

UNENUMERATED RIGHTS AND
THE LIMITS OF ANALOGY: A CRITIQUE
OF THE RIGHT TO MEDICAL SELF-DEFENSE

O. Carter Snead*

Responding to Eugene Volokh, *Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 HARV. L. REV. 1813 (2007).

Professor Volokh has produced a characteristically thoughtful, provocative, and well-argued case for a constitutional right to “medical self-defense” that would presumptively allow terminally ill patients access to unapproved drugs¹ and to purchase organs for transplant from willing sellers — activities that are presently illegal. His project is animated by one of the highest human aspirations, namely, to alleviate the suffering caused by dreaded diseases. He seeks to ground the unenumerated right to medical self-defense in the common law justification of self-defense (traditionally understood), which, he argues, has been extended to the medical context by virtue of the jurisprudence of abortion.

Professor Volokh’s project stands or falls with the claim that the entitlement he proposes is of constitutional dimension. If there is no fundamental right to medical self-defense, the individual must, for better or worse, yield to the regulation of this domain in the name of the values agreed to by the political branches of government. Indeed, the government routinely restricts the instrumentalities of self-help (including self-defense) in the name of avoiding what it takes to be more significant harms. This same rationale accounts for current governmental limitations on access to unapproved drugs and the current ban on organ sales. The FDA restricts access to unapproved drugs (subject to certain exceptions) in the interest of public health, that is, to prevent patient exposure to unsafe or ineffective drugs and to maintain a func-

* Associate Professor, Notre Dame Law School and former General Counsel for the President’s Council on Bioethics. Many thanks to John Finnis, Rick Garnett, Nicole Garnett, Bill Kelley, Gerry Bradley, John Robinson, Yuval Levin, Rob Mikos, and Leigh Fitzpatrick Snead.

¹ In his Essay, Professor Volokh argues that terminally ill patients should have access to drugs that have passed Phase I of the FDA approval process (i.e., testing for minimal safety (but not efficacy) sufficient to proceed to the subsequent phases clinical trial process, which involve larger samples of human subjects). Eugene Volokh, *Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 HARV. L. REV. 1813 (2007). However, Volokh argues that the right to medical self defense would, in principle, also entail access to drugs that have not been tested for safety. *Id.* at 1830 n.79.

tional clinical trial system (the chief mechanism of bringing safe and effective drugs to the market).² Congress banned the sale of organs to avoid what it took to be a number of practical and ethical harms, including coercion of the poor and commodification of the body and its parts.³ The only way for the individual to avoid the political process and substitute his own normative balancing of these goods and harms for that of the government, is to do so pursuant to a fundamental constitutional right. Thus, for Professor Volokh's project to succeed, he must demonstrate that the right he proposes is "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."⁴

This Article examines Professor Volokh's case for a fundamental right to medical self-defense, and concludes that none of his suggested common law grounds are adequate to justify it. Self-defense is not a fitting analogy to, and thus does not provide support for, this entitlement. The doctrine of necessity (or choice of evils) is a more promising common law analogy, but it is also an unsound foundation. Lacking any roots in the nation's history and tradition, the entitlement to medical self-help cannot, therefore, rise to the level of a fundamental constitutional right.⁵

I. MEDICAL SELF-DEFENSE GROUNDED IN ABORTION JURISPRUDENCE?

Professor Volokh's argument is elegant and straightforward. He begins by affirming the arguments made by some commentators that there is a substantive due process right to lethal self-defense grounded in longstanding tradition (dating back to the founding era), enshrined in forty-four state constitutions, and perhaps implied by the Second Amendment.⁶ He turns next to the jurisprudence of abortion in an effort to extend this right to the medical domain. He characterizes *Roe v. Wade*⁷ and *Planned Parenthood v. Casey*⁸ as establishing two rights

² See, e.g., Mary Ann Liebert, *FDA Proposes New Rules for Access to Experimental Drugs*, 26 BIOTECHNOLOGY L. REP. 16, 16 (2007).

³ See S. REP. NO. 98-382, at 2 (1984). For a philosophical case against commodification of the body and its parts, see Gilbert Meilaender, *Organ Procurement: What are the Questions?* (June 2006), http://www.bioethics.gov/background/meilaender_organ.html.

