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**The Right To Live:**  
**Do the Terminally Ill Have**  
**a Constitutional Right to**  
**Use Experimental Drugs?**  
*Abigail Alliance v. von*  
*Eschenbach*, 445 F.3d 470  
**(D.C. Cir. 2006)**

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INTRODUCTION

*“Tempt not a desperate man.”*  
*-William Shakespeare, Romeo and Juliet*

In 2002, Kianna Karnes, a forty-one year old nurse and mother, was diagnosed with kidney cancer.<sup>1</sup> Two years later, John Rowe, Kianna’s father and a congressional staffer, learned of an ongoing clinical trial testing two kidney cancer

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<sup>1</sup> Jerome Groopman, *The Right to a Trial; Should Dying Patients Have Access to Experimental Drugs?*, THE NEW YORKER, Dec. 18, 2006, at 40.

drugs.<sup>2</sup> Unfortunately, by then the cancer had spread to Kianna's brain and disqualified her from initial approval for participation in the study.<sup>3</sup> Using his media and congressional contacts, Rowe pressured the Food and Drug Administration (FDA) to allow Kianna to use the drugs under a "compassionate use" exception.<sup>4</sup> On March 24, 2005, an FDA official called Rowe with good news—the FDA would approve Kianna for this exception.<sup>5</sup> But that night, Kianna passed away.<sup>6</sup> Less than a year later, the FDA approved both drugs for use against advanced kidney cancer.<sup>7</sup>

Kianna's desperate situation is all too common for most families battling terminal illness. The American Cancer Society estimates that in 2006, over 560,000 Americans died of cancer.<sup>8</sup> According to the Centers for Disease Control, nearly 16,000 Americans died from AIDS in 2004.<sup>9</sup> As medicine has advanced in ways previously unimaginable, the progress has merely whet the public's appetite for new and better treatments for the most dangerous and puzzling diseases. Desperate patients continue to demand the newest drugs and medical treatments, regardless of factors such as price.<sup>10</sup> Worldwide spending on cancer medicines was \$24 billion in 2004, and is expected to rise to \$55 billion in 2009.<sup>11</sup> There appears to be a growing belief that the dying should have the right to do whatever they can to try to save their lives. But despite tragic stories like Kianna's, the system saves lives. For example, in December 2006, Pfizer cancelled its trial of torcetrapib, an experimental drug treating heart disease, after eighty-two patients in the study died.<sup>12</sup> Indeed, the FDA has a serious duty to give patients like Kianna access to drugs as quickly as possible, but it has an equally serious duty to do as much as it can to ensure those drugs are as safe as possible. The purpose of this paper is not to criticize the decisions of the FDA or even to determine if in fact patients like Kianna ought to have quicker access to experimental drugs. The question addressed below is much narrower: Do patients like Kianna have a *constitutional* right to use such treatments?

This paper examines a recent decision by the Court of Appeals for the District of Columbia that grants the terminally ill a constitutional right under the Due Process Clause to use drugs that have not yet been approved by the FDA.<sup>13</sup> It begins with a review of the history of federal drug regulation, including the events that led

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<sup>2</sup> *Id.*

<sup>3</sup> *Id.* Brain cancer can cause seizures in patients, which makes it hard to distinguish between symptoms of cancer and side effects of the treatment. *Id.*

<sup>4</sup> *Id.* A "compassionate use" exception allows pharmaceutical companies, with FDA approval, to release an experimental drug to a patient not enrolled in a study. *Id.*

<sup>5</sup> *Id.* at 41.

<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

<sup>8</sup> AMERICAN CANCER SOCIETY, CANCER FACTS AND FIGURES 6 (2006), <http://www.cancer.org/downloads/STT/CAFF2006PWSecured.pdf>.

<sup>9</sup> CENTERS FOR DISEASE CONTROL, HIV/AIDS SURVEILLANCE REPORT 16 (2004), <http://www.cdc.gov/hiv/topics/surveillance/resources/reports/2004report/pdf/2004SurveillanceReport.pdf>.

<sup>10</sup> Alex Berenson, *Hope, at \$4,200 a Dose*, N.Y. TIMES, Oct. 1, 2006, at C1.

<sup>11</sup> *Id.*

<sup>12</sup> Groopman, *supra* note 1, at 3.

<sup>13</sup> *See generally* Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach, 445 F.3d 470, 473 (D.C. Cir. 2006), *vacated and reh'g en banc granted* 2006 U.S. App. LEXIS 28974.

Congress to enact the first regulatory regime in 1938.<sup>14</sup> This section also highlights the three-stage approval process currently employed by the FDA for new drugs.<sup>15</sup> The Prior Law section then examines how the Supreme Court and lower courts have evaluated claims under the Due Process Clause. The section surveys both claims of new rights<sup>16</sup> and claims applying previously recognized rights.<sup>17</sup> The paper then outlines the procedural history of the *Abigail Alliance* case and explores in-depth the reasoning and justification used by the Court of Appeals and the dissenting judge.<sup>18</sup> Finally, the paper critiques the analysis and conclusion of the Court in finding a constitutional right of the terminally ill to use experimental drugs. Further, the paper argues that even if such a constitutional right exists, state interests are so great that any proper balancing of interests would affirm the current policy.

#### PRIOR LAW

##### I. History of Federal Drug Regulation

The federal government first began to monitor the introduction of new drugs into the marketplace in 1906, when Congress enacted the Pure Food Act.<sup>19</sup> The Pure Food Act merely prohibited the manufacturing of any “food or drug which is adulterated or misbranded.”<sup>20</sup> The effectiveness of the Pure Food Act came under congressional scrutiny in 1937, when a liquid form of Elixir Sulfanilamide, which contained an untested liquid solvent, caused the death of 107 people.<sup>21</sup> Massengill, the drug’s manufacturer, paid a paltry \$26,100 fine as prescribed in the Pure Food Act.<sup>22</sup> In response to this regulatory failure, Congress enacted the Federal Food, Drug, and Cosmetic Act (FDCA)<sup>23</sup> in 1938, which has become the basis for modern drug regulation.<sup>24</sup>

The FDCA, for the first time, required manufacturer testing and FDA review of all new drugs.<sup>25</sup> The Act required drug manufacturers to file a “new drug

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<sup>14</sup> See generally Steven R. Salbu, *Regulation of Drug Treatments for HIV and AIDS: A Contractarian Model of Access*, 11 YALE J. ON REG. 401, 406-18 (Summer 1994).

<sup>15</sup> See 21 C.F.R. § 312.21 (2007) (listing three-stage approval process).

<sup>16</sup> See, e.g., *Griswold v. Connecticut*, 381 U.S. 479 (1965) (identifying right of privacy in using birth control).

<sup>17</sup> See, e.g., *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992) (reaffirming right to abortion).

<sup>18</sup> *Abigail Alliance*, 445 F.3d 470.

<sup>19</sup> Pure Food Act, ch. 3915, 34 Stat. 768 (repealed 1938); see Salbu, *supra* note 14, at 406-18 (providing detailed background on federal regulatory process).

<sup>20</sup> Pure Food Act, § 1.

<sup>21</sup> Salbu, *supra* note 14, at 407.

<sup>22</sup> *Id.*

<sup>23</sup> Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (codified as amended at 21 U.S.C.A. §§ 301-381).

<sup>24</sup> See Salbu, *supra* note 14, at 408. Federal constitutional authority for drug regulation rests in the Commerce Clause, since the FDCA purports to regulate only those drugs introduced into interstate commerce. See Federal Food, Drug, and Cosmetic Act, § 301; U.S. CONST. art. I, § 8 (Commerce Clause).

