstrates, the description of the right is of crucial importance — too broad and a right becomes all-encompassing and impossible to evaluate; too narrow and a right appears trivial. *See Abigail Alliance I*, 445 F.3d at 477. The court asserts that "[t]his case is about whether there is a constitutional right to assume . . . 'enormous risks' in pursuit of *potentially* life-saving drugs." Op. at 28 (emphasis in original) (citation omitted). This description can be characterized as "careful" only if the objective of *Glucksberg* analysis is to produce abstractions that

[1] The *Glucksberg* framework arose from a situation involving a non-literal liberty interest. Although, as described below, the right to act to preserve one's own life passes the test laid down in that case, the healthy skepticism that *Glucksberg* prescribed for new-fangled non-literal liberty interests may be unduly restrictive as applied to a claim with a firm textual anchor in the right to life expressly protected by the Fifth Amendment to the Constitution.

shield a court from acknowledging the rights underlying a party's claims. As the court notes, fundamental rights cannot be "solely based upon 'abstract concepts of personal autonomy.'" Op. at 23 n.13 (quoting *Glucksberg*, 521 U.S. at 725). However, were it impermissible to draw any inferences from a broader right to a narrower right, nearly all of the Supreme Court's substantive due process case law would be out of bounds. *See, e.g.*, *Moore*, 431 U.S. at 503 (extrapolating specific right to determine extended family living arrangements from broader constitutional protection for "the sanctity of the family"); *Roe v. Wade*, 410 U.S. 113 (1973) (identifying specific right to terminate a pregnancy from broader right to privacy); *Griswold v. Connecticut*, 381 U.S. 479, 484-86 (1965) (inferring specific right to use contraception from general right to be free from intrusion into "sacred precincts of marital bedrooms"). In any event, the Alliance's liberty claims are not grounded in the abstract notion of personal autonomy but rather in the specific right to act to save one's own life.

The court fundamentally misunderstands the right claimed by the Alliance and trivially casts it as a function of the regulatory scheme. *See* Op. at 14 n.6. But the Alliance should not be penalized for anticipating a justification for infringing the right that might survive strict scrutiny. Applying the court's reasoning today, had "Jane Roe" been prescient enough to claim a right to abort a pre-viable fetus by a procedure that is demonstrably safer than all other alternatives, *cf. Gonzales v. Carhart*, 127 S. Ct. 1610, 1638 (2007), she would have failed to show a fundamental right to an abortion.[2] Again, the claimed

[2] Similarly, the Tenth Circuit has held that although parents have a fundamental constitutional right to direct the education and upbringing of their children, this right does not "allow parents to dictate that their children will attend public school for only part of the school day." *Swanson ex rel. Swanson v. Guthrie Indep. Sch. Dist.*

fundamental right is to attempt to preserve one's life; whether the risks associated with doing so justify restraining that right is properly considered only after the right is deemed fundamental. Under *Glucksberg*, the court's analysis should begin with an assessment of whether the right to attempt to preserve life can be found in the Nation's history and tradition. *See Abigail Alliance I*, 445 F.3d at 479. A review of this history demonstrates that this Nation has long entrusted in individuals those fundamentally personal medical decisions that lie at the core of personal autonomy, self-determination, and self-defense.

1. The heritage of this right predates the Founding. Samuel Adams referred to "the duty of self preservation" as "the first law of nature." Samuel Adams, *The Rights of the Colonists: Report of the Committee of Correspondence to the Boston Town Meeting*, 7 OLD SOUTH LEAFLETS 417 (No. 173) (Burt Franklin 1970) (1772). The common law's eminent commentator, William Blackstone, wrote of three "principal or primary articles" historically comprising "the rights of all mankind." First among these was "[t]he right of personal security . . . in a person's legal and uninterrupted enjoyment of his life, his limbs, his body, [and] his health." WILLIAM BLACKSTONE, 1 COMMENTARIES *129. Blackstone described the guarantee of "[t]he preservation of a man's health from such practices as may prejudice or annoy it." *Id.* at *134. 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

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No. I-L, 135 F.3d 694, 702 (10th Cir. 1998). By the court's reasoning, if parents had come to court claiming a fundamental right to educate their children but acknowledging that if they sent their children to public school, they could do so only full-time, the fundamental right never would have been recognized. *But see Meyer v. Nebraska*, 262 U.S. 390 (1923); *Pierce v. Soc'y of Sisters*, 268 U.S. 510 (1925).

as done upon the highest necessity and compulsion." *Id.* at *130.