⁴ *Abigail Alliance v. Eschenbach*, 495 F.3d 695, 702 (D.C. Cir. 2007) (apparently quoting without citation to *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997)); see *id.* (adding that such rights must be delineated with a high degree of specificity); see also Volokh, *supra* note 1, at 1818-19 (quoting *Glucksberg*, 521 U.S. at 720-21 (1997)).

⁵ It is therefore unnecessary to explore whether such an entitlement is "implicit in the concept of ordered liberty." *Palko v. Connecticut*, 302 U.S. 319, 325 (1937).

⁶ See Volokh, *supra* note 1, at 1820-21.

⁷ 410 U.S. 113 (1973).

to abortion. The first is rooted in reproductive liberty that “generally allows previability abortions for all women who choose them.”⁹ The second right, Professor Volokh argues, is grounded in medical self-defense which permits abortions at all gestational stages (i.e., pre- and post-viability) in order “to preserve the life or health of the mother.”¹⁰ He concludes that if a woman’s interests in preserving her own life outweigh the state’s interest in a viable fetus’s life, then surely the same right to self-defense would permit a dying patient access to less grave self-help measures, including the purchase of unapproved drugs or organs for transplantation.¹¹ In Professor Volokh’s words, “[n]othing about therapeutic postviability abortion makes it deserve protection more than any other medical self-defense procedure.”¹²

Despite the facial appeal of the argument, the invocation of abortion precedents is not a promising point of departure to establish a more general right to medical self-defense. To begin, Professor Volokh’s hope that his theory will gain wide political purchase is undermined by grounding it in perhaps the most controversial line of decisions in modern constitutional history. In fairness, Professor Volokh’s arguments focus on the least contentious aspect of this jurisprudence (namely, the “life exception” which, as he notes, enjoys wide political support), but this is probably not sufficient to avoid the polarizing effects that the larger subject of abortion provokes.

Mining the law of abortion for a generalizable right to medical self-defense is problematic for several deeper reasons. First, it is not clear that the right to post-viability abortion “share[s] the same moral core”¹³ as the right to lethal self-defense, such that the former is a fitting analytic foundation for a broader right to medical self-defense. The right to post-viability abortion is not rooted in self-defense principles. It is true that *Casey* held that states may regulate or even proscribe abortion after viability, provided that any such restriction include an exception for the life or health of the mother. But *Casey* left undisturbed the capacious definition of “health” articulated in *Doe v. Bolton*¹⁴ that includes a wide array of interests related to a woman’s well-being, including “physical, emotional, psychological, [and] familial” factors.¹⁵ This definition (and the rule it animates) strongly privileges a woman’s well-being, broadly understood, over the interest the state has in viable fetal human life. This is confirmed by the fact that

⁸ 505 U.S. 833 (1992).

⁹ Volokh, *supra* note 1, at 1824.

¹⁰ *Id.* (quoting *Wade*, 410 U.S. at 163–64; *Casey*, 505 U.S. at 846).

¹¹ *Id.* at 1826.

¹² *Id.*

¹³ *Id.* at 1825–26.

¹⁴ 410 U.S. 179 (1973).

¹⁵ *Id.* at 192.

several federal courts have invalidated bans on post-viability abortions because they lacked exceptions for “serious non-temporary threat[s] to [a] pregnant woman’s mental health.”¹⁶

Whatever principle is at work here, it does not resemble the right to lethal self-defense, traditionally understood. As Professor Volokh acknowledges,¹⁷ that right justifies the use of deadly force when it seems (to a reasonable person) necessary and proportionate to avert death or serious bodily injury. Threats to mental health (much less to familial interests) are never sufficient to justify lethal self-defense. But such interests are adequate to justify the termination of a viable fetus, which, in Professor Volokh’s opinion “is in many ways indistinguishable from a born baby.”¹⁸ Thus, the right to post-viability abortions seems to be an unfit foundation for a circumscribed right to medical self-defense applicable “only in the face of deadly or at least radically debilitating threats.”¹⁹

Professor Volokh suggests in a footnote that the aspect of abortion jurisprudence driving his analysis is the widely accepted right to terminate a viable fetus when necessary to defend one’s life.²⁰ But as is evident from above, that exception is imbedded in a much more sweeping right; it is one narrow application of an expansive license to abort post-viable fetuses in the name of a woman’s health (broadly construed). In other words, the “life exception” is not the defining feature of the right to postviability abortion.