<sup>25</sup> James J. 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, 264 (2005).

application” (NDA), which included information about the drug’s safety.<sup>26</sup> Introducing the drugs into the marketplace, however, did not require FDA approval; rather, the drug was automatically approved unless the FDA determined that the drug was unsafe.<sup>27</sup> Over time, the public became wary that this system would allow a dangerous drug to slip through the regulatory cracks.<sup>28</sup> In response to calls for increasing federal regulation, Congress enacted the Kefauver-Harris Amendment (Amendment) to the FDCA in 1962.<sup>29</sup> The Amendment, which prescribes the drug approval process used today, requires drug manufacturers to acquire FDA approval before marketing a new drug, requires FDA review of both safety and effectiveness, and gives the FDA greater authority over pre- and post-marketing activities, including human testing.<sup>30</sup>

Today, the FDA has promulgated a three-phase process for testing and approving new drugs before they may enter the marketplace.<sup>31</sup> In Phase I, drugs are first introduced into humans, usually twenty to eighty patients or volunteers.<sup>32</sup> This phase is used to determine the basic behavior of the drug, any possible side effects, and a preliminary determination of effectiveness.<sup>33</sup> Phase 2 expands the trial to several hundred subjects and evaluates the drug for specific effectiveness against an ailment as well as further side effects and other risks.<sup>34</sup> Phase 3, which can include several hundred or several thousand subjects, is intended to gather further information about the drug’s overall risk-benefit ratio and to assist in physician labeling.<sup>35</sup> Typically, Phase 1 testing lasts approximately one year, Phase 2 testing takes up to two years, and Phase 3 testing lasts three years.<sup>36</sup> Once Phase 3 testing is complete, the drug manufacturer files an NDA, which takes an average of thirty

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<sup>26</sup> *Id.* at 264-65.

<sup>27</sup> *Id.* at 265.

<sup>28</sup> *Id.* See also PETER TEMIN, TAKING YOUR MEDICINE: DRUG REGULATION IN THE UNITED STATES 123-24 (1980) (describing “close call” when FDA nearly failed to take the proper action to stop sales of thalidomide, which caused birth defects).

<sup>29</sup> Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962).

<sup>30</sup> Zelenay, *supra* note 25, at 266.

<sup>31</sup> See 21 C.F.R. § 312.21. Those ineligible to participate in these studies may apply for a “compassionate use” exception, which is known to the FDA as a “Single Patient Investigational New Drug Application.” *Compassionate Use INDs--Is the Current System Effective? Hearing Before the H. Comm. on Government Reform*, 107th Cong. (2001) (statement of Robert J. Temple, Associate Director for Medical Policy, Center for Drug Evaluation and Research, Food and Drug Administration) (*available at* <http://www.hhs.gov/asl/testify/t010620.html>). Mr. Temple testified regarding the breadth of access this provides: “Generally, however, if a physician makes a request for treatment use of an experimental drug, in a patient for whom no effective therapy exists, and there is an ongoing study of the drug and a sponsor agrees to provide the product, FDA does not object to the treatment use.” *Id.* See also Groopman, *supra* note 1, at 3 (describing application for “compassionate use” exception for Kianna Karnes).

<sup>32</sup> 21 C.F.R. § 312.21(a)(1).

<sup>33</sup> *Id.*

<sup>34</sup> *Id.* at § 312.21(b).

<sup>35</sup> *Id.* at § 312.21(c).

<sup>36</sup> Elizabeth M. Rutherford, *The FDA and “Privatization” – The Drug Approval Process*, 50 FOOD & DRUG. L.J. 203, 213 (1995). The FDA does allow expedited approval through an abbreviated new drug application (“ANDA”) or through sponsor approval under 21 U.S.C.A. § 505(b)(2); however, ANDA and sponsor approval are used for use of generic copies of already-approved drugs, not for the kind of drugs at issue here. See Zelenay, *supra* note 25, at 269-70.

months for the FDA to approve.<sup>37</sup> Only one in five drugs that begin the human testing process ultimately receives FDA approval.<sup>38</sup>

## II. Due Process Rights

The Fourteenth Amendment provides that “[n]o state shall ... deprive any person of life, liberty, or property, without due process of law.”<sup>39</sup> “The Due Process Clause guarantees more than fair process, and the ‘liberty’ it protects includes more than the absence of physical restraint.”<sup>40</sup> The Due Process Clause protects against government interference with fundamental rights and liberty interests.<sup>41</sup> Challenges asserting substantive due process violations generally fall into one of two categories: challenges that assert unlawful encroachment on a previously recognized right and challenges that assert a previously unrecognized due process right.<sup>42</sup>

### A. Existing Due Process Rights

The first consideration courts must make when facing a due process challenge is whether the asserted right has previously been recognized.<sup>43</sup> This may begin with a survey of “our Nation’s history, legal traditions, and practices.”<sup>44</sup> Such a survey has included common law practice,<sup>45</sup> state law,<sup>46</sup> law of other Western nations,<sup>47</sup> and constitutional framers’ intent.<sup>48</sup>

The right of a patient to control his or her own treatment was first recognized by the Supreme Court in *Cruzan v. Director, Missouri Department of Health*.<sup>49</sup> There, Nancy Cruzan was injured during a car accident leaving her in a persistent vegetative state.<sup>50</sup> Cruzan’s parents petitioned the Court for removal of her feeding tube, but

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<sup>37</sup> Rutherford, *supra* note 36, at 213. Approval takes this long notwithstanding the statutory requirement under 21 U.S.C.A. § 355(c)(1) of action within 180 days. *Id.*

<sup>38</sup> *Id.*

<sup>39</sup> U.S. CONST. amend. XIV, § 1.

<sup>40</sup> *Wash. v. Glucksberg*, 521 U.S. 702, 719 (1997).

<sup>41</sup> *Id.* at 720.

<sup>42</sup> *Compare Casey*, 505 U.S. at 844 (declaring unlawful infringement on previously recognized right to abortion), with *Griswold*, 381 U.S. at 484 (recognizing generally right to privacy).

<sup>43</sup> *See, e.g., Hutchins v. D.C.*, 188 F.3d 531, 536-38 (D.C. Cir. 1999) (en banc) (plurality) (distinguishing asserted right to free movement from previously recognized Due Process right of interstate travel).

<sup>44</sup> *Glucksberg*, 521 U.S. at 710.

<sup>45</sup> *See, e.g., id.* at 711 (noting that common law generally forbids assisted suicide); *Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 269 (1990) (noting that common law generally protects right to bodily integrity); *Hutchins*, 188 F.3d at 539 (noting that juvenile curfews were common in early American jurisprudence).

<sup>46</sup> *See Glucksberg*, 521 U.S. at 716 (noting that states have reaffirmed longstanding bans on assisted suicide); *Cruzan*, 497 U.S. at 275-76 (citing court decisions based on state statutes governing removal of life-sustaining treatment); *Hutchins*, 188 F.3d at 539 (noting that juvenile curfews were common in state law).

<sup>47</sup> *See Glucksberg*, 521 U.S. at 710 (noting assisted suicide bans in “almost every western democracy”).

<sup>48</sup> *See, e.g., Town of Castle Rock v. Gonzales*, 545 U.S. 748 (2005) (refusing to recognize enforcement of restraining order as right envisioned by the framers of the Fourteenth Amendment); *Michael H. v. Gerald D.*, 491 U.S. 110, 122 (1989) (quoting *Moore*, 431 U.S. at 544) (cautioning court to avoid creating rights unanticipated by constitutional framers); *but see Casey*, 505 U.S. at 848 (finding that framers’ intent does not mark “outer limits” of substantive due process).

<sup>49</sup> 497 U.S. at 277.