This principle is of early vintage, for "Anglo-American law starts with the premise of thorough-going self determination." *Natanson v. Kline*, 350 P.2d 1093, 1104 (Kan. 1960). Long before regulation of the efficacy of medications was contemplated by the federal government, courts recognized with "universal acquiescence" that "the free citizen's first and greatest right, which underlies all others," is "the right to the inviolability of his person, in other words, his right to himself." *Pratt v. Davis*, 118 Ill. App. 161, 166 (1905), *aff'd*, 79 N.E. 562 (Ill. 1906). So too, this court has recognized "the concept, fundamental in American jurisprudence, that '[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body.'" *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir. 1972) (alteration in original) (quoting *Schloendorff v. Soc'y of N.Y. Hosp.*, 105 N.E. 92, 93 (1914) (Cardozo, J.)).

2. This historical entitlement recognized in the legal tradition of this Nation is reflected in rights recognized at common law that are retained by an individual. Most notably, the right of self-defense enforces the right of a person facing death to take reasonable steps to protect her own life. Although this right is not unqualified, self-defense has been described as "an inherent right of man, older than states or Constitutions." *People v. Pignatoro*, 136 N.Y.S. 155, 160 (Magis. Ct. 1911). The privilege extends, of course, to repelling the attacks of aggressors, *see, e.g.*, *Brown v. United States*, 256 U.S. 335, 343-44 (1921); *cf. Montana v. Egelhoff*, 518 U.S. 37, 56 (1996) (plurality opinion), but also protects incursions into the property of others, *see, e.g.*, *Ploof v. Putnam*, 71 A. 188, 189 (Vt. 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." (citation omitted)); *Mouse's Case*, 12 Co. Rep. 63, 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 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). Although the concept of self-defense is most often thought of in terms of the response to an assault by another human being, its premise compels the same response in the face of other forms of aggression against life and limb, whether the aggressor be an animal[3] or a diseased cell within one's body. There is, accordingly, no reason to think that the efforts of Alliance members to repel their terminal diseases do not implicate this concept.

Aside from asserting that this case is not about efforts to preserve one's life, but rather the "right to assume any level of risk," the court further avoids the doctrines of self-defense and necessity by asserting that Congress can override the common law. *See* Op. at 26. This is true but irrelevant. It was also true in *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990), in which the Supreme Court discussed the fundamental right to refuse life-sustaining medical treatment, *id.* at 278. When the Court recognized that the common law tort of battery supported the fundamental right to refuse medical treatment, *id.* at 269, it did not constitutionalize the tort of battery. Similarly, recognizing that necessity has historically been protected does not constitutionalize the doctrine of necessity. Yet the court resists the implications of the historical protection for actions prompted by necessity out of an

[3] A person may assert self-defense rights against animals. *See, e.g.*, *People v. Lee*, 32 Cal. Rptr. 3d 745, 754-55 (Ct. App. 2005); *Credit v. Brown*, 10 Johns. 365 (N.Y. Sup. Ct. 1813).

unwarranted fear that acknowledging the historical record will constitutionalize the common law. *See* Op. at 22-23, 26. In so doing, it forgets the second part of the *Glucksberg* inquiry. A tradition of protection does not alone establish a fundamental right. The subsequent determination of whether a right is "implicit in the concept of ordered liberty" invalidates the court's fears of a slippery slope.

The common law also recognized the right of protection against interference with rescue. This right is infrequently invoked, but as early as 1889, it was acknowledged by the highest court of the State of Maryland, which explained that even prolongation of a fading life was not to be obstructed:

> Surely the law does not authorize the husband to say to his wife: "You shall die of the cancer; you cannot be cured, and a surgical operation affording only temporary relief, will result in useless expense." The husband had no power to withhold from his wife the medical assistance which her case might require.

State v. Housekeeper, 16 A. 382, 383-84 (Md. 1889). The Restatement of Torts, published in 1934, generalized this point of law: "One 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." RESTATEMENT OF TORTS § 326; *see also id.* § 327 (negligence); RESTATEMENT (SECOND) OF TORTS §§ 326, 327; W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS 382 (5th ed. 1984). This common law rule is firmly grounded.[4] By interposing itself between a terminally ill patient

[4] *See, e.g.*, *Beck v. Haik*, 377 F.3d 624, 633-34 (6th Cir. 2004) (discussing appropriate jury instruction for claim of interference

and her only means of prolonging her life, the FDA's policy runs counter to the common law's historical prohibition on interfering with rescue.

