

## RESPONSE

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

Professor Eugene Volokh's argument<sup>1</sup> disregards the common law context in which the doctrine of self-defense operates and the many problems associated with adopting his proposed *constitutional* right of *medical* self-defense.<sup>2</sup> Moreover, the common law doctrine of self-defense provides no or very little useful guidance for shaping a right of access to unapproved medical products.

The issue is not whether the terminally or otherwise desperately ill should have access to unapproved investigational drugs outside of clinical investigations. They should. Under current law, they do — to some extent. Arguments for increasing access to these drugs can be presented in the regulatory and congressional processes. The issue Professor Volokh raises is whether such an increase should be required by the courts, applying the doctrine of substantive due process (or some similarly ill-defined constitutional doctrine), or by the political branches as part of the democratic political process.

Is there some interest protected by Professor Volokh's conception of medical self-defense that transcends the interests that are subject to the public policy determinations and compromises routinely hammered out by the political branches? The jurisprudence of substantive due process (or that of privacy or privileges and immunities) does not provide a reliable method for finding an answer to that question.<sup>3</sup> We Americans entrust many areas affecting our lives and liberties to such determinations and compromises — for example, drafting citizens and waging war, imposing capital punishment, taking private property for public use, economic regulation, and taxation. In these and many

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<sup>1</sup> Eugene Volokh, *Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 HARV. L. REV. 1813, 1815 (2007).

<sup>2</sup> Professor Volokh argues in the alternative for legislative protection of medical self-defense rights, *id.* at 1815–16, a topic I bypass, as I do his proposed right of access to bodily organs.

<sup>3</sup> *Compare, e.g.*, *Washington v. Glucksberg*, 521 U.S. 702, 720–21 (1997), *with, e.g.*, *Lawrence v. Texas*, 539 U.S. 558, 568–72 (2003).

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other areas, we rely principally on the democratic process, not the courts, to prevent the political branches from trampling on important interests of individuals. Professor Volokh does not persuasively distinguish this area from those.

I. THE COMMON LAW DOCTRINE OF SELF-DEFENSE  
IS AN INAPT ANALOGUE TO ACCESS TO  
UNAPPROVED MEDICAL PRODUCTS

As Professor Volokh argues, if a man breaks into Katherine's home, the common law permits her to defend herself, even with lethal force if that is reasonably necessary to protect herself from death or serious injury.<sup>4</sup> If, on the basis of her defensive conduct, she were later subjected to a criminal charge or tort claim, the doctrine of self-defense would provide a complete defense. The "right" of self-defense is not a claim against anyone else, merely a defense against others' charges or claims.

From the aggressor's perspective, the doctrine of self-defense is an exception to the protection the law generally gives to people and property from nonconsensual injuries inflicted by other people. An aggressor (even if insane and so not morally culpable) is not protected by the criminal law or tort law against injuries or even death resulting from appropriate self-defense by the would-be victim.

The self-defense doctrine functions principally as part of the public law governing relations between individuals in society, particularly as to violence. Because genuine self-defense is, in substantial part, instinctive conduct (the "fight" in "fight or flight"), it is difficult to imagine a society functioning without recognizing its general legitimacy. The doctrine's application to scenarios other than those involving relations between individual human beings — for example, to attacks by animals — is ancillary to its principal function of regulating violent conduct between humans.

Most of the kinds of situations in which the doctrine may be invoked are relatively simple. Over the centuries, the common law has developed relatively noncontroversial solutions to the problems of application the doctrine has presented. Consequently, courts today apply the doctrine without much strain. The Supreme Court has never had to rule on whether the doctrine is constitutionally required.<sup>5</sup>

In arguing by analogy for a "right of medical self-defense," Professor Volokh disregards the ways in which the proposed analogy does not hold. He argues that Ellen should have the same right of self-defense against the bacteria, carcinomas, or whatever in her body

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<sup>4</sup> Volokh, *supra* note 1, at 1814.