<sup>50</sup> *Id.* at 266.

the Court declined because Missouri law required “clear and convincing evidence” of Cruzan’s intent to halt life-sustaining treatment in such a situation.<sup>51</sup> The District Court found that at age twenty-five, Cruzan had expressed to her housemate that she would not want continued nutrition and hydration if she could not live “at least halfway normally.”<sup>52</sup> The Supreme Court of Missouri upheld the constitutionality of the statute and determined that Cruzan’s statements to her roommate were not sufficient to satisfy the “clear and convincing evidence” standard.<sup>53</sup> In reviewing the case, the U.S. Supreme Court identified the carefully guarded right in common law of bodily integrity, which provided the basis for the informed consent doctrine.<sup>54</sup> If an informed patient has a fundamental right to choose a course of treatment, the Court reasoned, an informed patient also has the fundamental right to choose *no* course of treatment, which includes the right to refuse even life-saving food and hydration.<sup>55</sup>

The limits of this right were challenged in *Washington v. Glucksberg*.<sup>56</sup> There, physicians who treated terminally ill patients challenged a Washington statute prohibiting them from assisting their patients in ending their lives.<sup>57</sup> The District Court found the law unconstitutional under the Fourteenth Amendment, which was reversed by a panel of the Court of Appeals.<sup>58</sup> The Court of Appeals reheard the case en banc, reversed the panel’s decision, and affirmed the District Court decision.<sup>59</sup> The Supreme Court, reversing, began with an extensive survey of the right to assisted suicide through history and among legal jurisdictions, finding nearly universal prohibition of the practice.<sup>60</sup> The Court followed with its constitutional analysis, using the tests discussed *infra* in section B, and found no basis for the right to assisted suicide to be protected by the Fourteenth Amendment.<sup>61</sup> The Court distinguished the right to assisted suicide from the right in *Cruzan*, holding that the right to refuse hydration and nutrition, which was based in individual autonomy, does not imply a correlated right to have another assist in the active taking of a life.<sup>62</sup>

Other courts have ruled more directly on the issue of whether the terminally ill have a constitutional right to use drugs which have yet to pass FDA approval.<sup>63</sup> In

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<sup>51</sup> *Id.* at 265.

<sup>52</sup> *Id.* at 268.

<sup>53</sup> *Id.*

<sup>54</sup> *Id.* at 269.

<sup>55</sup> *Id.* at 270.

<sup>56</sup> 521 U.S. 702 (1997).

<sup>57</sup> *Id.* at 707-08.

<sup>58</sup> *Id.* at 708.

<sup>59</sup> *Id.* at 708-09.

<sup>60</sup> *Id.* at 710-719.

<sup>61</sup> *Id.* at 722-23.

<sup>62</sup> *Id.*

<sup>63</sup> The Ninth Circuit’s recent decision in *Raich v. Gonzales* casts new light on the Due Process rights of the terminally ill. *Raich v. Gonzales*, No. 03-15481, 2007 U.S. App. LEXIS 5834, at \*24-40 (9th Cir. March 14, 2007). There, Raich, a terminally ill patient with ten serious medical conditions, moved for an injunction allowing her to use marijuana as treatment. *Id.* at \*5. Raich asserted the *Glucksberg* right to make medical decisions, but the court rejected framing the right this way and narrowed its review simply to the right to use marijuana. *Id.* at \*32-34. Using the *Glucksberg* test, the Court found that the right to use marijuana, even for a terminally ill patient under a doctor’s supervision, does not rise to the level of “fundamental” or “implicit in the concept of ordered liberty.” *Id.* at \*39.

*Rutherford v. United States*,<sup>64</sup> the Tenth Circuit, citing the line of cases that established the right for a patient to choose whether or not to pursue a certain course of treatment, nevertheless held that the selection of a particular treatment or medication has traditionally been within lawful government power.<sup>65</sup> Similarly, in *Carnohan v. United States*,<sup>66</sup> the Ninth Circuit relied on its sister circuit in *Rutherford* and held that the Constitution does not protect the right of an individual to use unapproved drugs.<sup>67</sup>

### *B. New Due Process Rights*

When a party asserts a right previously unrecognized in Fourteenth Amendment jurisprudence, the court is required to determine whether the right is fundamental.<sup>68</sup> Two rationales have emerged for determining whether an asserted right is fundamental. The first, which may be called the “history and tradition” test, determines if the asserted right is “deeply rooted in this Nation’s history and tradition.”<sup>69</sup> For example, in *Moore v. City of East Cleveland*,<sup>70</sup> the Court faced a due process challenge to a city ordinance limiting occupants of a dwelling to one “family,” which the ordinance narrowly defined.<sup>71</sup> The Court found a deeply rooted tradition in the sanctity of the family and held that the tradition included relationships greater than the nuclear family.<sup>72</sup> Conversely, the Supreme Court rejected an argument that failure of government to regulate a certain practice over time erodes its ability to constitutionally regulate the activity.<sup>73</sup> In *Morton Salt*, the Court reasoned that powers “are not lost by being allowed to lie dormant, any more than nonexistent powers can be prescribed by an unchallenged exercise.”<sup>74</sup>

The second measure for determining if a right is fundamental, which may be called the “ordered liberty” test, determines if the asserted right is “implicit in the concept of ordered liberty such that neither liberty nor justice would exist if they were sacrificed.”<sup>75</sup> The Court used this rationale in *Casey*, which reaffirmed and narrowed the right to abortion identified in *Roe v. Wade*.<sup>76</sup> There, the Court

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<sup>64</sup> 616 F.2d 455 (10th Cir. 1980).

<sup>65</sup> *Id.* at 457 (citing *Whalen v. Roe*, 429 U.S. 589 (1977); *Planned Parenthood of Missouri v. Danforth*, 428 U.S. 52 (1976); *Paris Adult Theatre I v. Slaton*, 413 U.S. 49 (1973); *Roe*, 410 U.S. 113; *Doe v. Bolton*, 410 U.S. 179 (1973); and *Eisenstadt*, 405 U.S. 438).

<sup>66</sup> 616 F.2d 1120 (9th Cir. 1980) (per curiam).

<sup>67</sup> *Id.* at 1122.

<sup>68</sup> *Glucksberg*, 521 U.S. at 720.

<sup>69</sup> *Id.* at 721 (quoting *Moore v. City of East Cleveland*, 431 U.S. 494, 503 (1977)) (internal quotation marks removed). The Supreme Court substantially deviated from this test, and in fact appeared to reject this prong, in *Lawrence v. Texas*, 539 U.S. 558, 578-79 (2003). Brian Hawkins, *The Glucksberg Renaissance: Substantive Due Process Since Lawrence v. Texas*, 105 MICH. L. REV. 409, 421 (Nov. 2006). However, since *Lawrence*, Hawkins’ survey reveals that its rationale has been largely ignored. *Id.* at 424-43.

<sup>70</sup> 431 U.S. 494 (1977).

<sup>71</sup> *Id.* at 495-96.

<sup>72</sup> *Id.* at 503-504.

<sup>73</sup> *U.S. v. Morton Salt Co.*, 338 U.S. 632, 647-48 (1950).

<sup>74</sup> *Id.* at 647.

<sup>75</sup> *Glucksberg*, 521 U.S. at 721 (quoting *Palko v. Connecticut*, 302 U.S. 319, 325-26 (1937)) (internal quotation marks removed).