Second, the Court’s most recent decision, *Gonzales v. Carhart*²¹ (announced after Professor Volokh’s Essay went to press), appears to recalibrate the closely related “health exception” in a way that seems to undermine Professor Volokh’s thesis. In *Carhart*, the Court signaled its willingness to defer to legislative judgment about the medical necessity of certain interventions in the face of objections by individuals (supported by substantial but contested medical authority) that the policy adopted might be harmful to human health. This is an inversion of the priority of judgment (as between government and citizen) that the principle of medical self-defense envisions.

Carhart seems to represent a departure from the virtually absolute privilege of a woman’s health over the state’s interest in promoting respect for fetal human life. The Court entertained a facial challenge to a federal law banning the

¹⁶ *Women’s Med. Prof’l Corp. v. Voinovich*, 130 F.3d 187, 209 (6th Cir. 1997).

¹⁷ See Volokh, *supra* note 1, at 1821.

¹⁸ *Id.* at 1827.

¹⁹ *Id.* at 1821.

²⁰ See *id.* at 1824 n.56.

²¹ 127 S. Ct. 1610, 1639 (2007).

deliberate[] and intentional[] vaginal[] deliver[y] [of] a living fetus until, in the case of a head-first presentation, the entire fetal head is outside the body of the mother, or, in the case of breech presentation, any part of the fetal trunk past the navel is outside the body of the mother, for the purpose of performing an overt act that the person knows will kill the partially delivered living fetus.²²

The Court affirmed the constitutionality of the ban despite the fact that it lacked a “health exception.”²³ Medical experts disagreed whether a situation ever might arise in which the prohibited procedure would be necessary to preserve a woman’s health²⁴ — no evidence of actual cases of necessity was presented to any of the trial courts below. Opponents of the law argued that there were imaginable circumstances in which the procedure would be the safest method of abortion; defenders retorted that there were always safe alternatives available (including the *in utero* killing of the fetus followed by intact dilation and extraction). Contrary to its decision in *Stenberg v. Carhart*,²⁵ the Court held that “[m]edical uncertainty does not foreclose the exercise of legislative power in the abortion context any more than it does in other contexts.”²⁶ Thus, it affirmed the facial validity of the law in a five-to-four decision (the same margin as *Stenberg*, decided seven years earlier).

Carhart is particularly noteworthy in that the government interest cited for the abortion restriction was *not* the direct preservation of fetal human life.²⁷ Rather, the law aimed to promote respect for human life, to prevent the coarsening and numbing of society’s moral sense, and to safeguard the integrity of the medical profession by banning what Congress judged to be a particularly shocking and brutal procedure bearing a striking resemblance to infanticide.²⁸ In other words, the purpose of the law was actually to prevent the moral degradation

²² *Id.* at 1624.

²³ *Id.* at 1639. This holding is in deep tension with the 2000 decision *Stenberg v. Carhart*, 530 U.S. 914 (2000), which struck down a very similar array of state statutes because, among other defects, they lacked an exception for a woman’s health.

²⁴ Note that the contours of the “health exception” have been subtly altered since their announcement in *Doe v. Bolton*. Originally, the triggering event for the health exception was a determination by the abortion provider that an abortion is necessary to promote a particular woman’s well-being under the circumstances. In *Stenberg v. Carhart*, the health exception was triggered “if substantial medical authority supports the proposition that banning a particular procedure could endanger women’s health.” 530 U.S. at 938. Thus, the health exception is implicated in purely elective abortions when the safest option is taken off the table by a particular governmental restriction.

²⁵ 530 U.S. 914 (2000).

²⁶ *Id.* at 1637.

²⁷ Indeed, the Court’s decision seemed premised in part on the proposition that there were safe alternative means of abortion for the same class of women who might prefer the prohibited procedure.