The common law protection, of course, is for rescues that are reasonably necessary. In an effort to distinguish this historical protection, the court relies upon the fact that the new investigational drugs "have not been shown to be safe, let alone effective at (or 'necessary' for) prolonging life." Op. at 25. But this confuses what is necessary with what is sufficient. This is not a case about elective medical treatments. Without access, Alliance members will die. No doubt the deceased members of the Alliance who were denied access to experimental drugs that were subsequently approved by the FDA would have been surprised to learn that these drugs, under the court's analysis, were unnecessary to the preservation of their lives. *See* Br. of Appellants at 31 n.15; Reply Br. of Appellants at 23. *See generally Abigail Alliance for Better Access to Developmental*

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with rescue); *Ross v. United States*, 910 F.2d 1422 (7th Cir. 1990) (holding that a deputy sheriff committed a constitutional tort by interfering with efforts to rescue a drowning boy); *United States v. Lawter*, 219 F.2d 559, 562 (5th Cir. 1955) (holding that the government is liable when it prevents others from attempting a rescue and takes no action itself); *Sneider v. Hyatt Corp.*, 390 F. Supp. 976, 980 & n.2 (N.D. Ga. 1975) (noting that "deliberate interference with rescue efforts by third parties is a traditional basis for imposing liability"); *Soldano v. O'Daniels*, 190 Cal. Rptr. 310, 313, 316-18 (Ct. App. 1983) (applying Restatement); *Thomas v. Williams*, 124 S.E.2d 409, 414 (Ga. Ct. App. 1962) (sustaining cause of action for interference with rescue where defendant prevented rescue of inmate from jail cell during fire); *Riggs v. Colis*, 695 P.2d 413, 415 (Idaho 1985) (applying Restatement); *Byrne v. Long Island State Park Comm'n*, 323 N.Y.S.2d 442 (Sup. Ct. 1971); *see also Commonwealth v. Marcelli*, 441 N.E.2d 270, 271 (Mass. Ct. App. 1982) (criminal liability); CAL. PENAL CODE § 148.2(1) (same).

Drugs v. von Eschenbach, 469 F.3d 129 (D.C. Cir. 2006) ("*Abigail Alliance II*"). Thus, the court's apparent understanding of the meaning of "necessity" is manifestly flawed. *See* Op. at 25 n.15. By the court's reasoning, it is not "necessary" for the driver of a car that is hurtling toward a cliff to press the brake because we "cannot know until after" he has done so whether the car will stop in time. Alliance members, like the endangered driver, will perish without remedial steps. The question presented in this case is not whether investigational drugs are necessary to a terminally ill patient who has exhausted conventional treatment options — they are — but who will make the subsequent decision about using these medications, the patient with her doctor or the government. Moreover, as Prosser and Keeton have explained, "[t]he principle [that one may not prevent aid by others] has been carried even to the length of holding that there is liability for interfering with the possibility of such aid." KEETON ET AL., *supra*, at 382.

Throughout its discussion of self-defense and interference with rescue, the court recognizes that common law rights are not unlimited but fails to acknowledge that the evolved limitations on hallowed rights do not undercut the core concerns that animate them — here, the special importance of life and attempts to preserve it. That the ultimate protection of such varying attempts to save life is cabined by precedents discussing "necessity" speaks not to the absence of an underlying right to attempt to protect life but rather to the recognition of competing governmental interests that in various circumstances justify the deprivation of or a limitation upon the right. Whether similar countervailing interests exist in this case is a question bearing on the resolution of strict scrutiny analysis, not on whether it should apply.

3. Although the Supreme Court has not squarely addressed the right to use potentially life-saving *medications*, it has

developed a sizable body of law regarding the right to a potentially life-saving medical *procedure* when the life or health of a pregnant woman is on the line. In *Roe*, 410 U.S. at 164-65, and again in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 846, 880 (1992), the Court held that even after fetal viability, a state cannot constitutionally proscribe abortion "where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother," *Roe*, 410 U.S. at 164-65; *Casey*, 505 U.S. at 879 (plurality opinion); *accord Ayotte v. Planned Parenthood of N. New Eng.*, 546 U.S. 320, 327-28 (2006). In so doing, the Court acknowledged the tradition of "'preserving the life of the mother,'" *Roe*, 410 U.S. at 137 (quoting *Rex v. Bourne*, [1939] 1 K.B. 687 (Crim. App.)), both in the common law, *see id.*, and in early state statutes, *see id.* at 138 (citing "model" legislation enacted in New York in 1828).

In *Stenberg v. Carhart*, 530 U.S. 914 (2000), the Supreme Court squarely addressed whether a state may ban a particular medical procedure in cases where a patient's health or life is endangered. The Court held that "the governing standard requires an exception 'where it is necessary, in appropriate medical judgment for the preservation of the life or health of the mother.'" *Id.* at 931 (quoting *Casey*, 505 U.S. at 879). There, the State of Nebraska could not constitutionally ban particular abortion procedures, notwithstanding the state's "interest in the potentiality of human life," *id.* at 930, even though the state claimed that there were adequate alternatives, *id.* at 931-32. Here, the situation is even starker: The Alliance's terminally ill members have no remaining alternatives except the medications to which the FDA denies them access. This Term all nine justices of the Supreme Court agreed that controlling precedents forbid the government from banning an abortion procedure "if it 'subject[ed] [women] to significant health risks," *Gonzales v. Carhart*, 127 S. Ct. at 1635 (quoting *Ayotte*, 546 U.S. at 328)

(alterations in original); *accord id.* at 1641-42 (Ginsburg, J., with whom Stevens, Souter, and Breyer, JJ., join, dissenting), and the Court repeatedly emphasized the availability of safe alternative procedures before approving the ban, *see id.* at 1636, 1637, 1638. The right sought by the Alliance pertains only to those for whom no such alternatives exist.