<sup>76</sup> 410 U.S. 113 (1973).

characterized the abortion right as similar to other constitutionally protected personal decisions, including marriage, procreation, contraception, family relationships, child rearing, and education.<sup>77</sup> As with the “history and tradition” test, the *Casey* Court looked to previous cases for guidance, including *Griswold* and *Eisenstadt*;<sup>78</sup> however, unlike that test, here the prior law acted as evidence of a right more deeply rooted, rather than as the source of the right itself.<sup>79</sup>

These tests, however, have not been employed in isolation; that is, they have not been used as elements or factors within one test to determine whether a right is fundamental. Rather, they have been employed as complimentary methodologies for reaching a single conclusion. Each rationale has a common justification, which is to prevent a court from inventing constitutional rights that exceed the scope of the constitution.<sup>80</sup> Often, they are used in tandem to reach a common conclusion.<sup>81</sup>

The Supreme Court has urged caution in defining newly asserted rights as fundamental, “lest the liberty protected by the Due Process Clause be subtly transformed into the policy preferences of the Members of this Court.”<sup>82</sup> In addition, to avoid the explosion of new constitutional rights from a single decision, the Supreme Court requires that the asserted right be carefully and precisely described.<sup>83</sup> However, the Court has been divided over what that means. In *Michael H. v. Gerald D.*,<sup>84</sup> Chief Justice Rehnquist and Justice Scalia define this requirement as “the most specific level at which a relevant tradition protecting, or denying protection to, the asserted right can be identified.”<sup>85</sup> Conversely, Justices O’Connor and Kennedy, also writing in *Michael H.*, argued that prior cases have recognized rights that were not identified at the most specific level but failed to articulate a more specific standard than carefully and precisely described.<sup>86</sup>

Overall, the Supreme Court has been reluctant to recognize new rights without legislative action. Justice White issued a strong warning:

The Judiciary, including this Court, is the most vulnerable and comes nearest to illegitimacy when it deals with judge-made constitutional law having little or no cognizable roots in the language or even the design of the Constitution. ... [T]he Court should be extremely reluctant to breathe still further substantive content in to the Due Process Clause so as to strike down legislation adopted by a State or city to promote its welfare.<sup>87</sup>

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<sup>77</sup> *Casey*, 505 U.S. at 851.

<sup>78</sup> 381 U.S. 479; 405 U.S. 438.

<sup>79</sup> See *Casey*, 505 U.S. at 851 (“At the heart of liberty is the right to define one’s own concept of existence, of meaning, of the universe, and of the mystery of human life.”)

<sup>80</sup> See *Moore*, 431 U.S. at 501 (quoting *Pull v. Ullman*, 367 U.S. 497, 542-43 (1961)) (“A decision of this Court which radically departs from [living constitutional tradition] could not long survive, while a decision which builds on what has survived is likely to be sound.”).

<sup>81</sup> See, e.g., *Glucksberg*, 521 U.S. at 723-727; *Hutchins*, 188 F.3d at 540-41.

<sup>82</sup> *Id.*

<sup>83</sup> *Glucksberg*, 521 U.S. at 721.

<sup>84</sup> 491 U.S. 110 (1989).

<sup>85</sup> *Id.* at 127 n.6. This argument appeared in the opinion announcing the judgment of the Court, but only Chief Justice Rehnquist and Justice Scalia joined in this footnote.

<sup>86</sup> *Id.* at 132 (O’Connor, J., concurring in part).

<sup>87</sup> *Moore v. City of East Cleveland*, 431 U.S. 494, 544 (1977) (White, J., dissenting).

The D.C. Circuit has reasoned that this admonition applies even more strongly for lower federal courts.<sup>88</sup> The Court warned of specific danger from acting on due process rights without guidance from the Supreme Court:

If courts of appeals should, in such circumstances, begin to create new rights freely, the volume of decisions would mean that many would evade Supreme Court review, a great body of judge-made law would grow up, and we would have preempted for ourselves another part of the governance of the country without express constitutional authority.<sup>89</sup>

Consequently, the Court cautioned that lower federal courts should avoid creating new constitutional rights.<sup>90</sup>

### III. Balancing

Once the right has been classified, a court applies the appropriate test. Generally, when an asserted right has been recognized by a court as fundamental, any state action infringing on that right will be upheld only if it passes heightened scrutiny, which the Court in *Glucksberg* described: “[T]he infringement [must be] narrowly tailored to serve a compelling state interest.”<sup>91</sup> For example, once the *Cruzan* Court recognized a fundamental right to refuse treatment, the Court balanced the right against state interests to determine if it violated the Due Process Clause.<sup>92</sup> The Court recognized state interests in protecting and preserving life, preventing a person’s wish from being misrepresented by imposing heightened evidentiary requirements, and increasing the duration of life without making judgments as to quality.<sup>93</sup> The Court ultimately held that Missouri properly exercised those interests by imposing a “clear and convincing” standard of proof and upheld the law.<sup>94</sup> Conversely, if the right is not protected by the Fourteenth Amendment, a court applies the rational relations test, which is a low standard that merely requires the law to “be rationally related to legitimate government interests.”<sup>95</sup>

#### FACTS AND PROCEDURAL HISTORY

Abigail Alliance for Better Access to Developmental Drugs (the Alliance) is a non-profit corporation that was created in 2001 and named after a twenty-one year-old woman who suffered from terminal cancer.<sup>96</sup> Its mission is “[t]o help cancer patients and others with life threatening illnesses” by educating the public and Congress, encouraging government-sponsored research into potentially life-saving medications, negotiating with pharmaceutical companies for expanded access to

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<sup>88</sup> *Dronenburg v. Zech*, 741 F.2d 1388, 1396 (D.C. Cir. 1984).

<sup>89</sup> *Id.* at 1396-97 (internal quotation marks and brackets removed).

<sup>90</sup> *Id.*

<sup>91</sup> *Glucksberg*, 521 U.S. at 721.

<sup>92</sup> *Cruzan*, 497 U.S. at 279.

<sup>93</sup> *Id.* at 280-82.

<sup>94</sup> *Id.* at 282.

<sup>95</sup> *Glucksberg*, 521 U.S. at 728.

<sup>96</sup> Abigail Alliance for Better Access to Developmental Drugs: The Abigail Story, <http://abigail-alliance.org/story.htm> (last visited Sept. 22, 2006).

medications, and offering other assistance programs to the terminally ill.<sup>97</sup> On January 16, 2003, the Alliance petitioned the Food and Drug Administration (FDA) to allow drugs that had passed Phase 1 approval to be available to all terminally ill patients.<sup>98</sup> The FDA rejected the petition on April 25th. Pursuant to 21 C.F.R. § 10.30, the Alliance filed a Citizen Petition<sup>99</sup> on June 11th. The FDA did not respond to the Citizen Petition within 180 days, granting the Alliance a right of judicial review.<sup>100</sup> Subsequently, the Alliance sued the FDA Commissioner and the Secretary of the Department of Health and Human Services to enjoin the FDA from continuing to bar the distribution to the terminally ill of drugs that had passed Phase 1 human trials.<sup>101</sup>

The FDA filed a motion for failure to state a claim with the District Court. The Court granted the motion, holding that the Alliance sought creation of a new constitutional right not explicitly guaranteed by the Due Process Clause.<sup>102</sup> Additionally, the Court held that although the U.S. Supreme Court had recognized a right to choose death by refusing medical treatment in *Cruzan*, the right did not imply a complementary right to choose life by obtaining life-saving medication.<sup>103</sup> Since it concluded that no due process protection existed, the Court upheld the policy as “rationally related to a legitimate government interest.”<sup>104</sup> The Alliance appealed, and the Court of Appeals reviewed the decision regarding the Rule 12(b)(6) motion *de novo*.<sup>105</sup>

#### COURT’S ANALYSIS

The case presented the issue of whether the FDA’s policy violates the substantive due process rights of mentally competent, terminally ill patients who have no alternative government-approved treatment options.<sup>106</sup> The Court reversed the District Court ruling, holding that the right of the terminally ill to use drugs that have been only Phase 1 approved is protected by Due Process, and the Court remanded the case to the District Court to determine if the government policy satisfies strict scrutiny.<sup>107</sup>

The Court began with constitutional background. The Fifth Amendment to the United States Constitution guarantees that “[n]o person shall be . . . deprived of life, liberty, or property, without due process of law.”<sup>108</sup> The Court noted that Fifth

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<sup>97</sup> Abigail Alliance for Better Access to Developmental Drugs: The Abigail Alliance Mission, <http://abigail-alliance.org/mission.htm> (last visited Sept. 22, 2006).

<sup>98</sup> *Abigail Alliance*, 445 F.3d at 473.

<sup>99</sup> A Citizen Petition is a mechanism by which any citizen may request action by the Commissioner of Food and Drugs, and to which the Commissioner must respond. See 21 C.F.R. § 10.30.

<sup>100</sup> *Abigail Alliance*, 445 F.3d at 473.