<sup>5</sup> See *id.* at 1818.

makes her terminally ill that Katherine has against the intruder. The relation between Ellen and her bacteria is not closely analogous, however, to that between Katherine and the intruder.

Bodies of law prescribe what the intruder and Katherine may do to each other. In most circumstances, the intruder has committed crimes and torts, and consequently has forfeited his own right to legally protected self-defense against Katherine's reasonable defensive actions. Criminal law and tort law protect even the intruder from use of unreasonable force by Katherine. The doctrine of self-defense is merely a part of those laws.<sup>6</sup> No analogous laws regulate relations between the bacteria and Ellen; none protects them. So, Ellen does not need a defense of self-defense against criminal charges or tort claims, for none could arise from her actions. The laws governing violence between individuals in society are irrelevant to her situation.<sup>7</sup>

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<sup>6</sup> Professor Volokh's quotations from commentators on self-defense, *id.* at 1819, reflect the doctrine's role in the regulation of interpersonal conduct, and provide no historical basis for extending it beyond that realm.

<sup>7</sup> Ellen's situation arguably differs from Alice's. In Professor Volokh's depiction, Alice's life is threatened by another individual, the fetus, whose life the state has a legitimate interest in protecting, *see, e.g.*, *Gonzales v. Carhart*, 127 S. Ct. 1610, 1633 (2007), just as it has in protecting the life of the intruder into Katherine's home. Professor Volokh argues that the Court has held that Alice has a constitutional right to defend her life against that individual who threatens it. Volokh, *supra* note 1, at 1814. Even if his conceptualization of the abortion right were correct, however, it would not apply to Ellen because she faces no such threat from another individual.

Moreover, his conceptualization need not be accepted. The constitutional right to abortion to protect the woman's life or health was announced, and reaffirmed, in the same decisions that announced and reaffirmed the general constitutional right to abortion: *Roe v. Wade*, 410 U.S. 113, 163–64 (1973), and *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 846 (1992). The general right is rooted, not in self-defense, but in constitutional protection of "the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy," *id.* at 851. That protection covers the pre-viability right to an abortion in the absence of any risk to life or health and the right throughout a pregnancy to an abortion to protect life or health.

Deciding whether to abort or to accept a risk to maternal life or health undeniably "involve[s] one of] the most intimate and personal choices a person may make in a lifetime," *id.*, but is a different type of private decision from deciding whether to abort in the absence of such a risk because (1) it involves the woman's interest in deciding whether to risk her own health or life, and (2) the state's interest, although strong enough post-viability to override the woman's choice to abort in the absence of risk to herself, simply is not strong enough to defeat the woman's interest in deciding whether to risk her own life or health.

This alternative is closer than Professor Volokh's explanation to the actual conceptual scheme of the abortion decisions because it does not depend on an undeclared constitutional right of self-defense. What Professor Volokh conceptualizes as two independent abortion rights (one rooted in autonomy; the other, in self-defense) can at least equally well, and in accordance with Occam's razor (entities are not to be multiplied unnecessarily), be conceptualized as one abortion right (rooted in autonomy) that encompasses two types of situations involving a most intimate and personal reproductive choice.

Professor Volokh asserts that "it can't be that a woman has a constitutional right to protect her life using medical procedures, but only when those procedures kill a viable fetus." Volokh, *supra* note 1, at 1816; *see also id.* at 1826. The foregoing analysis shows, however, that autonomy justifies the abortion right throughout a pregnancy.

In exercising her “right” of self-defense, Katherine uses defensively whatever happens to be available — such as her fists or a gun. Her self-defense does not involve a transaction in interstate commerce. Ellen’s proposed constitutional right of medical self-defense inherently involves such a transaction: the purchase of an investigational drug not approved for commercial distribution.<sup>8</sup> Professor Volokh cites nothing in the history of, or scholarly commentary on, the doctrine of self-defense that extends it to the acquisition of a product in commerce. Indeed, the doctrine would not accommodate Katherine’s participation in a commercial transaction.