²⁸ *Carhart*, 127 S. Ct at 1633–35.

of society. The Court thus held that the governmental interest in preventing this moral harm outweighed the individual's belief that a particular abortion procedure might be necessary for her health.²⁹

The Court's balancing of interests in *Carhart* does not bode well for the proposed right to medical self-defense. It suggests that while the choice for abortion is vested squarely with the woman, the means of abortion is subject to governmental oversight, and can be limited (within reason) in the name of moral considerations, even over the objection that the preferred prohibited procedure might be the safest option.³⁰ This seems in tension with the spirit of the entitlement espoused in Professor Volokh's Essay.³¹

II. IS SELF DEFENSE THE RIGHT ANALOGY?

Abortion jurisprudence is not a sound foundation for the right to medical self-defense. There may, however, be an even more fundamental problem with the project as presently conceived by Professor Volokh. The New Jersey Supreme Court wrote in a landmark medical ethics case that "analogy is the vessel that carries meaning from old to new in the law."³² Granting for the sake of argument that there is a fundamental unenumerated right to lethal self-defense, it seems that this is materially different from the *kind* of entitlement Professor Volokh argues for in the medical domain. For the reasons set forth below, the traditional justification for use of force in self-protection is dis-analogous to a right of access to illegal instrumentalities of self-help in the name of combating a terminal illness. Moreover, even if one were to reconceptualize medical intervention as a species of justified force against an aggressor, there may be reasons not to do so.

²⁹ One might argue that it is ironic that Justice Kennedy would find such moral considerations sufficient to support the ban on partial birth abortions, given that in *Lawrence v. Texas*, 539 U.S. 558 (2003), he wrote that "the fact that the governing majority in a State has traditionally viewed a particular practice as immoral is not a sufficient reason for upholding a law prohibiting the practice." *Id.* at 577 (quoting *Bowers v. Hardwick*, 487 U.S. 186, 216 (1988) (Stevens, J., dissenting)).

³⁰ The Court has affirmed additional governmental limitations on the manner in which abortions are performed. *See, e.g.*, *Simopoulos v. Virginia*, 462 U.S. 506 (1983) (upholding a state law requiring that second trimester abortions be performed in a licensed hospital).

³¹ It must be noted that because *Carhart* was a facial challenge to a restrictive abortion law, the disagreement over medical necessity was abstract and speculative. The Court left open the possibility that in an as-applied challenge (involving an actual case of concrete health risks) government interests and a woman's health might be balanced differently. *See Carhart*, 127 S. Ct at 1638–39.

³² *In re Grady*, 426 A. 467, 473 (N.J. 1981) (setting forth the framework for analyzing requests for sterilization of individuals incapable of consent).

A. *The Use of Reasonable Force to Repel an Aggressor?*

Traditional self-defense is conceived of as a “use of force justifiable for protection of the person.”³³ According to the Model Penal Code, “the use of force upon or toward another person is justifiable when the actor believes that such force is immediately necessary for the purpose of protecting himself against the use of unlawful force by such other person on the present occasion.”³⁴ This account does not seem to fit the scenario in which a terminally ill patient is seeking access to unapproved drugs or to purchase organs for transplantation. Fundamentally, self-defense is conceived as a justification for the *use of force* to repel the application of *force* by another. What “use of force upon or toward another person” is in play here? What “unlawful force” is being brought to bear on the patient such that he has the right to meet it with proportional force? Professor Volokh rules out the possibility that the right he proposes would justify using force to obtain either unapproved drugs or organs for transplantation from people who are not the source of the threat to the patient.³⁵ He does not appear to be referring to the use of force against the federal agents who might try to intervene to prevent the distribution of unapproved drugs or the sale of organs. In fact, the Model Penal Code takes the position that use of force is not justified “to resist an arrest that the actor knows is being made by a peace officer, although the arrest is unlawful.”³⁶ The entitlement at the heart of Professor Volokh’s project seems to be grounded in a different principle. Of this, more later.

The principle of self-defense is squarely concerned with justifying the use of force that would otherwise be unlawful. The proposed right to medical self-defense does not involve the use of force against an aggressor, but rather the freedom to acquire certain instrumentalities of therapeutic self-help. It would thus seem that self-defense is not a fruitful analogy.

B. *The Perils of Metaphor: The “War” on Disease and Death*

The analogy could be restored, however, by re-characterizing the relevant threat to the patient seeking to invoke the right to medical self-defense. That is, the disease itself might be understood to be a kind of aggressor. President Nixon illustrated this concept in 1971 when he declared “war on cancer” as he signed The National Cancer

³³ MODEL PENAL CODE § 3.04(1) (1985).

³⁴ *Id.*

³⁵ Volokh, *supra* note 1, at 1821.