<sup>101</sup> *Id.* at 473-74.

<sup>102</sup> *Id.*

<sup>103</sup> *Id.* at 474-75.

<sup>104</sup> *Id.* at 475.

<sup>105</sup> *Id.*

<sup>106</sup> *Id.* at 472.

<sup>107</sup> *Id.*

<sup>108</sup> *Id.* at 475 (citing U.S. CONST. amend. V). Here, the Court analyzes substantive due process under the Fifth Amendment rather than the Fourteenth Amendment, despite the relevant language of each amendment being identical. Cf. *Cruzan*, 497 U.S. at 279 n.7 (“[T]his issue is more properly analyzed in

Amendment jurisprudence had found more than a right to fair process, but also substantive protection of due process rights.<sup>109</sup> The Court reviewed both the “ordered liberty” test, and the “history and tradition” test.<sup>110</sup> In its analysis of cases that use the “ordered liberty” test, the Court found strong reliance on individual rights, autonomy, and self-determination, and it found an unwillingness to allow the state to intrude on “certain protected domains” such as the bedroom or the body.<sup>111</sup> In cases that used the “history and legal tradition” test, the Court found two requirements.<sup>112</sup> First, there must be an inquiry into whether an asserted right is “objectively, ‘deeply rooted in this Nation’s history and tradition’ and ‘implicit in the concept of ordered liberty.’”<sup>113</sup> Second, “courts must provide a ‘careful description of the fundamental liberty interest.’”<sup>114</sup> After reviewing these two tests, the Court of Appeals applied only the “history and legal tradition” test, reasoning that if a right was deemed fundamental under this stricter test, then it would likely survive the “ordered liberty” test as well.<sup>115</sup>

In applying the “history and legal tradition” analysis, the Court began with an attempt to craft a “careful description” of the asserted fundamental right.<sup>116</sup> This requirement exists, the Court found, “as a means of constraining the inadvertent creation of rights that could fall within the scope of loosely worded descriptions and thus threaten the separation of powers.”<sup>117</sup> Citing the application of the requirement in *Michael H.*, the Court recognized that the Supreme Court had split regarding how specific the careful description must be.<sup>118</sup> Here, the Court held that the right was narrowly described, “conform[ing] to the demands of even the narrowest interpretation of the *Glucksberg* ‘careful description’ requirement.”<sup>119</sup> The Court described the narrow right as a “right of terminally ill patients, acting on a doctor’s advice, to obtain potentially life-saving medication when no alternative treatment approved by the government is available.”<sup>120</sup>

After carefully describing the fundamental right at issue, the Court considered the other half of the test, namely whether a long-standing tradition recognizing the right

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terms of a Fourteenth Amendment liberty interest.”); *Glucksberg*, 521 U.S. at 708.

<sup>109</sup> *Abigail Alliance*, 445 F.3d at 475.

<sup>110</sup> *Id.* at 476-77. In recognizing these rationales, the Court pointed to its own precedent which cautioned that “lower courts ‘should [not] freely create new constitutional rights’ without ‘guidance from the Constitution or . . . from articulated Supreme Court principle.’” *Id.* at 475-76. On this point, the dissent agrees. *Id.* at 491 (Griffith, J., dissenting).

<sup>111</sup> *Id.* at 476 (citing line of cases from *Griswold*, 381 U.S. 479, to *Casey*, 505 U.S. 833). This approach is not, as claimed by some, an application of the *Lawrence* standard. See Hawkins, *supra* note 69, at 443 (noting that applying the *Lawrence* standard would entail more analysis than the Court attempted). Rather, as explained in Prior Law, it is an analysis used frequently, including in *Glucksberg* itself, as a complement to the “history and tradition” test.

<sup>112</sup> *Abigail Alliance*, 445 F.3d at 476-77.

<sup>113</sup> *Id.* (quoting *Glucksberg*, 521 U.S. at 721) (citations and footnote omitted).

<sup>114</sup> *Abigail Alliance*, 445 F.3d at 477.

<sup>115</sup> *Id.*

<sup>116</sup> *Id.*

<sup>117</sup> *Id.* at 478.

<sup>118</sup> *Id.* at 477-78.

<sup>119</sup> *Abigail Alliance*, 445 F.3d at 478.

<sup>120</sup> *Id.*

existed.<sup>121</sup> Here, the Court first cited the common law doctrine of necessity, which provided that a person faced with death was permitted “extraordinary measures not otherwise justified,” even when such measures infringed on the property rights of others.<sup>122</sup> Similarly, the Court cited the liability created in the common law of torts for interfering with efforts to rescue or preserve someone’s life.<sup>123</sup> In its analysis of the history of drug regulation in the United States, the Court found that federal requirements for testing drugs were a recent development.<sup>124</sup> In fact, “[o]nly in 1962 did Congress require drug manufacturers to provide empirical evidence of the effectiveness of a drug as opposed to merely the drug’s safety.”<sup>125</sup> Consequently, the Court found that government control of access to potentially life-saving medication is not sufficiently ingrained in our understanding of the appropriate role of government.<sup>126</sup>

Applying the “ordered liberty” test, the Court held that the right asserted by the Alliance is “implicit in the concept of ordered liberty.”<sup>127</sup> From the Supreme Court’s conclusion in *Cruzan* that a due process right existed to make an informed decision to withhold treatment, the Court implied a fundamental liberty interest in saving one’s life, even if it results in death.<sup>128</sup> “The logical corollary is that an individual must also be free to decide for herself whether to assume any known or unknown risks of taking a medication that might prolong her life.”<sup>129</sup> Drawing another comparison to *Cruzan*, the Court reasoned that the Alliance asked merely to be free of government imposition on decisions regarding treatment.<sup>130</sup>

The Court rejected the FDA’s argument that the Alliance sought to impermissibly create a new constitutional right, holding that the admonition against the creation of new rights did not preclude the Court from engaging in a substantive due process inquiry or determining that a policy violates a fundamental right.<sup>131</sup> The Court distinguished the persuasive authority from sister circuits cited by the FDA.<sup>132</sup> For example, plaintiffs in *Rutherford* and *Carnohan* sought use of laetrile, a cancer drug that had not passed Phase 1 trials.<sup>133</sup> The Court distinguished these cases dealing with pre-Phase 1 drugs, which had not been approved for expanded human testing, because the possibility still existed that laetrile was a poison.<sup>134</sup> Because drugs that had passed Phase 1 approval had been approved for wider human testing, the Court echoed the Alliance’s argument that they merely sought “the same right of access

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<sup>121</sup> *Id.* at 479.

<sup>122</sup> *Id.* at 480.

<sup>123</sup> *Id.*

<sup>124</sup> See generally *id.* at 481-83 (outlining emergence of regulatory scheme from 1906 to the current, strict regulations).

<sup>125</sup> *Id.* at 482.

<sup>126</sup> *Id.* at 483.

<sup>127</sup> *Id.* at 483-84 (quoting *Palko v. Connecticut*, 302 U.S. 319, 325 (1937)).

<sup>128</sup> *Id.* at 484.

<sup>129</sup> *Id.*

<sup>130</sup> *Id.*

<sup>131</sup> *Id.* at 485.

<sup>132</sup> *Id.* at 485-86.

<sup>133</sup> *Id.* at 486.