The law that prevents Ellen from obtaining an unapproved drug she believes may save her life is the Federal Food, Drug, and Cosmetic Act (FDCA), under which a new drug may be approved for shipment in interstate commerce only on the basis of scientific showings of effectiveness and safety.<sup>9</sup> The Supreme Court has held that that provision of the FDCA has no exception for drugs for the terminally ill:

[E]ffectiveness does not necessarily denote capacity to cure. In the treatment of any illness, terminal or otherwise, a drug is effective if it fulfills, by objective indices, its sponsor’s claims of prolonged life, improved physical condition, or reduced pain.

So too, the concept of safety . . . is not without meaning for terminal patients. Few if any drugs are completely safe in the sense that they may be taken by all persons in all circumstances without risk. Thus, the Commissioner generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use. For the terminally ill, as for anyone else, a drug is unsafe if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit.<sup>10</sup>

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<sup>8</sup> The Supreme Court’s decisions on contraceptives do not support the proposed constitutional right or any general constitutional right of access to medical products. They culminated in the rationale that access to contraceptives is incident to due process protection of “[t]he decision whether or not to beget or bear a child.” *Carey v. Population Servs. Int’l*, 431 U.S. 678, 685 (1977). Terminal patients’ access to unapproved drugs is not incident to any type of decision the Court has held constitutionally protected.

Moreover, there is no general constitutional right to freedom from governmental restrictions on medical services and products. See *Carhart*, 127 S. Ct. 1610 (particular abortion procedure); *Glucksberg*, 521 U.S. 702 (medical assistance in suicide); see also *Gonzales v. Raich*, 125 S. Ct. 2195 (2005) (holding that there was no violation of the Commerce Clause in the Controlled Substances Act’s prohibition of access to marijuana for patients for whom it was prescribed to treat severe pain and possibly fatal illnesses after conventional medicines had not provided effective treatment).

<sup>9</sup> 21 U.S.C. § 355(a) (2000 & Supp. IV 2004), which prohibits the introduction, and delivery for introduction, into interstate commerce of any unapproved new drug. The term “new drug” is defined in 21 U.S.C. § 321(p) (2000).

<sup>10</sup> *United States v. Rutherford*, 442 U.S. 544, 555–56 (1979) (footnotes omitted) (citation omitted). Passages in the opinion referring to possible benefits of conventional therapies, *id.* at 556–57, do not limit this more general rationale, see *supra* note 10 and accompanying text, to situations

Moreover, Ellen needs no defense against a potential charge of violating the FDCA. It is long-settled Food and Drug Administration (FDA) policy not to seek enforcement against individuals who obtain unapproved drugs solely for personal use.<sup>11</sup>

What Ellen needs is an exemption from the FDCA for a drug manufacturer, so that the manufacturer may provide her the unapproved drug she wants. The legal doctrine she would invoke would be something like medical defense of another rather than medical self-defense. This articulation shows that acceptance of Ellen's claim would significantly constrain regulation of interstate commerce in medical products. The common law doctrines of self-defense and defense of another have not historically operated on such terrain and would provide no or very little useful guidance for applying their proposed constitutional analogues there.

## II. THE PROPOSED RIGHT OF ACCESS TO UNAPPROVED DRUGS WOULD BROADLY THREATEN REGULATORY SCHEMES ESSENTIAL FOR PROTECTING THE PUBLIC

Ellen might say that all she wants is to engage in a private consensual transaction with a drug manufacturer without either party being liable. What she wants, however, is an exemption for a large class of transactions from a central provision of the drug regulatory system that has been instrumental in creating the conditions in which medical products, including drugs to treat life-threatening and otherwise serious medical conditions, are developed.<sup>12</sup> Ellen's claim is, in effect, an attack on a substantial part of that system and the public good it fosters.

Professor Volokh describes Ellen's situation as follows:

Ellen is terminally ill. No proven therapies offer help. An experimental drug therapy seems safe because it has passed Phase I FDA testing, yet federal law bars the therapy outside of clinical trials because it hasn't been demonstrated to be effective (and further checked for safety) through Phase II testing.<sup>13</sup>

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in which the terminally ill patient has not exhausted all available conventional therapies. Rather, they are additional considerations not necessary to the rationale but supporting it.