³⁶ MODEL PENAL CODE § 3.04(2)(a)(i) (1985).

Act.³⁷ Politicians make such rhetorical moves all the time, but it seems that one should be particularly cautious about invoking such a metaphor in the medical context.

While the invocation of “war on disease” might be a colorful way to express how seriously we regard our obligations to alleviate human suffering and combat disease, it is conceptually and morally problematic. “War” is a state of emergency in which the usual moral norms and even laws are often altered to meet threatening exigencies. It is the realm of exceptions, not rules. As Hans Jonas has written:

[I]n time of war our society itself supersedes the nice balance of the social contract with an almost absolute precedence of public necessities over individual rights. In this and similar emergencies, the sacrosanctity of the individual is abrogated, and what for all practical purposes amounts to a near-totalitarian, quasi-Communist state of affairs is *temporarily* permitted to prevail. In such situations, the community is conceded the right to make calls on its members, or certain of its members, entirely different in magnitude and kind from the calls normally allowed. It is deemed right that a part of the population bears a disproportionate burden of risk of a disproportionate gravity; and it is deemed right that the rest of the community accepts this sacrifice, whether voluntary or enforced, and reaps its benefits — difficult as we find it to justify this acceptance and this benefit by any normal ethical categories. We justify it transethically, as it were, by the supreme collective emergency, formalized, for example, by the declaration of a state of war.³⁸

The conception of disease as a lethal aggressor to be vanquished by means of force opens the door to what one commentator has described “the provisional morality of crisis” in which “all stops are pulled, and all tactics are permitted.”³⁹ Disease, however, is a foe that will never be defeated. We are thus left in a state of perpetual emergency; permanently in the sphere of exceptions rather than rules. Taken to an extreme, this attitude might be corrosive of ethical safeguards crucial to the respect for persons in the realm of biomedical research — most obviously, the protections for human subjects. This temptation is reflected in the words of Dr. Francis Moore, past Chair of the Department of Surgery at Harvard Medical School: “By . . . protecting the individual patient, [the researcher] is exposing society to the hazard of a static rather than dynamic medicine.”⁴⁰

³⁷ See National Cancer Institute, Milestone (1971), http://dtp.nci.nih.gov/timeline/noflash/milestones/M4_Nixon.htm

³⁸ Hans Jonas, *Philosophical Reflections on Experimenting with Human Subjects*, in EXPERIMENTATION WITH HUMAN SUBJECTS 1, 6–7 (Paul A. Freund ed., 1970).

³⁹ Yuval Levin, *The Crisis of Everyday Life*, THE NEW ATLANTIS, Fall/Winter 2005, at 119–21.

⁴⁰ Francis D. Moore, *Therapeutic Innovation: Ethical Boundaries in the Initial Clinical Trials of New Drugs and Surgical Procedures*, in EXPERIMENTATION WITH HUMAN SUBJECTS, *supra* note 38, at 358, 365 (Paul A. Freund ed., 1970).

This is obviously not to say that medical therapies should not be pursued with the utmost vigor and focus. Undoubtedly they should. It is only to note that re-conceptualizing disease as an aggressor seeking to kill innocents carries with it certain perils that may counsel rhetorical restraint.

C. A Fitting Analogy: The Justification of Necessity

The entitlement Professor Volokh proposes does not fit comfortably within the traditional common law doctrine of self-defense for the reasons stated above. But another common law doctrine, namely the justification of necessity (also referred to as “choice of evils”), seems to be quite a close analogue to the proposed right to medical self-defense.⁴¹ According to the Model Penal Code:

Conduct [contrary to law] that the actor believes to be necessary to avoid a harm or evil to himself or to another is justifiable, provided that: (a) the harm or evil sought to be avoided by such conduct is greater than that sought to be prevented by the law defining the offense charged; and (b) neither the Code nor other law defining the offense provides exceptions or defenses dealing with the specific situation involved; and (c) a legislative purpose to exclude the justification claimed does not otherwise plainly appear.⁴²