Consequently, for the court to conclude that the Supreme Court has not already decided that medical self-preservation is fundamental, the court is forced to conclude that when a patient's life is on the line, medical procedures like abortion are to be analyzed differently than medical treatments consisting of prescription medications. To draw this distinction, the FDA offers only the empty assertion that "the right to abort a fetus to save the life or health of the mother is simply an aspect of the underlying constitutional right of abortion recognized in *Roe*." Brief for Appellees at 39. This *ipse dixit* cannot be reconciled with the fact that a woman's right to end a life-threatening pregnancy has long been uncontroversial in the face of state statutory prohibitions against abortion and distinct from the considerations that otherwise bear on the procedure. "The criminal abortion laws passed in every state by 1880 made exceptions for therapeutic abortions performed in order to save a woman's life." LESLIE J. REAGAN, WHEN ABORTION WAS A CRIME 5 (1997). Reaching farther back into history, as the Supreme Court discussed in *Roe*:

> The Ephesian, Soranos, often described as the greatest of the ancient gynecologists, appears to have been generally opposed to Rome's prevailing free-abortion practices. He found it necessary to think first of the life of the mother, and he resorted to abortion when, upon this standard, he felt the procedure advisable.

410 U.S. at 130. This approach continued into the modern era. When England imposed criminal sanctions for abortion in 1861, it provided no explicit exception for pregnancies that endanger the life or health of a mother. Offenses Against the Person Act of 1861, 24 & 25 Vict., c. 100, § 59. Nonetheless, an English court determined that the statute could not include procedures necessary to save the woman's life, because "as in the case of homicide, so also in the case where an unborn child is killed, there may be justification for the act." *Bourne*, [1939] 1 K.B. at 690. This history suggests, contrary to the FDA's view, that a woman's right to an abortion as an act of medical self-defense is independent from her right to an abortion based upon her right to make deeply personal decisions, *see Casey*, 505 U.S. at 581.

The court chooses not to distinguish the abortion cases on this flimsy basis but its approach is no less startling. The court holds that because the Alliance seeks access only to "*potentially* life-saving drugs," Op. at 28 (emphasis in original), the abortion cases are distinguishable. Nowhere in the Supreme Court's jurisprudence has it intimated that the government may ban procedures that represent a patient's only chance of survival because they might not be successful. The fundamental right does not accrue only upon a demonstration of surefire actualization; the trigger is the *necessity*, which is crucially different from the sufficiency to which the court repeatedly refers. Indeed, in *Stenberg*, the Supreme Court addressed the level of medical consensus needed for a procedure to become protected, holding that procedures supported by "substantial medical authority" could not be proscribed. *See* 538 U.S. at 938. The Court was careful not to require medical unanimity, *see id.* at 937, or even "general medical studies," *see id.* at 935, like those required for FDA approval of investigational new drugs for commercial marketing, *see* 21 C.F.R. pt. 312. Although *Gonzales v. Carhart* clarifies that government may regulate to some extent "where there is uncertainty over whether

the barred procedure is ever necessary to preserve . . . health, given the availability of other . . . procedures that are considered to be safe alternatives, 127 S. Ct. at 1638, *Stenberg* remains good law, and there are no alternatives to preserve life, let alone health, in this case.

Although the FDA does not contend that its approval process reflects the *Stenberg* standard, the court nonetheless makes the wholly unsupported assertion that "the collective judgment of the scientific and medical communities [is] expressed through the FDA's clinical testing process." Op. at 26. To the contrary, the Alliance specifically alleges in attachments to its complaint that the FDA has denied terminally ill Alliance members access to investigational new drugs "reported to have great potential," Decl. of Carole Steele ¶ 3, and acknowledged by the "medical community" as "far and away . . . superior to anything then available," Decl. of Victoria Jean Doran ¶ 2. At this stage of the proceedings, the court is required to accept the Alliance's allegations as true. *See, e.g.*, *Broudy v. Mather*, 460 F.3d 106, 116 (D.C. Cir. 2006). Thus, there are situations where a terminally ill patient seeks access to a new medication that has not yet been approved by the FDA for commercial marketing but that has been recognized by the medical community as that patient's best chance to survive. In such instances, the Fifth Amendment guarantee of due process protects the terminally ill patient's pursuit of those medications.