<sup>11</sup> Importation is the principal way individuals obtain new drugs for which approval is required but lacking. As an exercise of enforcement discretion, FDA permits individuals to import such drugs for personal use. FDA, REGULATORY PROCEDURES MANUAL, ch. 9, § 2 (2007), available at [http://www.fda.gov/ora/compliance\\_ref/rpm/chapter9/ch9-2.html](http://www.fda.gov/ora/compliance_ref/rpm/chapter9/ch9-2.html); see also FDA, *Information on Importation of Drugs Prepared by the Division of Import Operations and Policy*, <http://www.fda.gov/ora/import/pipinfo.htm>.

<sup>12</sup> See generally J. Richard Crout et al., *FDA's Role in the Pathway to Safe and Effective Drugs*, in *FDA: A CENTURY OF CONSUMER PROTECTION* 159–91 (Wayne L. Pines ed., 2006).

<sup>13</sup> Volokh, *supra* note 1, at 1814.

Although Professor Volokh may assume whatever he wants in a hypothetical, this hypothetical does not accurately reflect the circumstances of most unapproved drugs, the current state of the law on access to such drugs, or the serious attention the political branches have given, and are giving, to situations like Ellen's. Professor Volokh's hypothetical also disregards the realities of drug testing in humans, which generally fit the following description.

Phase 1 testing in humans, together with information from other sources, provides an insufficient basis to conclude that a drug "seems safe." Phase 1 studies involve few subjects (20–80), who need not have the disease or condition that the drug under investigation is designed to treat.<sup>14</sup> Such studies are of very short duration and yield quite limited information about safety. Moreover, most Phase 1 studies provide no information about a drug's effectiveness.

Because drugs to treat cancer are more toxic than most other drugs, Phase 1 studies of cancer drugs are conducted in cancer patients rather than healthy volunteers, and can show some evidence of efficacy, most commonly shrinkage of tumors, as well as some evidence of safety, in actual cancer patients. That evidence, however, is quite limited and preliminary.

In Phases 2 and 3, drugs are not merely "checked" for safety, as if the principal determination of safety were made after Phase 1. Phase 2 studies are conducted "in patients with the disease or condition under study and," with respect to safety, "to determine the common short-term side effects and risks associated with the drug."<sup>15</sup> The *range* of those short-term side effects and risks is not discovered in Phase 1. Phase 2 studies are closely monitored, and conducted in several hundred subjects.<sup>16</sup>

It is Phase 3 studies that are "intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling."<sup>17</sup> Before the results of Phase 3 studies are analyzed, there almost always is insufficient information to

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<sup>14</sup> See 21 C.F.R. § 312.21(a) (2007). Phase 1 studies usually are conducted in healthy volunteers. FDA, *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective* (2002, revised 2005), available at [http://www.fda.gov/fdac/features/2002/402\\_drug.html](http://www.fda.gov/fdac/features/2002/402_drug.html).

<sup>15</sup> 21 C.F.R. § 312.21(b) (2007).

<sup>16</sup> *Id.* Study protocols commonly provide for monitoring of subjects by the investigators. In addition, the sponsor of an investigation, or a contract research organization the sponsor engages, is required to monitor the investigators' conduct of the investigation. The sponsor usually is the manufacturer of the investigational drug. See generally 21 C.F.R. §§ 312.50, 312.52, 312.56 (2007). Institutional review boards, whose approval generally is required for research on human subjects within FDA's jurisdiction, 21 C.F.R. § 56.103 (2007), are also required to conduct continuing review of research they have approved, 21 C.F.R. § 56.109(f) (2007).