This framework seems to capture the spirit of the claim that patients facing death should be empowered balance this evil with that of otherwise unlawful conduct (such as the use of unapproved drugs or the purchase of organs). Indeed, the Comment section of MPC section 3.02 illustrates the contours of the necessity defense with several examples drawn from the medical context. For example, the Comment notes that “a druggist may dispense a drug without the requisite prescription to alleviate grave distress in an emergency,”⁴³ and “a ship’s captain may enter a forbidden port if medical treatment on shore is necessary to save a crewman’s life.”⁴⁴ Indeed, the case of therapeutic abortion is used to illustrate the principle of necessity in a regime that otherwise forbids “unlawful termination of a pregnancy.”⁴⁵

Is the common law defense of necessity sufficient to anchor a constitutional right to medical self-help? It would seem not, for several

⁴¹ Volokh asserts that “not much logically turns on” the choice to style his proposal as an instance of self-defense rather than an instance of necessity. Volokh, *supra* note 1, at 1815 n.6. The discussion set forth in this section illustrates that the two justifications are quite distinct both in their contours as well as their limiting principles.

⁴² MODEL PENAL CODE § 3.02(1) (1985).

⁴³ *Id.* cmt. 1 at 10.

⁴⁴ *Id.* at 12.

⁴⁵ *Id.* at 13.

reasons. Necessity is highly controversial and disfavored, particularly when applied to a regime that is governed by statute⁴⁶ (e.g., the Food Drug and Cosmetic Act (FDCA), or the National Organ Transplant Act). But even necessity's own internal limiting principles seem to rule out a right to medical self-help, at least as applied to the instrumentalities of unapproved drugs and organs for sale.

First, the individual must believe in good faith that the unlawful act will remedy the greater evil. "It is not enough that the actor believes that his behavior *possibly may be conducive to ameliorating* certain evils; he must believe it is "*necessary*" to avoid the evils."⁴⁷ This seems not to be the case where a patient seeks access to drugs that have passed only Phase I of the FDA approval process (i.e., clinical testing on a small sample of human subjects to demonstrate minimal safety (not efficacy) sufficient to proceed to the later stages of the approval process). Such drugs have not yet been proven effective.⁴⁸ In the face of such uncertainty, it would be difficult to claim that access to such drugs was believed in good faith to be "necessary" to preserve one's life. It seems more accurate to say that in cases like this, terminally ill patients strongly hope (with some evidence derived from animal models) that the experimental unapproved therapy will yield some benefit. But this does not seem sufficient for the exacting criteria of certainty prescribed by the doctrine of necessity.

Second, and most fatal to a right to medical self-help grounded in necessity, is the limiting principle that the justification may not be invoked in cases where the legislature has already spoken to the "determination of values" that the individual is seeking to balance for himself.⁴⁹ Because the necessity defense essentially allows people to act "as individual legislatures, amending a particular criminal provision, or crafting a one-time exception to it, subject to court review, when a real legislature would formally do the same under those circumstances,"⁵⁰ it is unavailable when the real legislature has already spoken to the proper disposition of the choice of evils in question. Thus, an appeal to necessity would not be an available defense where termi-

⁴⁶ See e.g., *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 490 (2001) ("[U]nder our constitutional system, in which federal crimes are defined by statute rather than by common law . . . [necessity] is especially [controversial].").

⁴⁷ MODEL PENAL CODE § 3.02 cmt. 2, at 12 (1985) (emphasis added).

⁴⁸ A recent study has shown that less than thirty-three percent of cancer drugs that pass Phase I of the approval process advance to Phase III. See Peter D. Jacobson & Wendy E. Parmet, *A New Era of Unapproved Drugs: The Case of Abigail Alliance v. von Eschenbach*, 297 JAMA 205, 206 (2007) (noting that only five percent of cancer drugs that begin the clinical trial process are finally approved for patient use).

⁴⁹ See *Oakland Cannabis*, 532 U.S. at 491 (citation omitted).

⁵⁰ *Raich v. Gonzales*, 2007 WL 754759, at *10 (9th Cir. Mar. 14, 2007) (quoting *U.S. v. Schoon*, 971 F.2d 193, 196-97 (9th Cir. 1991)).

nally ill patients seek access to unapproved drugs given the ample evidence that the FDCA has already balanced the competing values at stake. According to FDA Commissioner Andrew von Eschenbach, the approval framework set forth under that statute is meant “to enable many more patients who lack satisfactory alternatives to have access to unapproved medicines, while balancing the need for safeguarding the individual patient . . . [and] to ensure the continued integrity of the scientific process that brings safe and effective drugs to the market.”⁵¹ Thus, for better or worse, this seems to be a domain in which the legislature has already made the relevant “determination of values” at stake. The same could be said for the laws governing organ procurement; the Senate Report accompanying the National Organ Transplant Act reflects a balancing of the costs and benefits of permitting the sale of organs.⁵²