<sup>134</sup> *Id.*

enjoyed by those terminally ill patients lucky enough to secure a spot in Phase 2 trials.”<sup>135</sup> Thus, the Court held that the right of the terminally ill to use drugs that have passed Phase 1 approval is protected by the Due Process Clause and found that the District Court should apply strict scrutiny to determine if the government’s policy is lawful.<sup>136</sup>

Judge Thomas Griffith, dissenting, identified several flaws in the majority’s reasoning. First, with respect to the tests to determine if a right is fundamental, he disputed the majority’s characterization of the tests as an “or” test and argued that law established them as an “and” test.<sup>137</sup> That is, he interpreted *Glucksberg* as requiring an asserted right to be *both* “deeply rooted in this Nation’s history and tradition” *and* “implicit in the concept of ordered liberty.”<sup>138</sup> Noting that the majority lacked in-depth analysis of the “ordered liberty” test, the dissent focused on the disjuncture between the narrow right identified by the majority and the broad right discovered by the majority in common law, namely that a right to use any drug free from government regulation exists.<sup>139</sup> “The majority never provides evidence, however, that the Alliance’s *asserted* right is deeply rooted and implicit in ordered liberty.”<sup>140</sup> The dissent argued that the broad right that the majority found in common law would not meet its own requirement that the right must be carefully described.<sup>141</sup>

The dissent indicated that the majority lacked any evidence of a fundamental right to use experimental drugs anywhere in constitutional history and noted that for such a right to exist it must have been *asserted* at some time, not merely have existed passively.<sup>142</sup> In fact, the dissent argued that the majority’s evidence that drugs have been regulated since the early twentieth century does not establish a “deeply rooted” tradition.<sup>143</sup> Moreover, the dissent rejected the majority’s use of common law to show a “deeply rooted” right, arguing that a right must be rooted in “this Nation’s history and *constitutional* traditions.”<sup>144</sup> The dissent rejected the majority’s view that a defense of necessity was deeply rooted in common law, and argued the right is especially controversial in our constitutional system where “federal crimes are defined by statute rather than by common law.”<sup>145</sup> Citing the Supreme Court in *Morton Salt*, the dissent cautioned against concluding that a constitutional right

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<sup>135</sup> *Id.*

<sup>136</sup> *Id.*

<sup>137</sup> *Id.* at 487 (Griffith, J., dissenting).

<sup>138</sup> *Id.*

<sup>139</sup> *Id.* at 491.

<sup>140</sup> *Id.* at 493 (emphasis in original).

<sup>141</sup> *Id.*

<sup>142</sup> *Id.* at 491.

<sup>143</sup> *Id.*

<sup>144</sup> *Id.* at 492 (quoting *Glucksberg*, 521 U.S. at 725) (emphasis in original) (internal quotation marks removed).

<sup>145</sup> *Id.* at 492 (quoting *U.S. v. Oakland Cannabis Buyers’ Cooperative*, 532 U.S. 483, 490 (2001)) (internal quotation marks removed). Recently, the Ninth Circuit, in addressing whether common law necessity allowed injunctive relief where a terminally ill patient wanted to use marijuana as medical treatment, acknowledged that the *Oakland Cannabis* decision and federal regulations leave the status of necessity as a viable argument as an “unanswered question.” *Raich*, 2007 U.S. App. LEXIS 5834, at \*21.

exists simply because the government has failed to regulate a market.<sup>146</sup> Moreover, the dissent found some governmental regulation of drugs going back to England and continuing from early American independence through the mid-nineteenth century.<sup>147</sup>

The dissent disputed the reasoning of the majority in deriving its asserted right from the due process right to refuse treatment identified by the Supreme Court in *Cruzan*.<sup>148</sup> “[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.”<sup>149</sup> In fact, no legal entitlement to use experimental drugs has ever existed, and the Supreme Court has previously rejected challenges to the legitimacy of the FDCA.<sup>150</sup> The dissent also objected to characterizing the right as a “right to die,” preferring to identify the *Cruzan* right as a “constitutionally protected right to *refuse* lifesaving hydration and nutrition.”<sup>151</sup> Additionally, since *Cruzan* limited the right to refuse treatment to competent adults, the dissent argued that “competence” would be hard to define in this context because no one would know the potential harmful effects of the untested drugs.<sup>152</sup>

Finally, the dissent averred that the judiciary was not the proper forum to decide whether the terminally ill ought to be able to use experimental drugs.<sup>153</sup> The dissent noted that the FDA had concluded that the terminally ill would be best served only when there was reasonable knowledge of the likely benefit and risks associated with a drug.<sup>154</sup> This kind of determination, the dissent believed, is best left to Congress, exercising its Article I powers, and the FDA, to whom Congress has delegated this authority.<sup>155</sup> The FDA has scientific advisory panels at its disposal, the dissent argued, which makes them better suited to deal with scientific judgments.<sup>156</sup> Consequentially, the dissent would apply a simple rational basis test to the existing procedure, which identified that the government did have a legitimate interest in ensuring that patients who use drugs understand the potential risks and benefits associated with that drug. Thus, the dissent would affirm the District Court.<sup>157</sup>

## PERSONAL ANALYSIS

### I. Individual Interest

Did the Court properly recognize a fundamental, protected right for the terminally

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<sup>146</sup> *Id.* at 494 (Griffith, J., dissenting).

<sup>147</sup> *Id.* at 494-95.

<sup>148</sup> *Id.* at 495.

<sup>149</sup> *Id.* (emphasis in original).

<sup>150</sup> *Id.* at 496-97.

<sup>151</sup> *Id.* at 495 n.5 (internal quotation marks removed).

<sup>152</sup> *Id.* at 496.

<sup>153</sup> *Id.* at 498-99.

<sup>154</sup> *Id.* at 497-98.

<sup>155</sup> *Id.* at 498.

<sup>156</sup> *Id.*

<sup>157</sup> *Id.* at 500.

ill to use unapproved drugs? As noted *supra*, the Court could either reason that the right was previously recognized or recognize a new right, which would require finding the right either implicitly recognized in history and tradition,<sup>158</sup> or implicit in ordered liberty.<sup>159</sup> In either case, the identified right must be carefully and narrowly described.<sup>160</sup>

The Court of Appeals erred in finding a right for the terminally ill to use unapproved drugs implicit in history and tradition, and in particular it erred in extending the right recognized in *Cruzan* to this context. The Court asserts that regulation of access to drugs is a recent practice because its roots travel back only to the early twentieth century.<sup>161</sup> However, this constitutional analysis is flawed because a century of regulation does provide a considerable history.<sup>162</sup> For example, registration requirements for broker-dealers in the securities industry date back to the Securities Exchange Act of 1934,<sup>163</sup> but it seems inappropriate to imply from this only “recent” act a deeply rooted tradition of broker-dealers to be free from regulation. In fact, the majority struggles to find anywhere in history and tradition a right to use drugs free of regulation recognized by legislatures and courts. Drug regulation had yet to be contemplated at the time of the creation of the Fourteenth Amendment, so one cannot assert a specific framers’ intent to be free of such intrusions.<sup>164</sup> The reason that drugs have been regulated only in the last century has not been a previous “common consent” recognizing a right,<sup>165</sup> but rather has reflected advancing technology that began to create more complex drugs with unknown and dangerous consequences.<sup>166</sup> Moreover, while the Court identified in history and tradition a broad right “to act in order to save one’s own life,”<sup>167</sup> they have nowhere articulated why that right should only apply to the terminally ill. Previously, courts have examined history and tradition to find the *particular* right asserted by the plaintiff.<sup>168</sup> In fact, as the dissent correctly points out, the majority uses a broad historical analysis to identify a narrow constitutional right.<sup>169</sup>

*Glucksberg* should have provided the Court of Appeals guidance for applying the *Cruzan* right to patient choices beyond the right to reject a particular course of treatment. In *Glucksberg*, the Supreme Court rejected a broad reading of *Cruzan* implying a “right to die,” instead limiting the *Cruzan* right to a mere veto right over a recommended treatment.<sup>170</sup> Here, despite the best efforts of the Court to frame

<sup>158</sup> See *Glucksberg*, 521 U.S. at 723 (finding fundamental right in history and tradition).

<sup>159</sup> See *Moore*, 431 U.S. at 503-04 (finding fundamental right implicit in concept of ordered liberty).

<sup>160</sup> *Glucksberg*, 521 U.S. at 721.

<sup>161</sup> *Abigail Alliance*, 445 F.3d at 481.

<sup>162</sup> See *id.* at 491 (Griffith, J., dissenting).