<sup>17</sup> 21 C.F.R. § 312.21(c) (2007).

decide, for purposes of granting or denying approval, whether a drug is safe for its intended use — that is, whether its therapeutic benefit (its effectiveness) outweighs the risks of adverse effects it presents.<sup>18</sup> Until then, there also is insufficient information about the many aspects of a drug that are addressed in its labeling and that are necessary to guide use of the drug: its precise indications, contraindications, warnings, precautions, adverse effects, interactions with other drugs, dosage regimen, and so on.<sup>19</sup>

Preliminary assessments of potential risks and benefits of an investigational drug can be, and sometimes are, made before completion of Phase 3.<sup>20</sup> Such assessments are made in a context of substantial uncertainty about a drug's effects. In its most recent abortion decision, the Supreme Court observed that it “has given state and federal legislatures wide discretion to pass legislation in areas where there is medical and scientific uncertainty.”<sup>21</sup> Ellen's constitutional claim would apply exclusively in an area of such uncertainty.

Current federal law permits access to unapproved investigational drugs outside of clinical trials.<sup>22</sup> FDA regulations permit such access to treat “a serious or immediately life-threatening disease condition in patients for whom no comparable or satisfactory alternative drug or other therapy is available,”<sup>23</sup> and FDA has proposed to expand the current access.<sup>24</sup> Thus, the access Professor Volokh advocates already exists, albeit not under the rubric of “medical self-defense” and not to the extent he wants.

Ellen's claim is very broad. Professor Volokh specifies that she is “terminally ill.”<sup>25</sup> If she has a constitutional right to unapproved drugs, so, too, should a patient who faces endless severe pain or near-

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<sup>18</sup> Evaluation of a drug's safety continues even after approval. See 21 C.F.R. §§ 312.85, 314.80 (2007). If post-approval information shows that a drug is unsafe, its approval may be withdrawn. See 21 U.S.C. § 355(e)(1) (2000).

<sup>19</sup> 21 C.F.R. § 201.57 (2007).

<sup>20</sup> See 21 C.F.R. § 312.34(b)(2)-(3) (2007).

<sup>21</sup> *Gonzales v. Carhart*, 127 S. Ct. 1610, 1636 (2007).

<sup>22</sup> See 21 U.S.C. § 360bbb (2000 & Supp. IV 2004). This provision was added to the FDCA by the Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-15, § 402, 111 Stat. 2296, 2365-67 (1997).

<sup>23</sup> 21 C.F.R. § 312.34(a) (2007). See also 21 C.F.R. §§ 312.35, 312.83, 314.500-314.560 (2007). The FDCA and FDA generally treat death and serious injury similarly. See, e.g., 21 C.F.R. §§ 314.80(c)(1), 803.50(a)(1)-(2) (2007).

<sup>24</sup> 71 FED. REG. 75,147 (Dec. 14, 2006); FDA News, *FDA Proposes Rules Overhaul to Expand Availability of Experimental Drugs* (Dec. 11, 2006), available at <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01520.html>.

<sup>25</sup> In *United States v. Rutherford*, the Supreme Court found that the term “terminally ill” had no clear operational meaning. 442 U.S. 544, 556 n.14 (1979).

term irreversible decline into dementia.<sup>26</sup> The common law “right” of self-defense applies against potential infliction of bodily harm as well as against potential homicide.<sup>27</sup> Presumably, the proposed constitutional right should extend to any disease that threatens serious physical or mental impairment.<sup>28</sup>

The Controlled Substances Act (CSA) applies to some FDA-regulated therapeutic drugs.<sup>29</sup> If the CSA applies to the drug Ellen wants, her constitutional right would also apply against that statute. The Supreme Court has held, however, that medical necessity is not a defense to a charge of violating the CSA.<sup>30</sup> Ellen’s constitutional right presumably would trump that decision. Ellen’s constitutional right presumably would also reach beyond unapproved drugs to unapproved medical devices, and thus her claim would override central parts of *two* major FDA regulatory programs.