There is, then, no merit to the FDA's suggestion adopted by the court that in the medical context there can be no deeply rooted privilege to attempt to save one's own life with medical advances because medical advances capable of saving lives are a relatively recent phenomenon. Br. of Appellee at 34-35; Op. at 21 & n.12. As the prior discussion demonstrates, the Alliance correctly disputes the premise of this argument.

B.

Against this substantial historical record demonstrating the deep roots of the right to preserve one's own life, it is no coincidence that neither the court nor the FDA can marshal evidence from the early history of the Nation demonstrating that the federal government or any state thought to restrain the terminally ill from accessing medical treatments and procedures that had not proven unsafe but were of unknown efficacy. Still, the court asserts that "a lack of government interference . . . cannot be enough" to demonstrate that a right is deeply rooted. This reasoning is misguided.

First, the most fundamental rights are those that no government of the people would contemplate abridging — it is doubtful that many courts or legislatures have discussed whether the government can determine whether we are allowed to breathe air, but this does not make our access to oxygen any less grounded in history. *Cf.* U.S. CONST. amend. IX (stating that "[t]he enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people"). In considering whether the terminally ill patient's interest in self-preservation is protected by the Due Process Clause, the court overlooks the most fundamental evidence of the protection that the Alliance claims, namely that the words "life" and "liberty" are in the Due Process Clause itself. The right to life, and the asserted corollary right to attempt to preserve life, is not a second derivative species of "liberty" whose protection by the Constitution should be approached with skepticism. Insofar as courts should be skeptical of interfering with the legislative debate and ongoing democratic discussions about fundamental issues of life and death, that skepticism is better applied to the latter portion of the strict scrutiny analysis — the evaluation of the competing government interests and the greater or lesser narrowness of the tailoring required in the face of scientific uncertainty and conflicting opinions. *See Abigail*

Alliance I, 445 F.3d at 478 n.9. To deny the constitutional importance of the right to life and to attempt to preserve life is to move from judicial modesty to judicial abdication, as well as confusion, and deprive an express constitutional interest of its due weight in the court's analysis.

Second, the Supreme Court's statements on fundamental rights do not support the court's conclusion. In *Glucksberg* itself, the Supreme Court determined that the claimed right to assisted suicide was not deeply rooted because "for over 700 years, the Anglo-American common-law tradition has punished or otherwise disapproved of both suicide and assisting suicide." 521 U.S. at 711. In the Court's words: "[W]e are confronted with a consistent and almost universal tradition that has long rejected the asserted right, and continues explicitly to reject it today, even for terminally ill, mentally competent adults." *Id.* at 723. But the Supreme Court did not say, as the FDA argued and this court appears to agree, that a right can be fundamental only if it has been acknowledged by statute or decisional law. A plurality of the Supreme Court said the opposite in *Michael H. v. Gerald D.*, 491 U.S. 110, 122 n.2 (1989), in observing that historical "protection need not take the form of an explicit constitutional provision or statutory guarantee, but it must at least exclude . . . a societal tradition of enacting laws denying the interest."

Third, the court's concern that "such a premise [would] support sweeping claims of fundamental rights" neglects the existence of the second *Glucksberg* criterion. Strict scrutiny is not triggered just by a history of protection — otherwise, the entire common law would be constitutionalized. It is the second requirement, that a right be "'implicit in the concept of ordered liberty,' such that 'neither liberty nor justice would exist if they were sacrificed,'" 521 U.S. at 702 (quoting *Palko*, 302 U.S. at 325, 326), that guards against unwarranted expansion of

substantive due process rights. Just as in the context of the necessity defense at common law, the court conflates these two distinct inquiries, and in its haste to acquire a limiting principle, it constructs a significant and unwarranted roadblock to judicial recognition of fundamental rights. This roadblock starts from the Supreme Court's requirement, in the interest of judicial restraint, that '[s]ubstantive due process' analysis must begin with a careful description of the asserted right." *Reno v. Flores*, 507 U.S. 292, 301 (1993). Although the court appropriately assumes the Alliance has satisfied the requirement in this case, the court then errs by effectively holding that the first *Glucksberg* criterion can be satisfied only by historical evidence involving the exact situation that the Alliance presented to us today. It offers no principled reason for ignoring highly relevant evidence, particularly with respect to the historical record concerning abortion to save the life of the mother.