<sup>163</sup> See generally David A. Lipton, *A Primer on Broker-Dealer Registration*, 36 CATH. U. L. REV. 899, 900-04 (Summer 1987).

<sup>164</sup> See *Michael H.*, 491 U.S. at 122 (citing framers’ design of Constitution in rejecting asserted right).

<sup>165</sup> *Jackman v. Rosenbaum Co.*, 260 U.S. 22, 31 (1922).

<sup>166</sup> See *Salbu*, *supra* note 14, at 407-10 (describing increasingly strict regulatory regime from 1906 to present).

<sup>167</sup> *Abigail Alliance*, 445 F.3d at 481 n.12.

<sup>168</sup> See, e.g., *Cruzan*, 497 U.S. at 278 (informed consent rule in common law and previous cases precisely mirrored the recognized constitutional right to refuse treatment).

<sup>169</sup> *Abigail Alliance*, 445 F.3d at 493 (Griffith, J., dissenting).

<sup>170</sup> *Glucksberg*, 521 U.S. at 722-23.

*Cruzan* as recognizing a right to take affirmative action,<sup>171</sup> *Glucksberg* considered and rejected transmuting a right of refusal into a right of access.<sup>172</sup> This interpretation, *Glucksberg* found, was accurately based on the roots of the *Cruzan* right, where the common law doctrine of informed consent encompassed only a right of refusal and not a general right of personal autonomy.<sup>173</sup> Just as *Glucksberg* refused to extend the *Cruzan* right to assisted suicide, the Court of Appeals should have refused to extend *Cruzan* to imply a right to use drugs.

The Court of Appeals further erred when it found that the right asserted fell within ordered liberty.<sup>174</sup> The dissent identified the core of the flaw in the majority's reasoning on this prong:

The majority never provides evidence, however, that the Alliance's *asserted* right is deeply rooted and implicit in ordered liberty. Instead, the majority infers its new right from several broad principles, none of which would meet *Glucksberg's* careful description requirement.<sup>175</sup>

The majority's analysis, heavily rooted in *Cruzan*, makes little sense when its logic is read in context with *Cruzan*.<sup>176</sup> *Cruzan* recognized that since a deeply rooted right existed to control one's own person—including even the right to be free from unwanted touching—then such a right included a natural subset of freedom from unwanted medical treatment.<sup>177</sup> But a right of freedom to access treatment is not a “logical corollary” to the *Cruzan* right.<sup>178</sup> If it is a “logical corollary” of any right, it is the right to take any action to save one's own life.<sup>179</sup> But such a right has never been recognized as fundamental in the way the *Cruzan* right to self-determination has been recognized, particularly when the right forces action on another.<sup>180</sup> Even if read more narrowly, it is hard to imagine how the majority's right does not recognize a broad constitutional right for an individual, under fear of death, to have legal *carte blanche* to take any action he or she deems necessary. This explosion of rights is precisely what the Supreme Court wanted to avoid when it crafted the “careful description” requirement for ordered liberty claims.<sup>181</sup>

## II. State Interest

On remand, before the District Court may apply appropriate scrutiny, they must first identify the state interests involved; namely, those interests that the FDA approval process seeks to protect. In addition to the recognized state interests, the government has numerous interests that it did not have when scrutiny was applied in

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<sup>171</sup> See *Abigail Alliance*, 445 F.3d at 484.

<sup>172</sup> *Glucksberg*, 521 U.S. at 725; accord *Abigail Alliance*, 445 F.3d at 495 n.5 (Griffith, J., dissenting).

<sup>173</sup> *Glucksberg*, 521 U.S. at 724-25.

<sup>174</sup> See *Abigail Alliance*, 445 F.3d at 483-85.

<sup>175</sup> *Id.* at 493 (Griffith, J., dissenting) (emphasis in original).

<sup>176</sup> See *id.* at 484.

<sup>177</sup> *Cruzan*, 497 U.S. at 269-70.

<sup>178</sup> See *Abigail Alliance*, 445 F.3d at 484.

<sup>179</sup> See *id.* at 493 (Griffith, J., dissenting).

<sup>180</sup> See *id.* at 492 (criticizing the defense of necessity as controversial at best under common law).

<sup>181</sup> See *Glucksberg*, 521 U.S. at 721.

*Glucksberg* and *Cruzan*.<sup>182</sup> First, the FDA always has a proper interest in protecting and preserving life.<sup>183</sup> More specifically, though, the FDA can create a policy simply designed to lengthen an individual's life without any judgment regarding the quality of life.<sup>184</sup> That is, the Alliance's argument that the terminally ill should be able to bear any risks does not trump the recognized state interest—the state may refuse to allow the terminally ill to risk shortening or worsening their time left to live.<sup>185</sup> Moreover, while the FDA may not be able to permanently deprive the ill from access to drugs, it does have an interest in creating heightened intermediate steps to prevent abuse.<sup>186</sup> In *Cruzan*, those steps included heightened evidentiary requirements to be certain about the patient's intent;<sup>187</sup> here, the intermediate steps would be the approval process, which are designed to ensure both safety and effectiveness.<sup>188</sup>

Second, the FDA has a legitimate and compelling concern for public health. In fact, the FDA's mission statement provides:

The FDA is responsible for *protecting the public health* by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for *advancing the public health* by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.<sup>189</sup>

Not only does the FDA have a legitimate concern for public health, but it is mandated by law to enforce public health restrictions enacted by Congress.<sup>190</sup> The circumstances that brought about the FDA demonstrate how critical its drug regulation function is to the public health—the agency was born in part from events like the Elixir Sulfanilamide scare where “miracle” drugs produced unanticipated negative health effects.<sup>191</sup> Such dangers to the public health still exist, as the recent failed torcetrapib test revealed.<sup>192</sup> Here, the state's interest mirrors the individual's

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<sup>182</sup> See *Glucksberg*, 521 U.S. at 735 (applying rational basis scrutiny); *Cruzan*, 497 U.S. at 280-84 (applying strict scrutiny).

<sup>183</sup> See *Cruzan*, 497 U.S. at 281 (recognizing the Missouri's legitimate interest in safeguarding the decision between life and death through heightened evidentiary requirements).

<sup>184</sup> See *id.* at 282 (recognizing state interest in lengthening life).

<sup>185</sup> See Brief of Appellant at 46-48, *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 473 (D.C. Cir. 2006) (No. 04-5305) [hereinafter “Brief of Appellant”] (outlining plaintiff's argument).

<sup>186</sup> See *Cruzan*, 497 U.S. at 281 (permitting state to establish procedural standards even when recognizing a Due Process right).

<sup>187</sup> *Id.*

<sup>188</sup> See Zelenay, *supra* note 25, at 266 (discussing the requirements of the Kefauver-Harris Amendments of 1962 which mandated FDA approval of new drugs before they are marketed and an FDA review of new drugs for safety and effectiveness).

<sup>189</sup> FDA's Mission Statement, <http://www.fda.gov/opacom/morechoices/mission.html> (last visited Mar. 19, 2007) (emphasis added).

<sup>190</sup> See generally 21 C.F.R. § 310 (relating to FDA authority over new drug approval).

<sup>191</sup> See Salbu, *supra* note 14, at 408.

<sup>192</sup> See Groopman, *supra* note 1, at 2.

interest—both want to give the terminally ill every chance to survive. But unlike the individual, the FDA has a greater, codified duty to the public by ensuring the safety of any drugs it allows patients to take.<sup>193</sup> According to David Parkinson, an oncologist who worked at the National Cancer Institute before becoming senior vice-president at Biogen Idec, allowing patients to have access to unapproved drugs “opens the space for products that are sold by charlatans.”<sup>194</sup>

Third, the FDA has a legitimate and compelling concern in preserving the integrity of the testing process. According to one analysis of the *Abigail Alliance* decision, “It is also unclear whether adverse effects on terminally ill patients taking Phase I experimental drugs who are not participants of a clinical study will jeopardize the FDA approval process for the new drug.”<sup>195</sup> Doctors would have a difficult time detecting which drugs were working for which cancers if experimental drugs were taken outside a clinical trial.<sup>196</sup> It would also be difficult to recruit patients for clinical trials if they can obtain the drugs from their own doctors without the restrictions and red tape of a clinical trial.<sup>197</sup> A drug whose effects are unknown has only a small chance to save one patient, but conducting proper trials helps drug companies know what may be more likely to work for thousands of patients.