Given these limitations on the necessity defense it is not surprising that there is no history or tradition of courts privileging the preferences of patients (including those suffering from terminal illnesses) for a particular prohibited medical intervention over governmental concerns about public health. To the contrary, the record reflects a consistent deference to governmental judgment about such matters. In *Rutherford v. United States*,⁵³ the Tenth Circuit noted that “the decision by the patient whether to have a treatment or not is a protected right, but his selection of a particular treatment, or at least a medication [in this case an unapproved cancer drug], is within the area of governmental interest in protecting public health.”⁵⁴ In *Oakland Cannabis*, the Supreme Court rejected the invocation of necessity to avoid the strictures of the Controlled Substances Act in an effort to secure access to medical marijuana.⁵⁵ Similarly, in the recently decided *Raich v. Gonzales*,⁵⁶ the Ninth Circuit rejected a claim of necessity as well as a substantive due process “right to make a life-shaping decision on a physician’s advice to use medical marijuana to preserve bodily integrity, avoid intolerable pain, and preserve life, when all other prescribed medications and remedies have failed.”⁵⁷ Most recently, in the case

⁵¹ Liebert, *supra* note 2, at 16. Indeed, the FDA provides a regime of access to experimental drugs through the clinical trial system and other expanded access programs. See, e.g., Meghan K. Talbott, *The Implications of Expanding Access to Unapproved Drugs*, 35 J.L. MED. & ETHICS 316 (2007) (describing the present regulatory framework). This regime would seem to constitute a statutory “exception,” the existence of which would rule out a necessity defense.

⁵² See S. REP. NO. 98-382 (1984) (weighing the expanded access to organs that a market would bring against the possible abuses of commodification of body parts).

⁵³ 616 F.2d 455 (1980).

⁵⁴ *Id.* at 457.

⁵⁵ 532 U.S. at 491.

⁵⁶ 2007 WL 754759 (9th Cir. Mar. 14, 2007).

⁵⁷ *Id.* at *14.

that perhaps inspired Professor Volokh's Essay, *Abigail Alliance v. von Eschenbach*,⁵⁸ the D.C. Circuit sitting en banc held that the common law defense of necessity did not support a substantive due process right of terminally ill patients to have access to drugs that merely passed Phase I trials.⁵⁹

III. CONCLUSION

Professor Volokh makes compelling arguments against the present FDA drug approval framework and the current ban on organ sales.⁶⁰ He marshals impressive evidence that they are ineffective in meeting the needs of terminally ill patients. He proposes less restrictive approaches that would arguably serve such patients better. But he fails to establish that his policy judgment should override the considered judgment of the democratic branches of the federal government by virtue of an unenumerated right to medical self-help. Such a right cannot be grounded in abortion jurisprudence, or the common law justifications of self defense or necessity. Lacking any objective foundation in the Nation's history and tradition, the entitlement to medical self-help does not rise to the level of fundamental constitutional right. Thus, as with other contested matters in a morally pluralistic society, this issue must be resolved in the public square through the democratic process.

⁵⁸ 495 F.3d 695 (D.C. Cir. 2007) (en banc).

⁵⁹ *Id.* at 702. The court likewise rejected the arguments that such a fundamental right could be inferred from the common law doctrine of self-defense or the tort of interference with rescue.

⁶⁰ Though I would respectfully suggest that he does not grapple fully with the philosophical case against the sale of organs made by Leon Kass, which is not simply an appeal to visceral revulsion, but rather is animated by a particular view of the importance of embodiment and the ethical perils of regarding the human person either as simply an aggregate of parts that can be freely alienated (a kind of materialism) or simply a mind that happens to be housed in a body that is purely instrumental (a kind of dualism). See LEON R. KASS, *LIFE, LIBERTY, AND THE DEFENSE OF DIGNITY: THE CHALLENGE FOR BIOETHICS* 177–200 (2002). This argument is further elaborated by Meilaender. See Meilaender, *supra* note 3. Obviously, Volokh may not find this argument at all persuasive, but he does not seem to address it on its own terms.