Fourth, in the alternative, the court shifts the target and looks to historical evidence of regulation for *safety*. The court claims that post-Phase I testing is designed not only to test a drug's efficacy but also to continue monitoring its safety. Op. at 15. As support, the court lists instances in which drugs have been removed from the market after Phase I because of safety concerns. *See id.* at 20 n.11. This inquiry confuses the right — to save one's life — with the alleged deprivation, which here occurs by means of an agency policy. Whether the FDA policy actually impermissibly infringes upon the asserted right is a factual question that is not properly resolved at the motion-to-dismiss stage when all reasonable inferences must be drawn to the plaintiff's benefit, *see, e.g.*, *Broudy*, 460 F.3d at 116.[5]

[5] Although the FDA does not stop examining drug safety after Phase I, nor does it stop after drugs receive full marketing approval. The FDA has pulled approved such drugs from the market, but it does not follow that the FDA can take any action abridging any

Furthermore, safety restrictions are applicable to all medicines for any pallative purpose, as well as illegal drugs that serve no pallative purpose, *see Abigail Alliance I*, 445 F.3d at 478 & n.9, and therefore tell us little about the regulation of potentially life-

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right, related or not, on the basis of its legitimate interest in safety. At a certain point, the FDA determines that a drug is safe enough for widespread testing, and the Alliance alleges that this marker is Phase I approval, where the FDA authorizes expanded testing in up to "several hundred subjects," Am. Compl. ¶ 14; 21 C.F.R. § 312.21. In fact, between 1997 and 2000, 5.34 percent of fully approved new drugs were pulled from the market. Kris Hundley, *Drug's Chilling Path to Market*, ST. PETERSBURG TIMES, May 27, 2007, at 1A. Since then, many more approved drugs have been withdrawn. *See, e.g.*, Press Release, Food & Drug Admin., FDA Announces Discontinued Marketing of GI Drug, Zelnorm, for Safety Reasons (March 30, 2007), http://www.fda.gov/bbs/topics/NEWS/ 2007/NEW01597.html; Press Release, Food & Drug Admin., FDA Announces Voluntary Withdrawal of Pergolide Products (March 29, 2007), http://www.fda.gov/bbs/topics/NEWS/2007/NEW01596.html (Permax); Press Release, FDA Asks Purdue Pharma to Withdraw Palladone for Safety Reasons (July 13, 2005), http://www.fda.gov/bbs/topics/news/2005/NEW01205.html; Press Release, Food & Drug Admin., FDA Issues Public Health Advisory on Tysabri, A New Drug for MS (Feb. 28, 2005), http://www.fda.gov/bbs/topics/news/2005/NEW01158.html; Press Release, Food & Drug Admin., FDA Issues Public Health Advisory on Vioxx as its Manufacturer Voluntarily Withdraws the Product (Sept. 30, 2004), http://www.fda.gov/bbs/topics/news/2004/ NEW01122.html; *see also, e.g.*, Press Release, Food & Drug. Admin., Rezulin To Be Withdrawn from the Market (March 21, 2000), http://www.fda.gov/bbs/topics/NEWS/NEW00721.html; Press Release, Food & Drug Admin., FDA Announces Withdrawal Fenfluramine and Dexfenfluramine (Fen-Phen) (Sept. 15, 1997), http://www.fda.gov/cder/news/phen/fenphenpr81597.htm; Gina Kolata & Edmund L. Andrews, *Anticholesterol Drug Pulled After Link With 31 Deaths*, N.Y. TIMES, Aug. 9, 2001, at A12 (Baycol).

saving medicines sought by terminally ill patients who have no alternative treatment options.

By redirecting its inquiry, the court conveniently avoids the sparse history of drug regulation for efficacy. *See Abigail Alliance I*, 445 F.3d at 481-83. Prior to 1906, there was essentially no drug regulation in the United States save protections against fraud and adulteration.[6] In 1906, Congress enacted the Pure Food and Drug Act ("1906 Act"), ch. 3915, 34 Stat. 768 (repealed 1938), which prohibited misbranded and

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[6] *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); Lois K. Perrin, 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*, 545 U.S. 1, 11-13 (2005). 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) (hereinafter "Janssen, *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 Nation's early history there were no restrictions on a patient's access to potentially life-saving medications, 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*, *supra*, at 426-28. *But cf*. Op. at 16-18.

adulterated foods or drugs from entering interstate commerce, *id*. § 2, 34 Stat. at 768, and prohibited false and misleading labeling, *id*. § 8, 34 Stat. at 770. 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*. § 4, 34 Stat. at 769. 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 by the Harrison Narcotic Act of 1914, ch. 1, 38 Stat. 785.[7]

In 1938, Congress enacted the Federal Food, Drug, and Cosmetic Act ("1938 Act" or "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-MASSENGILL, S. DOC. NO. 75-124, at 1-3 (1937) ("1937 REPORT").[8] For the first time, Congress required that drug manufacturers test, and the FDA

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[7] *See* 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); 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); *cf. Minnesota ex rel. Whipple v. Martinson*, 256 U.S. 41, 45 (1921).