In view of the minimal safety information developed in most Phase I testing, why should Ellen’s constitutional right be limited to drugs that have survived Phase I?<sup>31</sup> If Ellen is willing to take the risks of a drug that has never been tested in humans but has shown good results in animals, why, under Professor Volokh’s reasoning, should she not have the constitutional right to obtain that drug from its manufacturer? Why require testing in animals? If Ellen wants to use a drug never tested at all, why should she not have the constitutional right to do so?

Professor Volokh comments that the panel decision in *Abigail Alliance v. von Eschenbach*<sup>32</sup> would have “secure[d] Ellen the constitutional right to try to save her life by hiring a doctor to administer the therapy.”<sup>33</sup> Why should the constitutional right be limited to individuals who have doctors? Katherine’s right of self-defense is not limited to individuals assisted by experts in martial arts.

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<sup>26</sup> Cf. *Garlic v. FDA*, 783 F. Supp. 4, 5 (D.D.C. 1992) (rejecting arguments by plaintiffs that “millions of Alzheimer’s sufferers need fast access to an effective medication before the disease causes irreparable mental and physical deterioration”).

<sup>27</sup> See generally 2 WAYNE R. LAFAVE, SUBSTANTIVE CRIMINAL LAW § 10.4 (2d ed. 2007).

<sup>28</sup> Professor Volokh so extends it, though with formulations of varying expansiveness. See Volokh, *supra* note 1, at 1821, 1821 n.37, 1829 n.78.

<sup>29</sup> See, e.g., 21 U.S.C. §§ 812(b)(2)(B), (b)(3)(B), (b)(4)(B), (b)(5)(B) (2000).

<sup>30</sup> *United States v. Oakland Cannabis Buyers’ Coop.*, 532 U.S. 483, 494 (2001).

<sup>31</sup> The FDA has proposed that, in some circumstances, access might be provided before completion of Phase I. See 71 FED. REG. at 75,151. Professor Volokh would similarly extend his proposed constitutional right to “drugs [that] have not been tested for safety.” Volokh, *supra* note 1, at 1830 n.79.

<sup>32</sup> *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470 (D.C. Cir. 2006), *rev’d*, 495 F.3d 695 (D.C. Cir. 2007) (en banc), *cert. denied*, No. 07-444, 2008 WL 114305 (U.S. Jan 14, 2008).

<sup>33</sup> Volokh, *supra* note 1, at 1815.

Constitutional protections of substantive due process and privacy presumably apply against federal as they do against state deprivations. Nevertheless, the Supreme Court has found it necessary to recognize and apply unenumerated constitutional rights under those doctrines predominantly against state, not federal, laws. Were Professor Volokh's argument and his methodology of elevating common law doctrines into federal constitutional rights to succeed, it would threaten many federal (and state) regulatory programs.<sup>34</sup> A Supreme Court decision accepting the new right potentially would be a new *Lochner v. New York*.<sup>35</sup>

### III. THE PROPOSED RIGHT OF ACCESS TO UNAPPROVED DRUGS IGNORES CLINICAL AND MARKET REALITIES

Professor Volokh's statement, "No proven therapies offer help,"<sup>36</sup> fails to reflect the possible complexities of Ellen's situation. Suppose a proven therapy might offer help, but only if Ellen followed a regimen that is beyond her capacity or willingness to endure.<sup>37</sup> Suppose a proven therapy might help, but carries a boxed warning (FDA's most severe form of warning)<sup>38</sup> against use by people in Ellen's circumstances, but an unapproved drug she wants carries no such warning, perhaps because little is known about it. Suppose Ellen is uninsured and cannot afford a proven therapy, but can afford an unapproved therapy. Suppose a proven therapy prolongs life for a few months, on average, but is not a cure and that an unapproved drug might be a cure (it has cured animals) but, for medical reasons, cannot be used by a patient who has used the proven therapy. Under Professor Volokh's proposal, each such situation would present a constitutional question.