Fourth, the FDA has a legitimate and compelling concern regarding the potential liability of drug manufacturers for the unknown effects of their drugs. By eliminating the FDA’s role in providing a legal standard of safety and due diligence in drug testing, the *Abigail Alliance* decision has already made drug manufacturers nervous about potential lawsuits when the drugs have unforeseen effects.<sup>198</sup> In fact, “it is unclear whether a drug company would be liable if a terminally ill patient took the company’s Phase I experimental drug and died.”<sup>199</sup> Since drug companies cannot be compelled to provide medication, and can only be permitted by the FDA, they may still be held liable for a drug’s effect if, for example, early testing revealed a particular side effect that was not disclosed. Even a proposed bill that would absolve drug companies from liability is not enough to reassure the industry.<sup>200</sup>

### III. Balancing

Although the decision in *Abigail Alliance* leaves the balancing of individual rights and state interests for the District Court on remand,<sup>201</sup> the answer should inevitably be denial of the Alliance’s claim. Even if the Court of Appeals decision is affirmed *en banc*, strict scrutiny will still result in upholding the FDA’s ability to restrict access to experimental drugs because the restriction is “narrowly tailored to

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<sup>193</sup> 21 C.F.R. § 310.

<sup>194</sup> Groopman, *supra* note 1, at 45.

<sup>195</sup> Jonathan Anderman, *Right to Access Experimental Drugs: Terminally Ill Patients Have the Right to Access Experimental Drugs Pending Final FDA Approval*, 32 AM. J.L. & MED. 611, 614 (2006).

<sup>196</sup> Groopman, *supra* note 1, at 47.

<sup>197</sup> *Id.*

<sup>198</sup> See Tresa Baldas, *Patients’ Rights to Experimental Drugs Debated*, 28 NAT’L L.J. 6, col. 1, 6 (Jan. 1, 2007) (noting that drug companies have been unsuccessfully sued in the past by plaintiffs demanding access to experimental drugs that the manufacturer considered harmful).

<sup>199</sup> Anderman, *supra* note 195, at 614.

<sup>200</sup> Groopman, *supra* note 1, at 45.

<sup>201</sup> *Abigail Alliance*, 445 F.3d at 486.

serve a compelling state interest.”<sup>202</sup> The Supreme Court in *Cruzan* recognized interests such as preservation of life, prevention of abuse, and concern for duration of life as compelling, even in the face of a Due Process right.<sup>203</sup> Similarly, the four state interests mentioned *supra*, especially when taken together, represent a compelling state interest in limiting access to drugs whose effects are unknown.<sup>204</sup> Also like *Cruzan*, the FDA’s policy is narrowly tailored to serve those interests.<sup>205</sup> In *Cruzan*, Missouri did not prevent any patient from asserting the right to refuse treatment, but rather adopted heightened procedural standards so doctors could be certain what the patient’s wishes were.<sup>206</sup> Similarly, the FDA policy places only necessary procedural roadblocks in order to advance its interests. Any drug deemed safe will be eventually approved. Patients even have the ability to use drugs during trial stages by participating in a clinical trial or applying for a “compassionate use” exception.<sup>207</sup> The policy eliminates the fewest number of needy patients as possible so the state may advance its compelling interests.<sup>208</sup>

Clearly, then, the FDA’s policy would also survive rational relations scrutiny. Applying this test, *Glucksberg* recognized interest of preservation of life, public health, and medical ethics as easily sufficient to amount to important and legitimate interests.<sup>209</sup> Given the history of drug scares that gave rise to the FDA, and the unquestioned role of drug testing in furthering the FDA’s role, the current testing process bears a rational relationship to the purpose of the FDA.<sup>210</sup> Given the particular nature of the state interests involved, especially the unique and compelling interests like testing integrity and liability that did not exist in the debates in *Cruzan* and *Glucksberg* over the right to die, the debate over whether or not a fundamental right exists is moot. Inevitably, properly weighing state interests will result in a court upholding the FDA’s policy.

#### CONCLUSION

Very few can imagine the desperation faced by Kianna, Abigail, and their families. It is understandable that the Court of Appeals stretched the limits of the Due Process Clause in the hope that just one future dying patient might get access to lifesaving care just in time. Perhaps the Court is right and the FDA has been too slow to approve these drugs. But perhaps the FDA’s approval process has saved lives. There is no way to measure how many people may have been killed had torcetrapib, for example, been approved without the Phase 3 tests that revealed its

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<sup>202</sup> See *Glucksberg*, 521 U.S. at 721.

<sup>203</sup> *Cruzan*, 497 U.S. at 280-81.

<sup>204</sup> See *id.* (outlining Missouri’s interests).

<sup>205</sup> See *id.* (The policy in *Cruzan* was limited to “certain circumstances” where a surrogate might have to act for an incompetent patient).

<sup>206</sup> *Id.* at 282.

<sup>207</sup> See Rutherford, *supra* note 36, at 213 (describing clinical trial process); Groopman, *supra* note 1, at 40 (identifying “compassionate use” exception).

<sup>208</sup> See Rutherford, *supra* note 36, at 314-15 (reviewing the background and current state of the FDA drug approval process).

<sup>209</sup> *Glucksberg*, 521 U.S. at 729-31.

<sup>210</sup> See Salbu, *supra* note 14, at 406-10 (discussing FDA’s history and purpose).

lethality.<sup>211</sup> The FDA approval process has emerged over a number of years, with each element of “red tape” critical to balancing quick access and safe access.<sup>212</sup>

Even if early access to experimental drugs is a worthwhile goal, the Constitution may be the improper venue for such a policy debate. In fact, it seems that proponents are exploring non-constitutional means of change. The FDA already has a “compassionate use” exception for the terminally ill, and almost no one has been denied under the program.<sup>213</sup> Changes are also coming. Two recent appointees of the Bush Administration to the FDA—Andrew von Eschenbach, the commissioner, and Scott Gottlieb, the deputy commissioner for medical and scientific affairs—have argued for a more flexible approach to drug approval.<sup>214</sup> In fact, Von Eschenbach met with a representative of Abigail Alliance in November 2006 to discuss new initiatives, a meeting that left the Alliance optimistic about reaching a solution.<sup>215</sup> In addition, Senator Sam Brownback (R-KS), a cancer survivor, introduced a bill that would force the FDA to make experimental drugs available to the seriously ill.<sup>216</sup> Finally, the FDA itself is considering a plan to encourage drug companies to distribute experimental drugs to cancer patients, the most ambitious initiative in the last two decades.<sup>217</sup> It seems that for the terminally ill, the debate about how to get them the best care as quickly as possible has been escalating. And most likely a change will be more effective, if not faster, outside of a constitutional challenge.

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<sup>211</sup> See Groopman, *supra* note 1, at 41.

<sup>212</sup> See Zelenay, *supra* note 25, at 263-66 (describing evolution of FDA approval process).

<sup>213</sup> See Salbu, *supra* note 14, at 410-11.

<sup>214</sup> Groopman, *supra* note 1, at 41-43.

<sup>215</sup> *Id.* at 46-47.

<sup>216</sup> *Id.* at 42. *Accord* Access, Compassion, Care, and Ethics for Seriously Ill Patients (ACCESS) Act, S. 1956, 109th Cong. (2005) (requiring FDA to allow terminal patients easier access to medication undergoing clinical trials).

<sup>217</sup> Groopman, *supra* note 1, at 42.