[8] *See* Salbu, *supra* note 7, at 407.

review, all new drugs for safety prior to their commercial distribution. Ch. 653, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 301 *et seq.*); 1937 REPORT, *supra*, at 1-3. Under the 1938 Act, a new drug could be commercially 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.[9] 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.[10] 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 that can be used while under a doctor's supervision. *See* Act of Oct. 26, 1951, ch. 578, 65 Stat. 648 (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 evidence of the drug's safety.[11] The Kefauver-Harris Amendments, Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified in scattered sections of 21 U.S.C. §§ 301-81), were enacted in response to the rash of birth defects discovered in babies whose mothers had taken Thalidomide to ease morning sickness caused

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[9] *See* Zelenay, *supra* note 7, at 264-65.

[10] *Id*.

[11] *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, 295, 300 & n.23 (1999–2000).

by pregnancy.[12] 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 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.[13] 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."[14] Thus, a doctor may — and approximately 21% of the time does — prescribe a drug to a patient for a purpose other than that for

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[12] *See* Salbu, *supra* note 7, at 408 n.41. *See generally* HARVEY TEFF & COLIN R. MUNRO, THALIDOMIDE: THE LEGAL AFTERMATH 1-10 (1976); Janssen, *Outline of the History*, *supra* note 6, at 438.

[13] *See* Walsh & Pyrich, *supra* note 6, at 901; *see also* Zelenay, *supra* note 7, at 266.

[14] Steven R. Salbu, *Off-Label Use, Prescription, and Marketing of FDA-Approved Drugs: An Assessment of Legislative and Regulatory Policy*, 51 FLA. L. REV. 181, 189-92 (1999); *see Chaney v. Heckler*, 718 F.2d 1174, 1180 (D.C. Cir. 1983), *rev'd on other grounds*, 470 U.S. 821 (1985).

which the FDA has approved the use of the drug.[15] Such "off-label" use may occur even if the drug is not deemed safe or effective for that use, such as when a drug studied only for adults is prescribed for a child. Further, it appears that the FDA has never prohibited either off-label prescription or off-label use of drugs.[16] 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.[17] *See* Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (codified in scattered sections of 21 U.S.C. §§ 301-81).

For more than half of this 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' efficacy. Rather, at that time, the FDA could interrupt the sale of new drugs only if it determined that the new drug was unsafe. Government regulation of such drugs premised on concern over a new drug's efficacy, as opposed to its safety, is of very recent origin. Even today, a patient may use a drug for unapproved purposes where the drug may be unsafe or ineffective for the off-label purpose. In short, encumbrances on the treatment decisions of a patient and her physician lack the historical pedigree of the rights that the Alliance seeks to vindicate.

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[15] *See* David C. Radley et al., *Off-Label Prescribing Among Office-Based Physicians*, 166 ARCHIVES INTERNAL MED. 1021 (2006) (studying 2001 data of office-based physicians).

[16] *See* Salbu, *supra* note 14, at 189-92.

[17] *See id.* at 211.

Instead of confronting this history, the court relies on statutory restrictions that address misbranded or adulterated drugs, sales of poisons, and fraudulent curative claims, *see* Op. at 17-18 & n.8, government restrictions that are not inconsistent with the right of a person to attempt to save her own life. None of the cited restrictions, focusing largely on the licensing of pharmacists, suggest a physician could not prescribe a new medication for a terminal patient. While Congress has imposed increased responsibilities on the drug industry and the FDA upon evidence of tragic consequences of some new drugs as a result of new technology, *see Abigail Alliance I*, 445 F.3d at 482, the FDA does not regulate physicians, *id*. at 483, and off-label prescription of medications is a long-standing practice that has not been outlawed, *id*. Elsewhere the court relies on straw men that are either acknowledged by the court to be irrelevant, Op. at 17 n.8 (an incident in 1630 not the result of "legislative or regulatory intervention"); or are in fact irrelevant, *id*. at 30 n.18 (discussing "affirmative access claim[s]" even though the Alliance makes no such claim); or are speculative, *id*. at 21 n.12 (noting "a more plausible explanation for the limited efficacy regulation"); *see also* Amicus Br. for Economists John E. Calfee et al. This analysis hardly overcomes the history and Constitutional recognition of the underlying right to life that the Alliance claims.

The common law traditions protecting necessity, forbidding interference with rescue, and supporting self-defense, and the Supreme Court's validation of the fundamental right of a pregnant woman to undergo a medical procedure to save her own life demonstrate that the protected liberty interest of the terminally ill to choose whether to pursue prescription medications that may save their lives is deeply rooted in this Nation's history. Nothing in the history of drug regulation demonstrates otherwise. In view of the common law history, there is no occasion to determine how the first *Glucksberg*

inquiry would be evaluated were there no evidence supporting or refuting a historical basis for a claimed fundamental right.

II.