The Abigail Alliance argued that its proposed constitutional right would have little practical effect if manufacturers were unwilling to supply investigational drugs to terminally ill people, and that, therefore, the right should have as a corollary a right of manufacturers to sell unapproved drugs for profit.<sup>39</sup> Thus, the proposed right would spawn a business of selling unproven medical products to desperate people. That market very probably would expand well beyond "ter-

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<sup>34</sup> The methodology, itself, is unsound. The Fourteenth Amendment's Due Process Clause "does not transform every tort committed by a state actor into a constitutional violation." *DeShaney v. Winnebago County Dep't of Soc. Servs.*, 489 U.S. 189, 202 (1989).

<sup>35</sup> 198 U.S. 45 (1905).

<sup>36</sup> Volokh, *supra* note 1, at 1814.

<sup>37</sup> See *Smith v. Shalala*, 954 F. Supp. 1, 2 (D.D.C. 1996) (describing plaintiff's argument for a "right of a competent terminally ill cancer patient to choose among available treatments that he or she can accept and endure").

<sup>38</sup> See 21 C.F.R. § 201.57(c)(1) (2007).

<sup>39</sup> Brief of Appellants at 18–19, *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 370 (D.C. Cir. 2006) (No. 04-5350), 2005 WL 1826286.

minal” patients. Today, if you search Google for “Laetrile” (an unapproved drug touted as a cancer treatment), the first two websites that appear offer it for sale.<sup>40</sup>

#### IV. AS A MATTER OF INSTITUTIONAL COMPETENCE, CONGRESS AND FDA ARE BETTER SUITED THAN COURTS TO DETERMINE THE EXTENT OF ACCESS TO UNAPPROVED DRUGS

In principle, FDA is better positioned than any patient, physician, or other organization in the country to assess independently what is known about the effectiveness and safety of unapproved drugs. FDA uniquely has access to the results in all clinical trials of drugs conducted to support a potential application for FDA approval. It also uniquely has personnel collectively qualified in all the medical and other disciplines necessary to review, and with vast institutional experience in reviewing, clinical trial data to draw conclusions about effectiveness and safety and the conditions for effective and safe use of drugs. If adequately directed by statute, adequately funded and staffed, and adequately overseen by Congress, FDA can be a valuable national resource for assessments of unapproved drugs.

If FDA’s current regulations are too stingy with access, or its programs for access are too user-unfriendly, too slow, too risk-averse, or otherwise unsatisfactory, such problems should be solvable through amendments to the FDCA, appropriations, and congressional oversight. The potential beneficiaries of access are all of us (including government officials), not any despised or disregarded minority that cannot get a fair hearing in the political process. Whatever your personal characteristics, you (and I) and people you (or I) care about might some day be in Ellen’s situation. There is no reason to believe that the political process is incapable of solving such problems.<sup>41</sup>

Are courts and their procedures better suited than Congress and FDA and their procedures to decide on access? Professor Volokh presents no reasons to think so. The courts’ centuries of experience with self-defense are of no or very little help in devising the optimal balance between access to unapproved medical products and maintenance of (and improvement in) the regulatory systems for ensuring that such medical products are adequately tested, that research subjects are adequately protected, and that to the extent practical marketed medical products are effective, safe, and adequately labeled. The lack of relevance of self-defense to devising that balance further underscores the lack of true analogy between self-defense and so-called medical self-defense.

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<sup>40</sup> See also *United States v. Rutherford*, 442 U.S. 544, 557–58 (1979).

<sup>41</sup> Cf. *Washington v. Glucksberg*, 521 U.S. 702, 737 (1997) (O’Connor, J., concurring).

Counsel for the Abigail Alliance stated that the Alliance's principal objection was to one regulatory provision:

The core of our claim is the challenge to [21 U.S.C. § ] 312.34(b)(3), which is where the FDA . . . reserves to itself the right to make the basic risk balancing decision for individual patients as to whether the risks outweigh the benefits of a particular treatment.<sup>42</sup>

Under section 312.34(b)(3), FDA may deny a patient with an immediately life-threatening disease access to an unapproved drug:

if the available scientific evidence, taken as a whole, fails to provide a reasonable basis for concluding that the drug:

(A) May be effective for its intended use in its intended patient population; or

(B) Would not expose the patients to whom the drug is to be administered to an unreasonable and significant additional risk of illness or injury.<sup>43</sup>

This is a low standard; perhaps no lower standard would be rational.<sup>44</sup>

Does Ellen have a constitutional right to prevent the operation of a congressionally authorized regulatory system that imposes that standard? I believe Justice Holmes provided the answer:

[A] constitution is not intended to embody a particular economic theory, whether of paternalism and the organic relation of the citizen to the State or of *laissez faire*. It is made for people of fundamentally differing views, and the accident of our finding certain opinions natural and familiar or novel and even shocking ought not to conclude our judgment upon the question whether statutes embodying them conflict with the Constitution of the United States.<sup>45</sup>

Professor Volokh advances a libertarian argument for access to unapproved drugs. Thus far, our society, through its elected federal officials and others answerable to them, has chosen a degree of paternalism to restrict such access.

Normally, differences of view about federal regulatory programs that violate no enumerated constitutional right should be resolved by the political branches. When the courts declare a new, unenumerated substantive due process right, they extract part of the subject matter of that right from the democratic process and they assert control over it. Implicit in such an assertion is a judgment that the democratic process has in some important way failed and cannot be relied on to correct

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<sup>42</sup> Transcript of Oral Argument at 11, *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007) (en banc) (No. 04-5350).

<sup>43</sup> 21 C.F.R. § 312.34(b)(3) (2007).

<sup>44</sup> The (much higher) standard for approval of a new drug appears in 21 U.S.C. § 355(d)(1)-(7) (2000 & Supp. IV 2004).

<sup>45</sup> *Lochner v. New York*, 198 U.S. 45, 75-76 (1905) (Holmes, J., dissenting).

itself. Professor Volokh does not justify, and I believe cannot justify, such an assertion about access to unapproved drugs.

Ultimately, he does not provide persuasive reasons for reading his libertarian preference into the Constitution. He provides no reason to believe that all rights or interests protected in some way by the common law are “fundamental” for purposes of constitutional analysis. Even if self-defense against aggressors were viewed as a fundamental right, it would not support a constitutional right of medical self-defense that would disable society from protecting terminally ill and other people from unapproved drugs in commerce for the reasons outlined in *Rutherford*.

Finally, there is no reason to believe that our political institutions have failed here. The *Abigail Alliance* case has stimulated discussion of whether terminally ill patients should have greater access to unapproved drugs.<sup>46</sup> In the last Congress, Senator Brownback introduced a bill to address Ellen’s situation;<sup>47</sup> the Abigail Alliance supported it.<sup>48</sup> Indeed, FDA has proposed expansion of the current access. Thus, the issue is alive in the political branches. It should be resolved there, not in the courts.

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<sup>46</sup> See, e.g., Jerome Groopman, *The Right to a Trial: Should dying patients have access to experimental drugs?*, NEW YORKER, Dec. 18, 2006, [http://www.newyorker.com/archive/2006/12/18/061218fa\\_fact](http://www.newyorker.com/archive/2006/12/18/061218fa_fact); Kerry Howley, *Dying for Lifesaving Drugs*, REASON, Aug.–Sept. 2007, <http://www.reason.com/news/show/120763.html>; Dr. Roger Pilon, Editorial, *The New Right to Life*, WALL ST. J., Aug. 10, 2007, at A11; *Whose Life Is It, Anyway? Abigail Alliance at the Crossroads* (Food & Drug Law Institute ed., 2007), available at <http://www.fdli.org/conf/414/materials/AbigailAllianceWhitepaper.pdf>.

<sup>47</sup> S. 1956, 109th Cong. (2005).

<sup>48</sup> See Press Release, Abigail Alliance, Abigail Alliance supports ACCESS Act (Nov. 10, 2005), available at [http://abigail-alliance.org/AbigailAlliancesupportsACCESSAct\\_1\\_.pdf](http://abigail-alliance.org/AbigailAlliancesupportsACCESSAct_1_.pdf).