For a right to be fundamental, the *Glucksberg* analysis requires that it also be "'implicit in the concept of ordered liberty,' such that 'neither liberty nor justice would exist if they were sacrificed,'" *Glucksberg*, 521 U.S. at 721 (quoting *Palko*, 302 U.S. at 325, 326). The Supreme Court has explained that this expression "encompasses and protects the personal intimacies of the home, the family, marriage, motherhood, procreation, and child rearing." *Paris Adult Theatre I v. Slaton*, 413 U.S. 49, 65 (1973). It also safeguards the "freedom of thought and speech," *Palko*, 302 U.S. at 326, and "[t]he security of one's privacy against arbitrary intrusion by the police," *Wolf v. Colorado*, 338 U.S. 25, 27-28 (1949), *overruled on other grounds by Mapp v. Ohio*, 367 U.S. 643 (1961). In the context of criminal trials, matters "implicit in the concept of ordered liberty" include "the right to counsel at trial," *Teague v. Lane*, 489 U.S. 288, 311 (1989) (plurality opinion) (quoting *Mackey v. United States*, 401 U.S. 667, 693-94 (1971) (opinion of Harlan, J.)); the presumption that "all are innocent until the state has proved them to be guilty," *United States v. Salerno*, 481 U.S. 739, 763 (1987); and "[t]he principle that a State may not knowingly use false evidence, including false testimony, to obtain a tainted conviction," *Napue v. Illinois*, 360 U.S. 264, 269 (1959).

Unlike *Glucksberg*'s historical inquiry, this step assesses whether the Alliance's claimed right is a component of the "compendious expression for all those rights which the courts must enforce because they are basic to our free society." *Wolf*, 338 U.S. at 27. As Justice Frankfurter wrote, these rights create "a realm of sanctuary surrounding every individual and

infrangible, save in a very limited class of circumstances, by the agents of government." *Monroe v. Pape*, 365 U.S. 167, 208-09 (1961) (Frankfurter, J., dissenting), *maj. op. overruled by Monell v. Dep't of Soc. Servs.*, 436 U.S. 658 (1978).

Setting aside the textual anchor of the Alliance's claim in the right to life, the claimed right also falls squarely within the realm of rights implicit in ordered liberty. The core of liberty is autonomy. As Professor Charles Fried writes, "[l]iberty is the exercise of our powers as self-conscious, judging individuals, individuals who in making our own lives cannot be responsible to anyone . . . else except as we choose to be." CHARLES FRIED, MODERN LIBERTY 180 (2007). It is difficult to imagine any context in which this liberty interest would be stronger than in trying to save one's own life. *Cf.* BRIAN CLARK, WHOSE LIFE IS IT ANYWAY? (1978).

The Supreme Court engaged in similar analysis in *Cruzan*. In evaluating the claim that due process protects a person's right to refuse life-sustaining treatment, the Court reasoned that "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." 497 U.S. at 281. The Court acknowledged that "[t]he principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment," could be inferred from its prior decisions. *Id.* at 278. 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, the Alliance seeks only to have the government step aside so as not to interfere with the individual right of self-determination. 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 been determined to be safe for substantial human testing. This reasoning tracks *Eisenstadt*

v. Baird, 405 U.S. 438 (1972), where the Supreme Court noted that the right to be free from unwanted government intrusion into the fundamental decision whether to have children establishes a right of access to contraceptives, *id*. at 453.

In summary, there is no logic to be found, in view of oft-limited rights considered inherent in the nature of ordered liberty, *see Abigail Alliance II*, 469 F.3d at 136-37, in the conclusion that the right to save one's life is unprotected notwithstanding the specific protection afforded life in the Fifth Amendment to the Constitution.

III.

For these reasons, I have serious disagreements with the court's assessment of the Alliance's claim to a fundamental right protected by the Fifth Amendment to the Constitution. It is no more than tragic wordplay to suggest that the Alliance's liberty claim to potentially life prolonging medications, when no other government approved alternatives exist, does not involve a corollary to the right to life enshrined in the Fifth Amendment to the Constitution. *See* Op. at 11 n.5. Denying a terminally ill patient her only chance to survive without even a strict showing of governmental necessity presupposes a dangerous brand of paternalism. As the court phrases it, because "*[w]e* . . . cannot know until the clinical testing process has been completed that these drugs are necessary," Op. at 25 n.15 (emphasis added), the terminally ill patient, informed by her physician, is denied a right to decide whether to bear those risks in an attempt to preserve her life. Such intervention is directly at odds with this Nation's history and traditions giving recognition to individual self-determination and autonomy where one's own life is at stake and should extend no further than the result in this case. Because the right of a terminally ill patient to access potentially life-saving investigational medications satisfies the *Glucksberg*

test, I would remand this case for the district court to assess in the first instance whether there exists a compelling governmental interest, narrowly tailored, to overcome the Alliance's interest. *Flores*, 507 U.S. at 302. Accordingly, I respectfully dissent.